

dysfunction, progression of carotid atherosclerosis and left ventricular hypertrophy, and responses to stress, racism, and discrimination as well as new components such as renal disease, body fat distribution and body composition, and metabolic consequences of obesity. The JHS Community Health Advisor Networks (CHANs) comprise another component of the study. The JHS data shows high prevalences of risk factors: 73% of recruited participants are hypertensive, 29% are diabetic, 56% are obese ($BMI > 30\text{kg}/\text{m}^2$), and 30% have the metabolic syndrome. Exploration of the impact on and interaction of high risk

factor levels with other measures of clinical and subclinical disease will help identify unique approaches through epidemiology and prevention research to reduce the disproportionate burden of CVD in African-Americans. The JHS CHANs play an important role to address CVD prevention by providing training to community members to spread health promotion and prevention messages within the Jackson community. The JHS Community Health Advisors (CHAs) are trained and certified to organize and conduct various outreach activities in five Jackson-area communities. Data on the JHS CHAs will be collected. *Frequency*

of Response: One-time. *Affected Public:* Individuals or households; Businesses or other for profit; not-for-profit institutions. *Type of Respondents:* Middle aged and elderly adults; doctors and staff of hospitals and nursing homes. The annual reporting burden is as follows: *Estimated Number of Respondents:* 478; *Estimated Number of Responses per Respondent:* 1.0; *Average Burden Hours Per Response:* 2.47); and *Estimated Total Annual Burden Hours Requested:* 1253. The annualized cost to respondents is estimated at \$24,206. There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

ESTIMATE OF ANNUAL HOUR BURDEN

Type of respondents	Number of respondents	Frequency of responses	Average time per response	Annual hour burden
Families	200	1	1/6	33½
Physicians	200	1	15/60	50
Communities:				
Bolton	16	10	90/60	240
Canton	14	10	90/60	210
Clinton	13	10	90/60	195
Jackson	15	10	90/60	225
Rankin	20	10	90/60	300
Total	478	1253 ½

Request for Comments: Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Ms. Cheryl Nelson, Project Officer, NIH, NHLBI, 6701 Rockledge Drive, MSC 7934, Bethesda, MD 20892-7934, or call non-toll-free number 301-435-0451 or Email your request, including your address to: *NelsonC@nhlbi.nih.gov*.

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received within 60-days of the date of this publication.

Dated: October 18, 2012.

Lynn Susulske,
NHLBI Project Clearance Liaison, National Institutes of Health.
Michael Lauer,
Director, DCVS, National Institutes of Health.
[FR Doc. 2012-26226 Filed 10-23-12; 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 *Elunice Kennedy Shriver National Institute of Child Health and Human Development.*

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 2012. The

BPCA seeks to improve the level of information on the safe and effective use of pharmaceuticals used to treat children. It 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.

SUPPLEMENTARY INFORMATION: The pediatric medical community, the public health community, and government agencies have recognized multiple gaps in knowledge regarding the use of therapeutics in children, including the correct dose, 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. Contributing factors to extensive off-label product use include limited access to patient populations for study, lack of knowledge related to the ethical conduct of clinical trials in

children, the absence of sufficient evidence-based information about medication use in children, and a general lack of long-term safety data on the medications that are used. All of these factors contribute to the lack of adequately collected pharmacokinetic, pharmacodynamic, safety, and efficacy data in children and can increase a child's risk for unknown and/or adverse effects.

The *Eunice Kennedy Shriver National Institute of Child Health and Human Development* (NICHD), the Food and Drug Administration (FDA), other federal agencies, and various non-profit and commercial organizations have taken steps to address the knowledge gaps that exist in pediatric therapeutics.

The 2002 BPCA Legislation

The initial BPCA legislation reauthorized an incentive program for on-patent drugs that met certain criteria that were first authorized in the FDA Modernization Act (FDAMA). The BPCA also contains provisions for off-patent drugs and general support for pediatric product development that were not included in the FDAMA. The legislation, as it applies to the NIH, authorizes a research program through the Department of Health and Human Services (HHS), with implementation through the NIH, specifically by the NICHD. The NICHD is responsible for the development of: (1) A priority list of needs in pediatric therapeutics, in consultation with the FDA and experts in pediatrics; (2) sponsorship of relevant pediatric clinical trials; and 3) submission of resulting clinical trial data to FDA for pediatric labeling changes.

The Updated BPCA Legislation of 2007

Title V of Public Law 110-85, the Best Pharmaceuticals for Children Act of 2007, was enacted on September 27, 2007, as part of the Food and Drug Administration Amendments Act of 2007. This legislation, which reauthorizes the BPCA (Section 409I of the Public Health Service Act), extends the 6-month patent exclusivity provision for currently on-patent drugs being studied for pediatric use, and also extends and expands the NIH research program that was established in the earlier law. The priority list procedure was revised to emphasize knowledge gaps in therapeutic areas in contrast to knowledge gaps about specific drug products.

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. Part of fulfilling 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 drugs/needs in pediatric therapeutics. The BPCA Priority List consists of key therapeutic needs in the medical treatment of children and adolescents; 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 April 1, 2011; all **Federal Register** notices can be found on the BPCA Web site: <http://bpca.nichd.nih.gov/prioritization/status.cfm>. NIH is required by BPCA 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 Branch of the NICHD has developed a prioritization process for determination of the needs in pediatric therapeutics. There are two main phases in the prioritization process. Phase I entails identifying therapeutic areas, which are general categories of conditions, diseases, settings of care, or populations with multiple therapeutic needs. Phase II involves determining more specific pediatric needs, including research associated with a particular drug, biologic, or device. Please visit the BPCA Web site for more details (http://bpca.nichd.nih.gov/prioritization/priority_list.cfm). Factors incorporated in the process include the following:

- Availability of information concerning the safe and effective use of a drug in the pediatric population and the need for additional information;
- Potential health benefits in the pediatric population resulting from new studies;
- Possible need for reformulation of existing products;
- Therapeutic gaps in pediatrics that may include developmental pharmacology, pharmacogenetic determinants of drug response, metabolism of drugs and biologics in children, and pediatric clinical trials;
- Particular pediatric diseases, disorders, or conditions where more complex knowledge and testing of therapeutics, including drugs and biologics, may be beneficial in pediatric populations; and

- The adequacy of necessary infrastructure to conduct pediatric pharmacological research, including research networks and trained pediatric investigators.

The NICHD evaluates the current list of needs in pediatric therapeutics regularly to determine target areas for the coming calendar year. The NICHD sponsored the BPCA Annual Prioritization Meeting, held December 9-10, 2011, with stakeholders from the NIH, the FDA, and the American Academy of Pediatrics (AAP), as well as other pediatric organizations, societies, and patient advocates. The meeting allowed all stakeholders to review the present progress from ongoing research, to discuss lessons learned since the implementation of the BPCA legislation, and to discuss the proposed therapeutic areas from the 2011 recommendations for future study under the BPCA. Meeting minutes can be found on the BPCA Web site: http://bpca.nichd.nih.gov/prioritization/meeting_summary.cfm.

Below is an updated list of therapeutic areas and drugs that have been prioritized for study since the inception of the BPCA, which includes new areas of prioritization from the 2010 outreach nominations, recommendations from the 2011 working groups, and a summary of the NICHD's plans and progress in all of these areas. The NICHD also solicits 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 contact information below.

Priority List of Needs in Pediatric Therapeutics 2012

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.*

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.

Date: October 17, 2012.

Francis S. Collins,

Director, National Institutes of Health.

[FR Doc. 2012-26214 Filed 10-23-12; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the Board of Scientific Counselors for Basic Sciences National Cancer Institute.

The meeting will be closed to the public as indicated below in accordance with the provisions set forth in section 552b(c)(6), Title 5 U.S.C., as amended for the review, discussion, and evaluation of individual intramural programs and projects conducted by the National Cancer Institute, including consideration of personnel qualifications and performance, and the competence of individual investigators, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Board of Scientific Counselors for Basic Sciences National Cancer Institute; BSC Basic Sciences Meeting.

Date: November 14, 2012.

Time: 9:00 a.m. to 3:30 p.m.

Agenda: To review and evaluate personal qualifications and performance, and competence of individual investigators.

Place: National Institutes of Health, Building 31, Conference Room 6, 31 Center Drive, Bethesda, MD 20892.

Contact Person: Florence E. Farber, Ph.D., Executive Secretary, Office of the Director, National Cancer Institute, National Institutes

of Health, 6116 Executive Boulevard, Room 2205, Bethesda, MD 20892, 301-496-7628, ff6p@nih.gov.

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit. Information is also available on the Institute's/Center's home page: <http://deainfo.nci.nih.gov/advisory/bsc-bs/bs.htm>, where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Date: October 18, 2012.

Melanie J. Gray,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2012-26097 Filed 10-23-12; 8:45 am]

BILLING CODE 4140-01-P

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; Member Conflict: Musculoskeletal Rehabilitation.

Date: November 1-2, 2012.

Time: 9:00 a.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

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

Contact Person: Rajiv Kumar, Ph.D., Chief, MOSS IRG, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4216, MSC 7802, Bethesda, MD 20892, 301-435-1212, kumarra@csr.nih.gov.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Cancer Therapeutics.

Date: November 7, 2012.

Time: 12:00 p.m. to 1:30 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: Syed M Quadri, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6210, MSC 7804, Bethesda, MD 20892, 301-435-1211, quadris@csr.nih.gov.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Cardiovascular and Respiratory AREA Review.

Date: November 13-15, 2012.

Time: 8:00 a.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20817, (Virtual Meeting).

Contact Person: Kimm Hamann, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4118A, MSC 7814, Bethesda, MD 20892, 301-435-5575, hamannk@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; SBSR/SBDD Conflicts.

Date: November 13, 2012.

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: Jo Pelham, BA, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4102, MSC 7814, Bethesda, MD 20892, (301) 435-1786, pelhamj@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)

Date: October 18, 2012.

Carolyn A. Baum,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2012-26099 Filed 10-23-12; 8:45 am]

BILLING CODE 4140-01-P