

meetings conducted under the BPCA can be found on the BPCA Web site listed above.

The "New" BPCA

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 provision of additional patent exclusivity for currently on-patent drugs that are being tested for pediatric use. This legislation also extends and expands the research program at the NIH established in the earlier law. The NICHD administers the research program through its Obstetric and Pediatric Pharmacology Branch, working in cooperation with the other NIH Institutes and Centers with significant pediatric research portfolios. Important changes to the 2002 BPCA legislation for the NIH include the following:

- Focus on condition-based approach.
- More flexible funding mechanisms.
- Development of Proposed Pediatric Study Requests (PPSR).
- Feasibility study for the development of a pediatric formulary.

The NICHD will prioritize all therapeutic areas over the upcoming years based on the following considerations:

- Building upon the current foundation established by the 2002 BPCA implementation;
- Evaluating all currently listed drugs and therapeutic areas for feasibility and identification of additional or new scientific and therapeutic gaps;
- Changing the listing process from an individual drug/indication approach to listing needs in pediatric therapeutic areas;
- Determining new areas of need based on consultation with other NIH Institutes and Centers, as well as experts in pediatric therapeutics and the pediatric medical community.

The overall goal of the NIH for implementing the provisions of the BPCA is to improve pediatric therapeutics through scientific advancements and labeling changes that will have an impact on the safe and effective use of drugs in children. This can be accomplished through the following:

- Data gathering
- Using the principles of pharmacoepidemiology research to quantify adverse drug reactions, drug efficacy, and patterns of drug use in

large populations to elucidate health services utilization.

- Bringing together multidisciplinary teams to provide input on needs in pediatric therapeutics through outreach to experts in pediatric research in academic institutions; other NIH Institutes and Centers; and pediatric organizations, societies, advocacy groups, and industry.

- Clinical trials

- Phase 1, 2, and 3 clinical trials to increase the knowledge of PK, safety, and efficacy of medicines used in children.

- Basic and translational research

- To inform such areas as developmental pharmacology, pharmacogenomics, and pediatric clinical trial design.

There will be an open scientific meeting annually, starting in 2008, to review and discuss the proposed therapeutic areas, to present progress from ongoing research, and to provide an opportunity for the medical community to provide input into the future therapeutic areas to be studied under the BPCA. Stakeholders will include the NIH, the FDA, and members of the American Academy of Pediatrics, and other pediatric organizations and societies. There will be a report to Congress at least every 3 years starting in 2008. Throughout the year, there will also be smaller group meetings with expert panels within prioritized therapeutic areas under the BPCA. The goals of the working group meetings will be to evaluate and discuss the gaps in scientific knowledge (whether necessary data are available or unavailable) as well as to determine gaps in the treatments of these conditions; for example, to determine what may be needed to enhance the treatment of these conditions in children. These consultations will assist the NICHD in the development of future proposed areas of study encompassing multiple therapeutic categories and/or addressing multiple questions within a therapeutic category.

A scientific prioritization meeting was held in Rockville, Maryland, from June 30 to July 1, 2008, to determine needs in pediatric therapeutics as mandated by the BPCA 2007 legislation. The final BPCA List of Needs in Pediatric Therapeutics, and information on the prioritization process, will be posted on the BPCA Web site <http://bpcanichd.nih.gov>.

Dated: April 7, 2009.

Raynard S. Kington,

Acting Director, National Institutes of Health.
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DEPARTMENT OF HOMELAND SECURITY

[Docket No. DHS–2009–0008]

The National Infrastructure Advisory Council

AGENCY: Directorate for National Protection and Programs, Department of Homeland Security.

ACTION: Committee Management; Notice of cancellation for Federal Advisory Committee Meeting.

SUMMARY: The meeting of the National Infrastructure Advisory Council (NIAC) scheduled for Tuesday April 14, 2009 at the J.W. Marriott, 1331 Pennsylvania Avenue, Washington, DC announced in the **Federal Register** on February 17, 2009 (73 FR 7456), will not be held.

FOR FURTHER INFORMATION CONTACT: Contact Matthew Sickbert by phone at 703–235–2888 or by e-mail at Matthew.Sickbert@associates.dhs.gov.

Dated: April 9, 2009.

Nancy J. Wong,

Designated Federal Officer for the NIAC.

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DEPARTMENT OF HOMELAND SECURITY

United States Immigration and Customs Enforcement

60-Day Notice of New Information Collection; Form 70–005, ICE Secure Communities Stakeholder ID Assessment Questionnaire; Agency Information Collection Activities: New Information Collection; Comment Request

ACTION: 60-Day Notice of New Information Collection; Form 70–005, ICE Secure Communities Stakeholder ID Assessment Questionnaire.

The Department of Homeland Security, U.S. Immigration and Customs Enforcement (USICE), has submitted the following information collection request for review and clearance in accordance with the Paperwork Reduction Act of 1995. The information collection is published to obtain comments from the public and affected agencies. Comments are encouraged and will be accepted for sixty days until June 15, 2009.