

Prevention and the Agency for Toxic Substances and Disease Registry.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Board of Scientific Counselors, National Institute for Occupational Safety and Health (BSC, NIOSH)

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), the Centers for Disease Control and Prevention (CDC) announces the following meeting for the aforementioned committee:

Time and Date: 8:30 a.m.–3:00 p.m., EDT, September 22, 2015.

Place: Patriots Plaza I, 395 E Street SW., Room 9000, Washington, DC 20201.

Status: Open to the public, limited only by the space available. The meeting room accommodates approximately 33 people. The meeting is also open to the public via webcast. If you wish to attend in person or by webcast, please see the NIOSH Web site to register (<http://www.cdc.gov/niosh/bsc/>) or call (404-498-2539) at least five business days in advance of the meeting. Teleconference is available toll-free; please dial (888) 397-9578, Participant Pass Code 63257516. Members of the public who wish to address the BSC, NIOSH are requested to contact the Executive Secretary for scheduling purposes (see contact information below). Alternatively, written comments to the BSC may be submitted via an on-line form at the following Web site: <http://www.cdc.gov/niosh/bsc/contact.html>.

Purpose: The Secretary, the Assistant Secretary for Health, and by delegation the Director, Centers for Disease Control and Prevention, are authorized under Sections 301 and 308 of the Public Health Service Act to conduct directly or by grants or contracts, research, experiments, and demonstrations relating to occupational safety and health and to mine health. The Board of Scientific Counselors provides guidance to the Director, National Institute for Occupational Safety and Health on research and prevention programs. Specifically, the Board provides guidance on the Institute's research activities related to developing and evaluating hypotheses, systematically documenting findings and disseminating results. The Board evaluates the degree to which the activities of the National Institute for Occupational Safety and Health: (1) Conform to appropriate scientific standards, (2) address current, relevant needs, and (3) produce intended results.

Matters for Discussion: NIOSH Director's update, Structuring Labor-Management

Participation in Research, Systematic Review (Grading Evidence and Recommendations), Occupational Exposure Banding, and an Update from the NIOSH Research Translation Office.

Agenda items are subject to change as priorities dictate. An agenda is also posted on the NIOSH Web site (<http://www.cdc.gov/niosh/bsc/>).

Contact Person for More Information: John Decker, Executive Secretary, BSC, NIOSH, CDC, 1600 Clifton Road NE., MS-E20, Atlanta, GA 30329-4018, telephone (404) 498-2500, fax (404) 498-2526.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities for both the CDC and the Agency for Toxic Substances and Disease Registry.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention (CDC)

Advisory Board on Radiation and Worker Health: Notice of Charter Renewal

This gives notice under the Federal Advisory Committee Act (Pub. L. 92-463) of October 6, 1972, that the Advisory Board on Radiation and Worker Health, Department of Health and Human Services, has been renewed for a 2-year period through August 3, 2017.

For information, contact Mr. Theodore Katz, Designated Federal Officer, Advisory Board on Radiation and Worker Health, Department of Health and Human Services, 1600 Clifton Road, M/S E20, Atlanta, Georgia 30341, telephone 404/498-2533, or fax 404/498-2570.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-N-2048]

Medical Device Epidemiology Network Registry Task Force Report; Availability, Web Site Location and Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the report and Web site location where the Agency has posted the report entitled "Recommendations for a National Medical Device Evaluation System: Strategically Coordinated Registry Networks to Bridge the Clinical Care and Research," developed by the Medical Device Epidemiology Network's Medical Device Registry Task Force. In addition, FDA has established a docket where stakeholders may provide comments.

DATES: Submit either electronic or written comments by October 26, 2015.

ADDRESSES: Submit electronic comments on this document to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Danica Marinac-Dabic, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4110, Silver Spring, MD 20993-0002, 301-796-6689, email: Danica.marinac-dabic@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA's Center for Devices and Radiological Health is responsible for protecting the public health by assuring the safety and effectiveness of medical devices and radiation-emitting products. A key part of this mission is to monitor medical devices and radiological products for continued safety and effectiveness after they are in use and to help the public get the accurate, science-based information they need to improve their health.

In September 2012, the FDA published a report, "Strengthening Our National System for Medical Device Postmarket Surveillance," that proposed

a strategy for improving the current system for monitoring medical device safety and effectiveness. In April 2013, the FDA issued an update to the September 2012 report that incorporated public input received and described the next steps towards fulfilling the vision for building a national postmarket surveillance system. These reports can be found at FDA's Web site <http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHReports/ucm301912.htm>.

One of these next steps consisted of establishing a multistakeholder Medical Device Registry Task Force to promote the development of national and international device registries for selected products (Ref. 1). Under a cooperative agreement with the FDA, Duke University convened the Medical Device Registry Task Force as a part of the Medical Device Epidemiology Network public-private partnership in 2014. The Task Force membership included representatives from a broad array of stakeholder groups and areas of expertise including patients, provider organizations, hospitals, health plans, industry, government agencies, as well as methodologists and academic researchers.

The Medical Device Registry Task Force was charged to: (1) Identify existing registries that may contribute to the system; (2) leverage ongoing registry efforts focused on quality improvement, reimbursement, patient-centered outcomes and other activities to best meet the needs of multiple stakeholders; (3) identify priority medical device types for which the establishment of a longitudinal registry is of significant public health importance; (4) define registry governance and data quality practices that promote rigorous design, conduct, analysis, and transparency to meet stakeholder needs; and (5) develop strategies for the use of registries to support premarket approval and clearance (Ref. 1).

This notice announces the availability and Web site location of the Medical Device Registry Task Force's report, entitled "Recommendations for a National Medical Device Evaluation System: Strategically Coordinated Registry Networks to Bridge the Clinical Care and Research." FDA invites interested persons to submit comments on this report. We have established a docket where comments may be submitted (see **ADDRESSES**). We believe this docket is an important tool for receiving feedback on this report from interested parties and for sharing this information with the public. To access "Recommendations for a National Medical Device Evaluation System:

Strategically Coordinated Registry Networks to Bridge the Clinical Care and Research" report, visit FDA's Web site <http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHReports/ucm301912.htm>.

II. Request for Comments

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

III. Reference

The following reference has been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday. We have verified the Web site address, but we are not responsible for subsequent changes to the Web site after this document publishes in the **Federal Register**.

1. "Strengthening Our National System for Medical Device Postmarket Surveillance: Update and Next Steps," April 2013, available at <http://www.fda.gov/downloads/MedicalDevices/Safety/CDRHPostmarketSurveillance/UCM348845.pdf>.

Dated: August 19, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

National Vaccine Injury Compensation Program; List of Petitions Received

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: The Health Resources and Services Administration (HRSA) is publishing this notice of petitions received under the National Vaccine Injury Compensation Program (the Program), as required by Section 2112(b)(2) of the Public Health Service (PHS) Act, as amended. While the

Secretary of Health and Human Services is named as the respondent in all proceedings brought by the filing of petitions for compensation under the Program, the United States Court of Federal Claims is charged by statute with responsibility for considering and acting upon the petitions.

FOR FURTHER INFORMATION CONTACT: For information about requirements for filing petitions, and the Program in general, contact the Clerk, United States Court of Federal Claims, 717 Madison Place NW., Washington, DC 20005, (202) 357-6400. For information on HRSA's role in the Program, contact the Director, National Vaccine Injury Compensation Program, 5600 Fishers Lane, Room 11C-26, Rockville, MD 20857; (301) 443-6593, or visit our Web site at: <http://www.hrsa.gov/vaccinecompensation/index.html>.

SUPPLEMENTARY INFORMATION: The Program provides a system of no-fault compensation for certain individuals who have been injured by specified childhood vaccines. Subtitle 2 of Title XXI of the PHS Act, 42 U.S.C. 300aa-10 *et seq.*, provides that those seeking compensation are to file a petition with the U.S. Court of Federal Claims and to serve a copy of the petition on the Secretary of Health and Human Services, who is named as the respondent in each proceeding. The Secretary has delegated this responsibility under the Program to HRSA. The Court is directed by statute to appoint special masters who take evidence, conduct hearings as appropriate, and make initial decisions as to eligibility for, and amount of, compensation.

A petition may be filed with respect to injuries, disabilities, illnesses, conditions, and deaths resulting from vaccines described in the Vaccine Injury Table (the Table) set forth at 42 CFR 100.3. This Table lists for each covered childhood vaccine the conditions that may lead to compensation and, for each condition, the time period for occurrence of the first symptom or manifestation of onset or of significant aggravation after vaccine administration. Compensation may also be awarded for conditions not listed in the Table and for conditions that are manifested outside the time periods specified in the Table, but only if the petitioner shows that the condition was caused by one of the listed vaccines.

Section 2112(b)(2) of the PHS Act, 42 U.S.C. 300aa-12(b)(2), requires that "[w]ithin 30 days after the Secretary receives service of any petition filed under section 2111 the Secretary shall publish notice of such petition in the