

and over-the-counter (OTC) medications to stay healthy. Yet it is widely known that too many people incur preventable injury and even die from medication errors or misuse. Preventable injuries can result from a variety of sources, including informational errors (mistakes made in prescribing or using a medicine because of inadequate information); unintended, or accidental exposure; intentional drug misuse and abuse; and rarely because of manufacturing and/or distribution defects. The Institute of Medicine (IOM) estimates that 1.5 million preventable injuries, or adverse drug events, occur in the United States healthcare system each year,^{1,2} at a cost exceeding \$4 billion annually.

Additionally, incorrect use of OTC medications results in thousands of preventable injuries. Furthermore, unintended exposure to medications causes a significant number of injuries and deaths, mainly in children. Between 2003 and 2006 alone, more than 9,000 children were accidentally exposed to prescription opioid drugs.³

These potentially avoidable injuries and deaths represent our society's collective failure to adequately manage medication risks. Because the shortcomings in the healthcare system have been broadly acknowledged, FDA and many other healthcare stakeholders have been working hard to improve the way in which the nation's healthcare system manages medication risks. However, much more needs to be done, and coordinated cross-sector efforts, involving all stakeholders, would have the greatest impact.

To this end, FDA is launching the Safe Use Initiative, through which it will collaborate with stakeholders—including patients, consumers, caretakers, healthcare practitioners, pharmacists, healthcare systems, health insurers, drug manufacturers, and Federal agencies—to identify specific candidate cases associated with important, measurable amounts of preventable harm. In the coming months, FDA plans to develop, through extensive consultation with all interested public and private stakeholders, a general list of candidate cases for collaborative analysis and

intervention. FDA also intends to work with federal partners to develop population-based national estimates of preventable harm from medications, categorized by drug, drug classes, and therapeutic situations. In addition to opening a docket to receive public input, FDA plans to hold a series of public meetings to gather broad public feedback as the candidate list is being developed. It is FDA's goal to implement a small number of interventions during the next 12 months.

For more information, see FDA's Safe Use Web page at <http://www.fda.gov/Drugs/DrugSafety/ucm187806.htm>.

II. Submission of Feedback on the Contents of This Docket

Interested parties may submit to the Division of Dockets Management (see **ADDRESSES**) electronic or written comments on this information. Submit a single copy of electronic comments or two paper copies of any mailed comments. Individuals may submit one paper copy. Comments should be identified with the docket number found in brackets in this document's heading. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday. FDA will accept electronic comments or submissions only at <http://www.regulations.gov>.

Dated: October 30, 2009.

David Horowitz,

Assistant Commissioner for Policy.

[FR Doc. E9-26530 Filed 11-4-09; 8:45 am]

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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 Conflicts in Motor Function.

Date: November 13, 2009.

Time: 1 p.m. to 3 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: Dana Jeffrey Plude, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3176, MSC 7848, Bethesda, MD 20892, 301-435-2309, pluded@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; Review of BSCH Member Conflict Applications

Date: November 17, 2009.

Time: 2:30 p.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Ritz Carlton Hotel, 1150 22nd Street, NW., Washington, DC 20037.

Contact Person: Jose H. Guerrier, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5218, MSC 7852, Bethesda, MD 20892, 301-435-1137, guerriej@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business: Genes, Genomes, and Genetics.

Date: November 19, 2009.

Time: 8 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: Melrose Hotel, 2430 Pennsylvania Avenue, NW., Washington, DC 20037.

Contact Person: Michael A. Marino, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2216, MSC 7890, Bethesda, MD 20892, (301) 435-0601, marinomi@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: October 30, 2009.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E9-26689 Filed 11-4-09; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Eye Institute; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as

¹ Institute of Medicine of the National Academies, *Preventing Medication Errors*, National Academies Press, p. 124, 2007.

² *Ibid.*, p. 4. The IOM defines an adverse drug event (ADE) as any injury due to medication. Examples include a wrong dosage leading to injury (e.g., rash, confusion, or loss of function) or an allergic reaction occurring in a patient not known to be allergic to a given medication.

³ Bailey, J.E., E. Campagna, R.C. Dart, "The Underrecognized Toll of Prescription Opioid Abuse on Young Children," *Annals of Emergency Medicine*, 53:4129-24, 2009.