

telephone 301-435-6865 (not a toll-free number).

**SUPPLEMENTARY INFORMATION:** The NIH is providing notice of a "List of Drugs for Which Pediatric Studies Are Needed," as authorized under section 3, Public Law 107-109 (42 U.S.C. 409I). On January 4, 2002, President Bush signed into law the Best Pharmaceuticals for Children Act (BPCA). The BPCA mandates that not later than one year after the date of enactment, the NIH in consultation with the FDA and experts in pediatric research shall develop, prioritize, and publish an annual list of certain approved drugs for which pediatric studies are needed. For inclusion on the list, an approved drug must meet the following criteria: (1) There is an approved application under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)); (2) there is a submitted application that could be

approved under the criteria of section 505(j) of the Federal Food, Drug, and Cosmetic Act; (3) there is no patent protection or market exclusivity protection under the Federal Food, Drug, and Cosmetic Act; or (4) there is a referral for inclusion on the list under section 505A(d)(4)(c); and additional studies are needed to assess the safety and effectiveness of the use of the drug in the pediatric population. The BPCA further stipulates that in developing and prioritizing the list, the NIH shall consider for each drug on the list: (1) The availability of information concerning the safe and effective use of the drug in the pediatric population; (2) whether additional information is needed; (3) whether new pediatric studies concerning the drug may produce health benefits in the pediatric population; and (4) whether reformulation of the drug is necessary. In developing this list, the NIH

consulted with the FDA, the American Academy of Pediatrics, and other experts in pediatric research and practice. A preliminary list of drugs was drafted and categorized as a function of indication and use. The drugs were then prioritized based on frequency of use in the pediatric population, severity of the condition being treated, and potential for providing a health benefit in the pediatric population.

The following are the drugs newly added to the list for which pediatric studies are most urgently needed and their indications for use:

- Ampicillin—infections;
- Ketamine—sedation;
- Vincristine—malignancies;
- Dactinomycin—malignancies;
- Metolazone—diuresis.

Drugs that were previously listed as urgently needing studies, their indications for use, and their current status, are described in the table.

Drug needing pediatric study	Indications for pediatric use	Status
Lorazepam	Sedation in the Intensive Care Unit	1
	Treatment of status epilepticus	1
Nitroprusside	Reduction of blood pressure	1
Baclofen	Oral treatment of spasticity of cerebral palsy	1
Azithromycin	Prevention of bronchopulmonary dysplasia in neonates colonized with <i>U. urealyticum</i>	1
	Treatment of Chlamydia pneumonia, prevention of Chlamydia conjunctivitis and pneumonia	2
Lithium	Treatment of mania in bipolar disorder	1
Ampicillin/sulbactam	Pediatric infections	2
Diazoxide	Hypoglycemia	2
Isoflurane	Maintenance of general anesthesia	2
Meropenem	Pediatric infections	2
Metoclopramide	Gastroesophageal reflux	2
Piperacillin/tazobactam	Pediatric infections	2
Promethazine	Nausea/vomiting	2
Rifampin	Staphylococcus endocarditis	2
	CNS shunt infections	2
Lindane	2nd line treatment of scabies	2
Heparin	Anticoagulant	1
Bumetanide	Diuresis	3
Furosemide	Diuresis	3
Dobutamine	Increase cardiac output	3
Dopamine	Increase cardiac output	3
Spironolactone	Diuresis	3

<sup>1</sup> Drug labeled for use in children.

≤ Status: 1 = Contract being developed; 2 = Written Request being developed; 3 = Drug undergoing extensive review by NIH and FDA.

Dated: February 6, 2004.

Elias A. Zerhouni,

Director, National Institutes of Health.

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Substance Abuse and Mental Health Services Administration**

**Office for Women's Services; Notice of Meeting**

Pursuant to Public Law 92-463, notice is hereby given of a meeting of the Advisory Committee for Women's Services of the Substance Abuse and Mental Health Services Administration (SAMHSA) in February 2004.

The meeting of the Advisory Committee for Women's Services will include discussion around the activities of the Substance Abuse and Mental Health Services Administration involving substance abuse and mental health disorders affecting women, care services provided within the prison system, education and training curriculums within institutions of higher learning regarding the integration of primary care and substance abuse services and the services to science initiative. A summary of the meeting

and/or a roster of committee members may be obtained from: Nancy P. Brady, Executive Secretary, Advisory Committee for Women's Services, Office for Women's Services, SAMHSA, Parklawn Building, Room 12C-26, 5600 Fishers Lane, Rockville, Maryland 20857, Telephone: (301) 443-1135.

Attendance by the public and public comments are welcome. Please communicate with the individual listed as contact below to make arrangements to comment or to request special accommodations for persons with disabilities.

Substantive information may be obtained from the contact whose name and telephone number is listed below.

*Committee Name:* Advisory Committee for Women's Services.

*Meeting Date/Time:* Open: Thursday, February 26, 2004, 9 a.m.-5 p.m.; Open: Friday February 27, 2004, 9 a.m.-12 p.m.

*Place:* Gaithersburg Marriott Washingtonian Center, 9751 Washingtonian Boulevard, Gaithersburg, MD 20878.

*Contact:* Nancy P. Brady, Executive Secretary, 5600 Fishers Lane, Parklawn Building, Room 12C-26, Rockville, MD 20857, Telephone: (301) 443-1135; Fax: (301) 594-6159 and email: [nbrady@samhsa.gov](mailto:nbrady@samhsa.gov).

Dated: February 6, 2004.

**Toian Vaughn,**

*Committee Management Officer, Substance Abuse and Mental Health Services Administration.*

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## DEPARTMENT OF HOMELAND SECURITY

### Directorate of Science and Technology; Notice of Meeting of Homeland Security Science and Technology Advisory Committee

**AGENCY:** Office of the Under Secretary for Science and Technology, Department of Homeland Security.

**ACTION:** Notice.

**SUMMARY:** The Homeland Security Science and Technology Advisory Committee (HSSTAC) will meet in a partially closed session in Potomac, MD on February 26 & 27, 2004.

**DATES:** The HSSTAC will meet in open session on February 26, 2004, from 11 a.m. to 2 p.m. HSSTAC will meet in closed session on February 26, 2004, from 2:30 p.m. to 5:30 p.m. and on February 27, 2004, from 8:25 a.m. to 3 p.m.

**FOR FURTHER INFORMATION CONTACT:** Craig Wilson, Homeland Security Science and Technology Advisory Committee, Department of Homeland

Security, Science and Technology Directorate, Washington, DC 20528; telephone (202) 205-5041; e-mail [HSSTAC@dhs.gov](mailto:HSSTAC@dhs.gov).

**SUPPLEMENTARY INFORMATION:** Notice of this meeting is given under the Federal Advisory Committee Act, 5 U.S.C. App.2. The HSSTAC will meet for purposes of: (1) Welcoming and introducing members of the committee; (2) receiving briefings on the mission and organization of the department; (3) receiving briefings on the mission and approaches of the Science and Technology Directorate; (4) holding roundtable discussions with the Committee members; (5) discussing the role of the Committee in advising the Department; (6) receiving briefings on detailed historical background, organization, programs, accomplishments, and plans of the Science and Technology Directorate; (7) receiving briefings on activities and accomplishments of the Office of Research & Development, the Homeland Security Advanced Projects Research Agency, the Office of Systems Engineering and Development, and the Office of Weapons of Mass Destruction Operations and Incident Management. This meeting will be partially closed; the open portions of the meeting for purposes of (1) through (5) above will be held in the Gymnasium Room of the William F. Bolger Center from 11 a.m. to 2 p.m. on February 26, 2004. The closed portions of the meeting, for purposes of (6) and (7) above will be held at the William F. Bolger Center from 2:30 p.m. to 5:30 p.m. on February 26, 2004, and from 8:25 a.m. to 3 p.m. on February 27, 2004. The William F. Bolger Center is located at 9600 Newbridge Drive, Potomac, MD 20854.

*Public Attendance:* Members of the public will be registered to attend the public session on a first-come, first-served basis per the procedures that follow. Security requires that any member of the public who wishes to attend the public session provide his or her name, social security number, and date of birth no later than 5 p.m. EST, Tuesday, February 18, 2004. Please provide the required information to Craig Wilson via email at [HSSTAC@dhs.gov](mailto:HSSTAC@dhs.gov), or via phone at (202) 205-5041. Persons with disabilities who require special assistance should indicate so in their admittance request. Photo identification will be required for entry into the public session, and everyone in attendance must be present and seated by 10:45 a.m. on February 26, 2004.

*Basis for Closure:* In accordance with section 10(d) of the Federal Advisory

Committee Act, Public Law 92-463, as amended (5 U.S.C. App. 2), the Under Secretary for Science and Technology has issued a determination that portions of this HSSTAC meeting will concern matters sensitive to homeland security within the meaning of 5 U.S.C. 552b(c) (7) and (c)(9)(B) and that, accordingly, these portions of the meeting will be closed to the public.

*Public Comments:* Members of the public who wish to file a written statement with the HSSTAC may do so by mail to Craig Wilson at the following address: Homeland Security Science and Technology Advisory Committee, Department of Homeland Security, Science and Technology Directorate, Washington, DC 20528. Comments may also be sent via email to [HSSTAC@dhs.gov](mailto:HSSTAC@dhs.gov) or via fax at (202) 772-9916.

Dated: February 6, 2004.

**Charles E. McQueary,**

*Under Secretary for Science and Technology, Department of Homeland Security.*

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## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

[USCG-2004-17063]

### National Offshore Safety Advisory Committee

**AGENCY:** Coast Guard, DHS.

**ACTION:** Notice of meeting.

**SUMMARY:** The National Offshore Safety Advisory Committee (NOSAC) will meet to discuss various issues relating to offshore safety and security. The meeting will be open to the public.

**DATES:** NOSAC will meet on Thursday, April 1, 2004, from 9 a.m. to 3 p.m. The meeting may close early if all business is finished. Written material and requests to make oral presentations should reach the Coast Guard on or before March 18, 2004. Requests to have a copy of your material distributed to each member of the committee should reach the Coast Guard on or before March 18, 2004.

**ADDRESSES:** NOSAC will meet in room 2415, of the Coast Guard Headquarters Bldg, 2100 Second Street, SW., Washington, DC. Send written material and requests to make oral presentations to Captain D.L. Scott, Commandant (G-MSO), U.S. Coast Guard Headquarters, 2100 Second Street SW., Washington, DC 20593-0001. This notice is available on the Internet at <http://dms.dot.gov>.