

e. What are the implications of these contracting provisions and their changes for the probability, severity, and duration of drug shortages?

f. How much competition exists throughout the supply chain? Over the past 15 years, have there been challenges to competition and if so, what factors are responsible for these challenges? For example, has consolidation in different parts of the supply chain created market barriers to entry and reduced competition? If so, what effect has the reduction in competition had on drug shortages?

C. Identifying Strategies for Preventing or Mitigating Drug Shortages

1. What policies could the Federal Government adopt, and what strategies could it implement, that would reduce the likelihood, severity, and duration of shortages? Would additional authorities be necessary or helpful? For example:

a. Establish a list of “essential medicines” for use in preventing and mitigating shortages. If such a list were established, what should be the criteria for inclusion? And how should such a list be maintained and administered?

b. Provide financial incentives, such as tax credits or revised reimbursement policies: *e.g.*, to allow additional payments for drugs in or at risk of shortage or to encourage investment to expand manufacturing capacity or to modernize aging infrastructure, to enhance process capability and variability control, or to prevent manufacturing problems that affect product availability;

c. Allow other entities (*e.g.*, contract manufacturers) to fill gaps in supply;

d. Require risk management plans to help manufacturers prepare to respond efficiently and effectively to potential shortages;

e. Require the extension of expiration dates for drugs in shortage or at risk of shortage, where scientifically justified;

f. Revise trade policies and authorities: *e.g.*, to allow federal purchasers to buy imported drugs or raw materials to prevent or mitigate a shortage;

g. Heighten scrutiny of proposed mergers and acquisitions that increase market concentration or the likelihood of shortages;

h. Revise payment policies and authorities: *e.g.*, that would be coupled with a requirement to establish contingency plans for supplying medicines that go into shortage; and

i. Federal investment in production capacity for essential medicines directly related to national security, emergency preparedness, and defense.

2. In designing new policies to prevent or mitigate shortages, how can the Federal Government avoid creating perverse incentives or negative cascading effects in the health care financing and delivery system? For example, how might changes to government payment and reimbursement affect the other sectors of the market?

3. Are there lessons for the Federal Government, or practices that it can emulate, from strategies used to prevent or mitigate shortages in other commodity markets that face shortage issues?

4. What challenges does the global nature of drug manufacturing and marketing pose for efforts to prevent shortages in the U.S. market?

5. As drug shortages are a national problem, what are the sources of funding that can be applied to provide incentives to remedy the root causes?

III. Participating in the Public Meeting

Registration: To register for the public meeting, please visit the following website: <https://healthpolicy.duke.edu/events/drug-shortage-task-force>. Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone. Registration is free and based on space availability, with priority given to early registrants. Persons interested in attending this public meeting must register by Wednesday, November 21, 2018, midnight Eastern Time. There will be no onsite registration. Early registration is recommended because seating is limited; therefore, FDA may limit the number of participants from each organization. Registrants will receive confirmation when they have been accepted. If you are unable to attend the meeting in person, you can register to view a live webcast of the meeting. The Duke-Margolis Center for Health Policy will post on its website if registration closes before the day of the public meeting.

If you need special accommodations due to a disability, please contact Sarah Supsiri at the Duke-Margolis Center for Health Policy (phone: 202-791-9561, email: sarah.supsiri@duke.edu) no later than November 20, 2018.

Streaming webcast of the public workshop: This public workshop will be webcast live. Persons interested in viewing the live webcast may register ahead of the event by visiting <https://healthpolicy.duke.edu/events/drug-shortage-task-force>. The live webcast will also be available at the website above on the day of the event without pre-registration. Archived video footage

will be available at the Duke-Margolis website following the workshop.

Transcripts: Please be advised that as soon as a transcript of the public meeting is available, it will be accessible at <https://www.regulations.gov>. It may be viewed at the Dockets Management Staff (see **ADDRESSES**). A link to the transcript will also be available on the internet at <https://www.fda.gov/Drugs/DrugSafety/DrugShortages/default.htm>.

Other Issues for Consideration: A 1-hour lunch break is scheduled, but food will not be provided. There are multiple restaurants within walking distance of the Washington Marriott at Metro Center, 775 12th St. NW, Washington, DC 20005.

All event materials will be provided to registered attendees via email prior to the workshop and will be publicly available at the Duke-Margolis Center for Health Policy website at <https://healthpolicy.duke.edu/events/drug-shortage-task-force>.

Dated: September 5, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018-19612 Filed 9-7-18; 8:45 am]

BILLING CODE 4164-01-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, 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: Vascular and Hematology Integrated Review Group; Hypertension and Microcirculation Study Section.

Date: October 2-3, 2018.

Time: 8:00 a.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Embassy Suites at the Chevy Chase Pavilion, 4300 Military Road NW, Washington, DC 20015.

Contact Person: Ai-Ping Zou, M.D., Ph.D., Scientific Review Officer, Center for

Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4118, MSC 7814, Bethesda, MD 20892, 301-408-9497, zouai@mail.nih.gov.

Name of Committee: Integrative, Functional and Cognitive Neuroscience Integrated Review Group; Mechanisms of Sensory, Perceptual, and Cognitive Processes Study Section.

Date: October 4–5, 2018.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

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

Contact Person: Kirk Thompson, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5184, MSC 7844, Bethesda, MD 20892, 301-435-1242, kgt@mail.nih.gov.

Name of Committee: Interdisciplinary Molecular Sciences and Training Integrated Review Group; Enabling Bioanalytical and Imaging Technologies Study Section.

Date: October 4–5, 2018.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Crystal City Marriott, 1999 Jefferson Davis Highway, Arlington, VA 22202.

Contact Person: Kenneth Ryan, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3218, MSC 7717, Bethesda, MD 20892, 301-435-0229, kenneth.ryan@nih.hhs.gov.

Name of Committee: Risk, Prevention and Health Behavior Integrated Review Group; Interventions to Prevent and Treat Addictions Study Section.

Date: October 4–5, 2018.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Palomar Hotel, 2121 P Street NW, Washington, DC 20037.

Contact Person: Miriam Mintzer, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3108, Bethesda, MD 20892, (301) 523-0646, mintzermz@csr.nih.gov.

Name of Committee: Cell Biology Integrated Review Group; Biology of the Visual System Study Section.

Date: October 4–5, 2018.

Time: 8:00 a.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Michael H Chaitin, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5202, MSC 7850, Bethesda, MD 20892, (301) 435-0910, chaitinm@csr.nih.gov.

Name of Committee: Surgical Sciences, Biomedical Imaging and Bioengineering Integrated Review Group; Bioengineering, Technology and Surgical Sciences Study Section.

Date: October 4–5, 2018.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hilton Washington/Rockville, 1750 Rockville Pike, Rockville, MD 20852.

Contact Person: Khalid Masood, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5120, MSC 7854, Bethesda, MD 20892, 301-435-2392, masoodk@csr.nih.gov.

Name of Committee: Emerging Technologies and Training Neurosciences Integrated Review Group; Neuroscience and Ophthalmic Imaging Technologies Study Section.

Date: October 4–5, 2018.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Renaissance Washington DC Downtown Hotel, 999 9th St. NW, Washington, DC 20001.

Contact Person: Yvonne Bennett, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5199, MSC 7846, Bethesda, MD 20892, 301-379-3793, bennetty@csr.nih.gov.

Name of Committee: Molecular, Cellular and Developmental Neuroscience Integrated Review Group; Cellular and Molecular Biology of Glia Study Section.

Date: October 4–5, 2018.

Time: 8:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: St. Gregory Hotel, 2033 M Street NW, Washington, DC 20036.

Contact Person: Linda MacArthur, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4187, Bethesda, MD 20892, 301-537-9986, macarthurlh@csr.nih.gov.

Name of Committee: Immunology Integrated Review Group; Cellular and Molecular Immunology—B Study Section.

Date: October 4–5, 2018.

Time: 8:30 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Wyndham Grand Chicago Riverfront, 71 E Wacker Dr., Chicago, IL 60601.

Contact Person: Betty Hayden, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4206, MSC 7812, Bethesda, MD 20892, 301-435-1223, haydenb@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: September 4, 2018.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018-19484 Filed 9-7-18; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting 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: National Institute on Aging Special Emphasis Panel; Developing Infrastructure for Interdisciplinary Aging Research.

Date: September 24, 2018.

Time: 10:00 a.m. to 1:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute on Aging, Gateway Building, Suite 2W-200, 7201 Wisconsin Avenue, Bethesda, MD 20892.

Contact Person: Anita H. Undale, Ph.D., MD, Scientific Review Branch, National Institute on Aging, Gateway Building, Suite 2W200, 7201 Wisconsin Avenue, Bethesda, MD 20892, 240-747-7825, anita.undale@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS)

Dated: September 4, 2018.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018-19481 Filed 9-7-18; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Director, National Institutes of Health; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the Advisory Committee to the Deputy Director for Intramural Research, National Institutes of Health.

The meeting will be open to the public, with attendance limited to space available. Individuals who plan to attend and need special assistance, such