

either by eliminating significant current or potential competition in concentrated existing markets, or by eliminating significant potential competition among a limited number of likely competitors in a future market. In each of these markets, Mylan and Agila are two of only a limited number of current or likely future suppliers of the drugs in the United States. The evidence shows that prices may continue to decrease even after a number of suppliers have entered a generic injectable drug market. Thus, although Mylan or Agila have not entered some of the markets at issue yet, both companies likely will compete in those markets in the future, and that competition is expected to reduce prices for consumers. The evidence also shows that the removal of an independent generic injectable drug supplier from the relevant markets in which Mylan and Agila currently compete would result in significantly higher prices post-acquisition. Therefore, by eliminating the significant current and future competition between the parties, the Proposed Acquisition will likely cause U.S. consumers to pay significantly higher prices for these generic injectable drugs, absent a remedy.

#### The Consent Agreement

The Consent Agreement effectively remedies the Proposed Acquisition's anticompetitive effects in each relevant market. Under the Consent Agreement, the parties are required to divest either Mylan's or Agila's rights and assets related to (1) Amiodarone hydrochloride injection, (2) etomidate injection, (3) fluorouracil injection, (4) mesna injection, (5) methotrexate sodium preservative-free injection, (6) acetylcysteine injection, (7) fomepizole injection, (8) ganciclovir injection, (9) meropenem injection, and (10) mycophenolate mofetil injection. In addition, Mylan is required to release all of its rights and assets related to labetalol hydrochloride injection. The parties must accomplish these divestitures and relinquish their rights no later than ten days after the acquisition.

The proposed Consent Agreement requires Mylan to terminate its contract with Gland and to release all rights related to labetalol hydrochloride injection. Gland, a global pharmaceutical company based in India, is Mylan's contract manufacturer for this drug. Given its experience with this drug, Gland is well positioned to replicate the competition that would otherwise have been lost as a result of the Proposed Acquisition. The proposed Consent Agreement also requires Mylan to divest assets related to fluorouracil

injection and methotrexate sodium preservative-free injection to Intas and to divest assets related to etomidate injection, ganciclovir injection, meropenem injection, and mycophenolate mofetil injection to JHP. In addition, the proposed Consent Agreement requires Agila and Strides to divest assets related to acetylcysteine injection and mesna injection to Sagent and to divest assets related to amiodarone hydrochloride injection and fomepizole injection to JHP. Intas is a global pharmaceutical company based in India with approximately 79 prescription drugs approved for sale in the United States, as well as an active product development pipeline. JHP is a New Jersey based pharmaceutical company with approximately 22 approved ANDAs and an active product development pipeline. Finally, Sagent, a pharmaceutical company based in Illinois, has approximately 58 approved ANDAs and an active product development pipeline. With their experience in generic markets, Intas, JHP, and Sagent are expected to replicate fully the competition that would otherwise have been lost as a result of the Proposed Acquisition.

The Commission's goal in evaluating possible acquirers of divested assets is to maintain the competitive environment that existed prior to the acquisition. If the Commission determines that Intas, JHP, Sagent, or Gland are not acceptable acquirers, or that the manner of the divestitures or releases is not acceptable, the parties must unwind the sale or release of rights to Intas, JHP, Sagent, or Gland and divest the products to a Commission-approved acquirer within six months of the date the Order becomes final. In that circumstance, the Commission may appoint a trustee to divest the products if the parties fail to divest the products as required.

The proposed Consent Agreement contains several provisions to help ensure that the divestitures are successful. The Order requires Mylan, Agila, and Strides to take all action to maintain the economic viability, marketability, and competitiveness of the products to be divested until such time that they are transferred to a Commission-approved acquirer. Mylan and Agila must transfer their respective manufacturing technologies for generic amiodarone hydrochloride injection, etomidate injection, and fomepizole injection to JHP and must supply JHP with these drugs during the transition period. Further, Agila and Strides must transfer the manufacturing technology for acetylcysteine injection and mesna injection to Sagent and must supply

Sagent with the two drugs during the transition period.

The purpose of this analysis is to facilitate public comment on the proposed Consent Agreement, and it is not intended to constitute an official interpretation of the proposed Order or to modify its terms in any way.

By direction of the Commission.

**Donald S. Clark,**

*Secretary.*

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## GENERAL SERVICES ADMINISTRATION

[Notice-MK-2013-09; Docket No. 2013-0002; Sequence 31]

### The President's Management Advisory Board (PMAB); Notification of Upcoming Public Advisory Meeting

**AGENCY:** Office of Executive Councils, U.S. General Services Administration (GSA).

**ACTION:** Meeting Notice.

**SUMMARY:** The President's Management Advisory Board (PMAB), a Federal Advisory Committee established in accordance with the Federal Advisory Committee Act (FACA), 5 U.S.C., App., and Executive Order 13538, will hold a public teleconference meeting on Monday, October 21, 2013.

**DATES:** *Meeting date:* The meeting will be held on Monday, October 21, 2013, beginning at 11:00 a.m. eastern time, ending no later than 12:30 p.m.

**FOR FURTHER INFORMATION CONTACT:** Mr. Stephen Brockelman, Designated Federal Officer, President's Management Advisory Board, Office of Executive Councils, General Services Administration, 1800 F Street NW., Washington, DC 20006, at [stephen.brockelman@gsa.gov](mailto:stephen.brockelman@gsa.gov).

#### SUPPLEMENTARY INFORMATION:

*Background:* The PMAB was established to provide independent advice and recommendations to the President and the President's Management Council on a wide range of issues related to the development of effective strategies for the implementation of best business practices to improve Federal Government management and operation.

*Agenda:* The main purpose for this meeting is for the PMAB to discuss and define areas of work for the PMAB emerging from the new President's Management Agenda. Focal areas are likely to involve recommendations for

initiatives designed to improve the effectiveness of federal government operations. The meeting will also cover planning and logistics for PMAB during the coming year.

**Meeting Access:** The teleconference meeting is open to the public; interested members of the public may listen to the PMAB discussion using 1-888-673-9806 and pass code 7836092. Members of the public will not have the opportunity to ask questions or otherwise participate in the teleconference. However, members of the public wishing to comment should follow the steps detailed in *Procedures for Providing Public Comments* below.

**Availability of Materials for the Meeting:** Please see the PMAB Web site (<http://www.whitehouse.gov/administration/advisory-boards/pmab>) for any materials available in advance of the meeting and for meeting minutes that will be made available after the meeting. Detailed meeting minutes will be posted within 90 days of the meeting.

**Procedures for Providing Public Comments:** In general, public statements will be posted on the PMAB Web site (see above). Non-electronic documents will be made available for public inspection and copying in PMAB offices at GSA, 1800 F Street NW., Washington, DC 20006, on official business days between the hours of 10 a.m. and 5 p.m. eastern time. You can make an appointment to inspect statements by telephoning 202-501-1398. All statements, including attachments and other supporting materials, received are part of the public record and subject to public disclosure. Any statements submitted in connection with the PMAB meeting will be made available to the public under the provisions of the Federal Advisory Committee Act (FACA).

The public is invited to submit written statements for this meeting until 12:30 p.m. eastern time on Friday, October 18, 2013, by either of the following methods: *Electronic or Paper Statements:* Submit electronic statements to Mr. Brockelman, Designated Federal Officer at [stephen.brockelman@gsa.gov](mailto:stephen.brockelman@gsa.gov); or send paper statements in triplicate to Mr. Brockelman at the PMAB GSA address above.

Dated: September 27, 2013.

**Anne Rung,**

*Associate Administrator, Office of Government-wide Policy, General Services Administration.*

[FR Doc. 2013-24145 Filed 10-2-13; 8:45 am]

**BILLING CODE 6820-BR-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Advisory Council on Alzheimer's Research, Care, and Services; Meeting

**AGENCY:** Assistant Secretary for Planning and Evaluation, HHS.

**ACTION:** Notice of meeting.

**SUMMARY:** This notice announces the public meeting of the Advisory Council on Alzheimer's Research, Care, and Services (Advisory Council). The Advisory Council on Alzheimer's Research, Care, and Services provides advice on how to prevent or reduce the burden of Alzheimer's disease and related dementias on people with the disease and their caregivers. During the October meeting, the Advisory Council will welcome new members and discuss the timeline for the 2014 recommendations. The subcommittees will discuss priorities and areas for recommendations. The Advisory Council will hear presentations on work underway to harness "big data" to address Alzheimer's research.

**DATES:** The meeting will be held on October 28, 2013 from 9:00 a.m. to 5:00 p.m. EDT.

**ADDRESSES:** The meeting will be held in the Great Hall of the U.S. Department of Health and Human Services, 200 Independence Avenue SW., Washington, DC 20201.

Comments: Time is allocated on the agenda to hear public comments. In lieu of oral comments, formal written comments may be submitted for the record to Helen Lamont, Ph.D., OASPE, 200 Independence Avenue SW., Room 424E, Washington, DC 20201. Comments may also be sent to [napa@hhs.gov](mailto:napa@hhs.gov). Those submitting written comments should identify themselves and any relevant organizational affiliations.

**FOR FURTHER INFORMATION CONTACT:** Helen Lamont, Ph.D. (202) 690-7996, [helen.lamont@hhs.gov](mailto:helen.lamont@hhs.gov). Note: Seating may be limited. Those wishing to attend the meeting must send an email to [napa@hhs.gov](mailto:napa@hhs.gov) and put "October 28 meeting attendance" in the Subject line by Friday, October 18, 2013, so that their names may be put on a list of expected attendees and forwarded to the security officers at the Department of Health and Human Services. Any interested member of the public who is a non-U.S. citizen should include this information at the time of registration to ensure that the appropriate security procedure to gain entry to the building is carried out. Although the meeting is open to the public, procedures

governing security and the entrance to Federal buildings may change without notice. If you wish to make a public comment, you must note that within your email.

**SUPPLEMENTARY INFORMATION:** Notice of these meetings is given under the Federal Advisory Committee Act (5 U.S.C. App. 2, section 10(a)(1) and (a)(2)). Topics of the Meeting: The Advisory Council will welcome new members and discuss the timeline for the 2014 recommendations. The subcommittees will discuss priorities and areas for recommendations. The Advisory Council will hear presentations on work underway to harness "big data" to address Alzheimer's research.

**Procedure and Agenda:** This meeting is open to the public.

**Authority:** 42 U.S.C. 11225; Section 2(e)(3) of the National Alzheimer's Project Act. The panel is governed by provisions of Public Law 92-463, as amended (5 U.S.C. Appendix 2), which sets forth standards for the formation and use of advisory committees.

Dated: October 1, 2013.

**Donald Moulds,**

*Acting Assistant Secretary for Planning and Evaluation.*

[FR Doc. 2013-24206 Filed 10-2-13; 8:45 am]

**BILLING CODE P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Agency for Healthcare Research and Quality

#### Notice of Meetings

**AGENCY:** Agency for Healthcare Research and Quality (AHRQ), HHS.

**ACTION:** Notice of Five AHRQ Subcommittee Meetings.

**SUMMARY:** The subcommittees listed below are part of AHRQ's Health Services Research Initial Review Group Committee. Grant applications are to be reviewed and discussed at these meetings. Each subcommittee meeting will commence in open session before closing to the public for the duration of the meeting. These meetings will be closed to the public in accordance with 5 U.S.C. App. 2 section 10(d), 5 U.S.C. 552b(c)(4), and 5 U.S.C. 552b(c)(6).

**DATES:** See below for dates of meetings:

1. *Healthcare Effectiveness and Outcomes Research (HEOR)*  
Date: October 16, 2013 (Open from 8:00 a.m. to 8:30 a.m. on October 16 and closed for remainder of the meeting)
2. *Health System and Value Research (HSVR)*