Sales Price (ASP) as required by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA). This shift reduced the reimbursement amount to physicians by 35 percent for the powder form of IVIG and by 15 percent for the liquid form of IVIG. Since January 2005, some patient advocacy groups and physicians have reported difficulty acquiring IVIG. The FDA Center for Biologics Evaluation and Research, however, has not identified a shortage of IVIG. There have also been reports of IVIG being diverted to secondary markets with increases in prices.

The focus of the Town Hall meeting is on receiving information from stakeholders that will be helpful in the analysis. The Town Hall meeting will accept comments from all stakeholders, but is focused on patient and physician concerns with access to IVIG including:

(1) Patients switching IVIG products due to access problems,

(2) Changes in the administration location,

(3) Patients receiving fewer treatments,

(4) Patients receiving reduced dosages, and

(5) Reimbursement problems with IVIG products,

(6) Patients receiving reduced dosages, and

(7) Health consequences for patients of any access issues.

II. Registration

Registration procedures: Registration can be completed online at *https://www2.ergweb.com/projects/conferences/hhs/*. To register by telephone, contact ERG's Conference Registration Line at 781–674–7374. The following information must be provided when registering: Name, organization name and address (if applicable), and consent to publish contact information on a participants list and other reports to document the Town Hall meeting. An ERG staff member will confirm your registration by mail, e-mail, or fax. Attendees may participate in person or by phone. If you wish to participate by phone, please indicate this in your registration and a call-in conference number will be provided in your registration confirmation. Attendees must register by September 21.

III. Comment Format

a. ''5-Minute'' Public Comment

Meeting attendees can sign up on a first-come, first-served basis to present their comments (maximum of 5 minutes) via the meeting Web site when you register. Comments may be made in person or by phone. Commenters should focus on issues related to access to IVIG and quantify these impacts when possible. Commenters must provide their name, title, and organization (if applicable) on their registration and identify the topic area they will address. Presenters that can not attend in person can participate via phone. If you are unable to attend in person, you should indicate at registration that you wish to participate via phone. A call-in conference number will be provided to you in your registration confirmation.

b. Written Comments From Meeting Attendees

Written comments are welcome from the public regardless of whether you attend the Town Hall Meeting or whether you make an oral presentation at the Town Hall Meeting. Written comments can be submitted either at the meeting, or before or after the meeting via e-mail to *meetings@erg.com* (subject: IVIG Meeting Comments). Or via regular mail to Attn: IVIG Meeting, ERG, 110 Hartwell Avenue, Lexington, MA 02421. Please note that electronic submissions are preferred due to delays in receiving US Postal Mail. We are able to consider only those comments received in writing and/or via e-mail by 5 p.m. EST on October 15, 2006.

IV. Special Accommodations

Individuals attending the meeting who are hearing- or visually-impaired and have special requirements, or a condition that requires special assistance or accommodations, must provide this information when registering for the meeting and accommodations will be made.

Dated: August 31, 2006.

Jerry Regier,

Principal Deputy Assistant Secretary for Planning and Evaluation, Office of the Assistant Secretary for Planning and Evaluation.

[FR Doc. 06–7510 Filed 9–7–06; 8:45 am]

BILLING CODE 4151–06–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the National Vaccine Advisory Committee

AGENCY: Department of Health and Human Services, Office of the Secretary.

ACTION: Notice.

SUMMARY: As stipulated by the Federal Advisory Committee Act, the Department of Health and Human Services (DHHS) is hereby giving notice that the National Vaccine Advisory Committee (NVAC) will hold a meeting. The meeting is open to the public.

DATES: The meeting will be held on September 26, 2006, from 9 a.m. to 5 p.m., and on September 27, 2006, from 9 a.m. to 4 p.m.

ADDRESSES: Department of Health and Human Services; Hubert H. Humphrey Building, Room 800; 200 Independence Avenue, SW., Washington, DC 20201.

FOR FURTHER INFORMATION CONTACT: Ms. Emma English, Program Analyst, National Vaccine Program Office, Department of Health and Human Services, Room 443–H Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201; (202) 690–5566, *nvac@hhs.gov.*

SUPPLEMENTARY INFORMATION: Pursuant to Section 2101 of the Public Service Act (42 U.S.C. 300aa–1), the Secretary of Health and Human Services was mandated to establish the National Vaccine Program to achieve optimal prevention of human infectious diseases through immunization and to achieve optimal prevention against adverse reactions to vaccines. The National Vaccine Advisory Committee was established to provide advice and make recommendations to the Assistant Secretary for Health, as the Director of the National Vaccine Program, on matters related to the program's responsibilities.

Topics to be discussed at the meeting include: the 2006–2007 influenza season, increasing immunization among adolescents, vaccine financing, implementation plans for new vaccines, and vaccine safety. Updates will be given by various subcommittees and working groups. A tentative agenda will be made available on or about September 5, 2006 for review on the NVAC Web site: *http://www.hhs.gov/nvpo/nvac.*

Public attendance at the meeting is limited to space available. Individuals must provide a photo ID for entry into the Humphrey Building. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the designated contact person. Members of the public will have the opportunity to provide comments at the meeting. Public comment will be limited to five minutes per speaker. Any members of the public who wish to have printed material distributed to NVAC members should submit materials to the Executive Secretary, NVAC, through the contact person listed above prior to close of business September 19, 2006. Preregistration is required for both public attendance and comment. Any

individual who wishes to attend the meeting and/or participate in the public comment session should e-mail *nvac@hhs.gov* or call 202–690–5566.

Dated: September 5, 2006.

Bruce Gellin,

Director, National Vaccine Program Office.

[FR Doc. E6–14882 Filed 9–7–06; 8:45 am]

BILLING CODE 4150–44–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Public Health Emergency Preparedness; Draft HHS Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) Strategy for Chemical, Biological, Radiological and Nuclear (CBRN) Threats [1]

AGENCY: Office of Public Health Emergency Preparedness.

ACTION: Draft HHS Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) Strategy for Chemical, Biological, Radiological and Nuclear (CBRN) Threats.

SUMMARY: The United States faces serious public health threats from the deliberate use of weapons of mass destruction (WMD)—chemical, biological, radiological, or nuclear (CBRN)—by hostile States or terrorists, and from naturally emerging infectious diseases that have a potential to cause illness on a scale that could adversely impact national security. Effective strategies to prevent, mitigate, and treat the consequences of CBRN threats is an integral component of our national security strategy. To that end, the United States must be able to rapidly develop, stockpile, and deploy effective medical countermeasures to protect the American people. The ultimate goal of this HHS Public Health Emergency Medical Countermeasures Enterprise Strategy (*PHEMCE Strategy*) is to establish the foundational elements and guiding principles that will support medical countermeasure availability and utilization for the highest priority CBRN threats facing our nation.

[1] This Strategy excludes pandemic influenza which is addressed in the HHS Pandemic Influenza Plan, a blueprint for pandemic influenza preparation and response. It provides guidance to national, state, and local policy makers and health departments. The HHS Pandemic Influenza Plan includes an overview of the threat of pandemic influenza, a description of the relationship of this document to other Federal plans and an outline of key roles and responsibilities during a pandemic. It is aligned with the .National Strategy for Pandemic Influenza, issued by President Bush November 1, 2005, and the *Implementation Plan for the National Strategy for Pandemic Influenza* which guide our nation's preparedness and response to an influenza pandemic.

DATES: The public is invited to submit comments on the draft HHS *PHEMCE Strategy* up to thirty days from the date of publication in the **Federal Register**. After consideration of the comments submitted, HHS will issue a final *PHEMCE Strategy.*

Comments: Address all comments to Dr. Susan Coller at *PHEMCSTRAT@hhs.gov.*

FOR FURTHER INFORMATION CONTACT: Dr. Susan Coller, Policy Analyst, Office of Public Health Emergency Medical Countermeasures, Office of Public Health Emergency Preparedness at 330 Independence Ave., SW., Room G640 Washington, DC 20201, or by phone at 202–260–1200.

Overview

The United States faces serious public health threats from the deliberate use of weapons of mass destruction (WMD)—chemical, biological, radiological, or nuclear (CBRN)—by hostile States or terrorists, and from naturally emerging infectious diseases that have a potential to cause illness on a scale that could adversely impact national security. A failure to anticipate these threats, or the lack of a capacity to effectively respond to them could leave an untold number of Americans dead or permanently disabled. Thus, effective strategies to prevent, mitigate, and treat the consequences of CBRN threats are an integral component of our national security strategy. To that end, the United States must be able to rapidly develop, stockpile, and deploy effective medical countermeasures (MCM) to protect the American people.

The key role for development and acquisition of effective medical countermeasures for WMD was previously identified in the *National Strategy to Combat Weapons of Mass Destruction* and *Biodefense for the 21st Century,* the President's blueprint for addressing the nation's biodefense programs. Research and early development support of CBRN MCM by the National Institutes of Health has grown from $53 million in Fiscal Year (FY) 2001 to $1.8 billion in FY 2006. Funding for the Strategic National Stockpile similarly has grown from $52 million in FY01 to $530 million in FY06. Furthermore, on July 21, 2004, President George W. Bush signed into law the Project BioShield Act of 2004 (Project BioShield) to accelerate the research, development, acquisition, and availability of effective medical countermeasures to protect our citizens against CBRN threats. Project BioShield provided $5.6 billion over 10 years to acquire these medical countermeasures.

During its first two years of implementation, Project BioShield acquisitions were guided by a policy and requirements document derived from interagency deliberations in 2003 that involved Cabinet-level Departments and the Executive Office of the President. This document served as the initial strategic plan for acquisition under Project BioShield. Under this strategy, the Department of Health and Human Services (HHS) pursued acquisitions for those highest priority threats for which there were candidate products at relatively advanced stages of development. These products included medical countermeasures for anthrax, smallpox, botulinum toxins and radiological/nuclear agents, the four threat agents deemed by the Department of Homeland Security (DHS) to pose a ''material threat'' to national security. The relatively advanced nature of the products pursued resulted from years of investment, made in large part by the Department of Defense in advance of the BioShield program, as well as aggressive development programs launched by the National Institutes of Health soon after the anthrax attacks in 2001.

Despite these achievements, more can and must be done. HHS will continue to shape and execute a comprehensive, focused MCM program to protect our citizens against CBRN threats today and into the future. On behalf of the Secretary, the Office of Public Health Emergency Preparedness is dedicated to the mission of preventing and mitigating the adverse public health consequences of disasters resulting from these threats. This mission encompasses the breadth of activities required to accomplish the goal including: threat agent and disease surveillance and detection; and research, development, acquisition, storage, deployment and utilization of medical countermeasures.

A focused medical countermeasure program will reflect threat priorities, threat agent characteristics, medical/public health consequence assessments, and the likelihood that effective medical and public health intervention will prevent and mitigate adverse health consequences. Given the expense and time required to develop each countermeasure, and the wide range of pathogens and compounds that potentially could be used in an attack, we must develop a strategy that prioritizes investment in a manner that optimizes our ability to mitigate the public health impact of current and future threats.

The type and magnitude of both CBRN and natural threats are evolving. New diseases emerge and existing diseases change. World-wide travel is