

take to reduce those barriers while assuring the safety, effectiveness, and quality of medical devices marketed in the United States.

The Council seeks input from a wide range of constituencies to include but not be limited to industry, academia, patient/consumer advocacy groups, professional organizations, and other State and Federal bodies under aligned public health missions, to address the issues outlined in this document.

During the public workshop, there will be an open dialogue between Federal Government Council members and experts from the private and public sectors regarding the topics described in this document. Workshop participants will not be expected to develop consensus recommendations, but rather to provide their perspectives on priority areas in which medical device innovations can have the highest positive impact on public health. Participants will also be encouraged to comment on devices not being developed or redesigned due to barriers that the Federal Government can and should directly or indirectly remove or minimize.

Additional information on the public workshop, including an agenda, will be made available in advance of June 24, 2010, at <http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm> (select the appropriate meeting from the list).

## II. Public Participation

If you wish to make an oral presentation during the public workshop, you must indicate this at the time of registration. There are two types of opportunities for participation planned for the public workshop. In one, formal presentations will address one of the two topics (see section III of this document) that will be limited to 15 minutes and require submission of the presentation in advance of the meeting. The other will be time-limited, based on the number of requests, as part of the public comment period. When registering, you will be required to identify the title of the topic you wish to address in your presentation and answer all the related questions on the web registration form. FDA will do its best to accommodate requests to present and will focus discussions to the topics described in this document (see section III of this document). Individuals and organizations with common interests are urged to consolidate or coordinate their presentations, and to request time for joint presentations. FDA will determine the amount of time allotted to each

presenter and the approximate time that each oral presentation is to begin.

## III. Issues for Discussion

The workshop will focus on three topics: (1) Identification of the most important unmet public health needs; (2) delineation of the barriers to the development, redesign, and patient and healthcare professional access to medical devices that can cure, significantly improve, or prevent these illnesses or injuries; and (3) identification of the actions the Federal Government can take to remove or minimize these barriers. The discussion of these general topics should not be limited by current statutes or regulations and will include, but not be limited to, discussion of the following questions:

1. Identifying areas of public health need:
  - a. Which unmet public health needs could be most effectively addressed by the development of new, or the redesign of existing, medical devices?
  - b. How should the Council set priorities amongst the identified public health needs? Are there specific factors that should be considered? If so, which and why?
2. Addressing barriers to development and/or redesign of medical devices:
  - a. What are the significant barriers facing innovators, academics, and/or industry that limit the availability and clinical use of medical devices that have the potential to improve public health?
  - b. How should any perceived or actual barriers be evaluated to determine whether federal intervention is appropriate?
  - c. How should federal agencies—including those present and others not represented—address those barriers that are out of proportion to what is warranted based on the public health needs?

## IV. Transcripts

Please be advised that as soon as a transcript is available, it can be obtained in either hardcopy or on CD-ROM, after submission of a Freedom of Information request. Written requests are to be sent to Division of Freedom of Information (HFI-35), Office of Management Programs, Food and Drug Administration, 5600 Fishers Lane, rm. 6-30, Rockville, MD 20857. A transcript of the public workshop will be available on the Internet at <http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm> (select the appropriate meeting from the list).

Dated: May 20, 2010.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

#### Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Surveillance, Natural History, Quality of Care and Outcomes of Diabetes Mellitus with Onset in Childhood and Adolescence, RFA DP 10-001, Initial Review

*Correction:* This notice was published in the **Federal Register** on March 22, 2010, volume 75, Number 54, Page 13560. The Place and time should read as follows:

*Time and Date:* 8:30 a.m.–6 p.m., June 15, 2010 (Closed).

*Place:* W Hotel, 3377 Peachtree Road, NE., Atlanta, GA 30326, Telephone: 678-500-3100.

*Contact Person for More Information:* Donald Blackman, Ph.D., Scientific Review Officer, National Center for Chronic Disease Prevention and Health Promotion, Office of the Director, Extramural Research Program Office, 4770 Buford Highway, NE., Mailstop K-92, Atlanta, GA 30341, Telephone: (770) 488-3023, E-mail: [DBY7@cdc.gov](mailto:DBY7@cdc.gov).

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both CDC and the Agency for Toxic Substances and Disease Registry.

Dated: May 20, 2010.

**Andre Tyler,**

*Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2010-N-0004]  
[FDA 225-09-0012]

#### Memorandum of Understanding Between the Food and Drug Administration and Drugs.Com

AGENCY: Food and Drug Administration, HHS.