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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-N-3224]

Request for Nominations for Voting Members for the Patient Engagement Advisory Committee

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is requesting nominations for members to serve on the Patient Engagement Advisory Committee (the Committee), Office of the Center Director, Center for Devices and Radiological Health.

FDA seeks to include the views of women and men, members of all racial and ethnic groups, and individuals with and without disabilities on its advisory committees and, therefore, encourages nominations of appropriately qualified candidates from these groups.

DATES: Nominations received by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER], will be given first consideration for membership on the Committee. Nominations received after [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER], will be considered for nomination to the Committee as later vacancies occur.

ADDRESSES: All nominations for membership should be sent electronically by logging into the FDA Advisory Committee Membership Nomination Portal:

<https://www.accessdata.fda.gov/scripts/FACTRSPortal/FACTRS/index.cfm>, by mail to Advisory Committee Oversight and Management Staff, Food and Drug Administration, 10903 New

Hampshire Ave., Bldg. 32, rm. 5103, Silver Spring, MD 20993-0002, or by FAX: 301-847-8640.

Information about becoming a member on an FDA advisory committee can also be obtained by visiting FDA's Web site at <http://www.fda.gov/AdvisoryCommittees/default.htm>

FOR FURTHER INFORMATION CONTACT: Letise Williams, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 5441, 301-796-8398, FAX: 301-847-8510, [Letise.Williams@fda.hhs.gov](mailto:Letise.Williams@fda.hhs.gov).

SUPPLEMENTARY INFORMATION: FDA is requesting nominations for voting members for the Committee.

Elsewhere in this issue of the Federal Register, FDA is publishing separate documents regarding:

1. Patient Engagement Advisory Committee; Notice of Establishment
2. Request for Nominations of Individuals and Industry Organizations for the Patient Engagement Advisory Committee
3. Request for Nominations of Individuals and Consumer Organizations for the Patient Engagement Advisory Committee

#### I. General Description of the Committee's Duties

The Committee provides advice on complex issues relating to medical devices, the regulation of devices, and their use by patients. Agency guidance and policies, clinical trial or registry design, patient preference study design, benefit-risk determinations, device labeling, unmet clinical needs, available alternatives, patient reported outcomes and device-related quality of life or health status issues are among the topics that may be considered by the Committee. Members are knowledgeable in areas such as clinical research, primary care patient experience, healthcare needs of patient groups in the United States, or are experienced in the work of patient

and health professional organizations, methodologies for eliciting patient preferences, and strategies for communicating benefits, risks, and clinical outcomes to patients and research subjects.

## II. Criteria for Voting Members

The Committee consists of a core of nine voting members including the Chair. Members and the Chair are selected by the Commissioner of Food and Drugs or designee from among authorities who are knowledgeable in areas such as clinical research, primary care patient experience, healthcare needs of patient groups in the United States, or are experienced in the work of patient and health professional organizations, methodologies for eliciting patient preferences, and strategies for communicating benefits, risks, and clinical outcomes to patients and research subjects. Members will be invited to serve for overlapping terms of up to 4 years. Prospective members should also have an understanding of the broad spectrum of patients in a particular disease area. Almost all non-Federal members of this Committee serve as Special Government Employees.

## III. Nomination Procedures

Any interested person may nominate one or more qualified individuals for membership on the Committee. Self-nominations are also accepted. Nominations should include a cover letter; a current, complete resume or curriculum vitae for each nominee, including a current business and/or home address, telephone number, and email address if available; and should specify the advisory committee for which the nominee is recommended. Nominations should also acknowledge that the nominee is aware of the nomination, unless self-nominated. FDA will ask potential candidates to provide detailed information concerning such matters related to

financial holdings, employment, and research grants and/or contracts to permit evaluation of possible sources of conflicts of interest.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to advisory committees.

Dated: September 15, 2015.

Jill Hartzler Warner,

Associate Commissioner for Special Medical Programs.

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