This document is scheduled to be published in the
Federal Register on 09/21/2015 and available online at
http://federalregister.gov/a/2015-23521, and on **FDsys.gov**

4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-N-3166]

Establishment of the Patient Engagement Advisory Committee; Establishment of a Public Docket; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of public docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the establishment of the Patient Engagement Advisory Committee (the Committee). The Committee will provide advice to the Commissioner of Food and Drugs (the Commissioner) or designee, on complex issues relating to medical devices, regulation of devices, and their use by patients. The Committee may consider topics such as 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, and other patient-related topics. The Agency is also announcing the establishment of a public docket for comments on the potential topics.

DATES: Comments received by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER], will be provided to the Agency.

ADDRESSES: Submit electronic comments to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration,

5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments are to be identified with the docket number found in brackets in the heading of this document.

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.

SUPPLEMENTARY INFORMATION:

I. Background

The Committee will provide advice to the Commissioner or designee, on complex issues relating to medical devices, the regulation of devices, and their use by patients. The Committee may consider topics such as: 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, and other patient-related topics. The Committee will provide relevant skills and perspectives, in order to improve communication of benefits, risks, clinical outcomes, and increase integration of patient perspectives into the regulatory process for medical devices. It will perform its duties by discussing and providing advice and recommendation in ways such as: Identifying new approaches, promoting innovation, recognizing unforeseen risks or barriers, and identifying unintended consequences that could result from FDA policy.

A. Composition of the Committee

The Committee will consist of a core of nine voting members, including the Chair. Members and the Chair are selected by the Commissioner or designee from experts who are knowledgeable in areas such as clinical research, primary care patient experience, and health care needs of patient groups in the United States. Selected Committee members may also be

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. Almost all non-Federal members of this committee serve as Special Government Employees. The voting members may include one consumer representative who is a technically qualified member, selected by the Commissioner or designee, identified with consumer interests, and is recommended by either a consortium of consumer oriented organizations or other interested persons.

The Commissioner or designee will also have the authority to select from a group of individuals nominated by industry to serve temporarily as non-voting members who are identified with industry interests. The number of temporary non-voting members selected for a particular meeting will depend on the meeting topic.

B. Topics

FDA is also soliciting public feedback on potential topics for this Committee to discuss and advise the Agency. The following topics may include, but are not limited to:

- Where can patients provide input across the medical device total product lifecycle? What should be the focus of that input (e.g., input on unmet medical needs; input on endpoints of interest for particular diseases/conditions; input on feasibility of clinical study plans and protocols to reduce barriers to patient participation and retention; input on draft patient labeling; postmarket data reported directly from patients; input on potential risk communication related to products already on the market)? How should the process of soliciting patient input for various purposes work?

- How should FDA directly engage patients for input related to medical device premarket considerations (e.g., in considering public health impact criterion for eligibility for Expedited Access Program)?
- How should FDA engage patients for input related to medical device performance once products are available on the market?
- Under what conditions should health care professional or patient labeling include information about patient preference studies or patient reported outcomes (PROs)?
- How should sponsors present patient preference information or PROs in the health care professional and patient labeling?
- How should labeling indicate that only a portion of patients in a patient preference study were willing to accept certain risks in order to achieve probable benefits?
- How should sponsors and the FDA ensure that patients receive and understand patient preference information?
- How can patient preferences be obtained in an unbiased manner if the device study has already enrolled and/or been published?
- How do patients view clinical study informed consent forms?

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

1. Request for Nominations for Voting Members for the Patient Engagement Advisory Committee
2. Request for Nominations of Individuals and Consumer Organizations for the Patient Engagement Advisory Committee

3. Request for Nominations of Individuals and Industry Organizations for the Patient Engagement Advisory Committee

FDA intends to publish a final rule in the Federal Register, adding the Patient Engagement Advisory Committee to 21 CFR part 14.100.

II. Comments

FDA is opening a docket for 60 days to provide an opportunity for public comment on the potential topics. Interested persons may submit either electronic comments regarding the potential topics to http://www.regulations.gov or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Divisions of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at http://www.regulations.gov.

Dated: September 15, 2015.

Jill Hartzler Warner,

Associate Commissioner for Special Medical Programs.

[FR Doc. 2015-23521 Filed: 9/18/2015 08:45 am; Publication Date: 9/21/2015]