ACRP Regulatory Affairs Committee Review of FDA Request for Comments

Establishment of the Patient Engagement Advisory Committee

What is the document?
The FDA requested comments on its establishment of public docket Establishment of the Patient Engagement Advisory Committee. This proposed new Committee would provide advice to the FDA Commissioner on patient-related topics related to medical devices such as: unmet clinical needs, regulation of devices, use by patients, clinical trial or registry design, device labeling, patient preference study design, and other patient-related topics.

Who does it impact & how?
This new Committee would impact sponsors, manufacturers and ultimately, the end users of medical devices.

What did ACRP RAC have to say about it?
ACRP fully supports the FDA's endeavors in establishing this new Patient Engagement Advisory Committee. The FDA's proposed committee composition and topics for discussion are comprehensive and ACRP's RAC did not have any additional suggestions for Agency consideration.

When were the RAC's comments sent to the agency?
November 20, 2015

Where can I access this document?
http://www.gpo.gov/fdsys/pkg/FR-2015-09-21/pdf/2015-23521.pdf

ACRP
ASSOCIATION OF CLINICAL RESEARCH PROFESSIONALS

MISSION:
ACRP promotes excellence in clinical research.

99 Canal Center Plaza
Suite 200
Alexandria, VA 22314
USA

T | 703.254.8100
F | 703.254.8101

office@acrpnet.org
www.acrpnet.org

November 20, 2015

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, rm. 1061
Rockville, MD 20852

In reference to docket number: **FDA-2015-N-3166**

The Association of Clinical Research Professionals (ACRP) is the primary resource for clinical research professionals in the pharmaceutical, biotechnology and medical device industries, and those in hospital, academic medical centers and physician office settings. ACRP was founded in 1976 to address the educational and networking needs of research nurses and others who supported the work of clinical investigations. Almost 40 years later, ACRP is a global association comprised of individuals dedicated to clinical research and development. Our mission is "ACRP promotes excellence in clinical research." The Academy of Physicians in Clinical Research (APCR) is an affiliate of ACRP and is the leading professional organization, exclusive to physicians, that supports and addresses these unique issues and challenges of all physicians involved in clinical research.

ACRP reviewed the docket requesting comments on the Establishment of the Patient Engagement Advisory Committee. We are pleased that the FDA plans to establish this committee as this is an important area for the FDA to become involved in and we fully support the Agency's efforts in this regard. The committee composition and topics for discussion as proposed are comprehensive and we have no additional suggestions.

We applaud the FDA's efforts on this important issue and hope that our feedback helps improve the final version of the document. Please let me know if you have any questions regarding our comments, or if we may otherwise serve as a resource on issues related to clinical research.

Sincerely,

Jim Kremidas
Executive Director

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 November 20, 2015, 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 9–18–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the Board of Scientific Counselors, NHLBI.

The meeting will be closed to the public as indicated below in accordance with the provisions set forth in section 552b(c)(6), Title 5 U.S.C., as amended for the review, discussion, and evaluation of individual intramural programs and projects conducted by the NATIONAL HEART, LUNG, AND BLOOD INSTITUTE, including consideration of personnel qualifications and performance, and the competence of individual investigators, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Board of Scientific Counselors, NHLBI.

Date: October 27, 2015.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate personal qualifications and performance, and competence of individual investigators.

Place: National Institutes of Health, Porter Neuroscience Research Center, Building 35A, Convent Drive, Bethesda, MD 20892.

Contact Person: Robert S. Balaban, Ph.D. Scientific Director, National Heart, Lung, and Blood Institute, National Institutes of Health, Building 10, 10 Center Drive, CRC, 4th Floor, Room 1581, Bethesda, MD 20892, 301–496–2116, *balabanr@nhlbi.nih.gov.*

Information is also available on the Institute's/Center's home page: *www.nhlbi.nih.gov/meetings/index.htm,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: September 15, 2015.

Michelle Trout,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015–23505 Filed 9–18–15; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel NIAID Clinical Trial Implementation Grant (R01).

Date: October 20, 2015.

Time: 1:00 p.m. to 2:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Room 3E73, 5601 Fishers Lane, Rockville, MD 20892, (Telephone Conference Call).

Contact Person: Jane K. Battles, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, National Institutes of Health/NIAID, 5601 Fishers Lane, Room 3F30B, Rockville, MD 20852, 240–669–5029, *battlesja@mail.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: September 15, 2015.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015–23565 Filed 9–18–15; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel Member Conflict: Cancer Immuno Therapeutics.

Date: October 1, 2015.

Time: 2:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Malaya Chatterjee, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6192, MSC 7804, Bethesda, MD 20892, (301) 806–2515, *chatterm@csr.nih.gov*.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel PAR Panel: Investigations on Primary Immunodeficiency Diseases.

Date: October 15, 2015.

Time: 1:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Jin Huang, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4095G, MSC 7812, Bethesda, MD 20892, 301–435–1230, *jh377p@nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel PAR–13–