November 20, 2015

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

Re: Docket No. FDA-2015-N-3166: Establishment of the Patient Engagement Advisory Committee; Establishment of a Public Docket; Request for Comments

Dear Sir/Madam:

The Biotechnology Industry Organization (BIO) thanks the Center for Devices and Radiological Health (CDRH) at the Food and Drug Administration (FDA) for the opportunity to submit comments to the public docket entitled *Establishment of the Patient Engagement Advisory Committee; Establishment of a Public Docket; Request for Comments*[1] (the "Public Docket").

BIO is the world's largest trade association representing biotechnology companies, academic institutions, state biotechnology centers, and related organizations across the United States and in more than 30 other nations. BIO members are involved in the research and development of innovative healthcare, agricultural, industrial, and environmental biotechnology products.

BIO fully supports and applauds the establishment of the Patient Engagement Advisory Committee (PEAC). We strongly believe that placing patients at the center of the development process will significantly improve the development of technologies for interventions that matter most to patients and their caregivers. In tandem with the recent publication of CDRH draft guidance on patient preference information in medical device regulatory submissions,[2] CDRH's efforts will help enhance the patient voice within the medical product development process and advance the science of patient preference information.

Patient preferences can be sophisticated and nuanced, and it is critical that this information, feedback, and data are captured in a systematic, data-driven way, and used to inform FDA regulatory decision-making. Both sponsors and patients will benefit

[1] 80 Fed. Reg. 182,57007 (September 21, 2015)
[2] U.S. Food and Drug Administration. "Patient Preference Information – Submission, Review in PMAs, HDE Applications, and De Novo Requests, and Inclusion in Device Labeling." 18 May 2015. Available at http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM446680.pdf

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from increased collaboration with the Agency. Thus, we are encouraged to see a comprehensive and inclusive proposed list of topics for discussion by PEAC.

Finally, we encourage CDRH to work with their colleagues in the Center for Drug Evaluation and Research (CDER) and Center for Biologics Evaluation and Research (CBER) to share its ongoing experiences with the PEAC. We believe that the success of PEAC can provide a model for further patient engagement efforts by the Agency.

BIO appreciates this opportunity to comment on the Public Docket. We look forward to continued dialogue with the Agency as it furthers the matter, and would be pleased to provide further input or clarification of our comments as needed.

Sincerely,

/S/

Scott V. McGoohan, JD
Director, Science and Regulatory Affairs
Biotechnology Industry Organization (BIO)

cc: Robert M. Califf, MD, Deputy Commissioner for Medical Products and Tobacco
Janet Woodcock, MD, Director, Center for Drug Evaluation and Research
Karen Midthun, MD, Director, Center for Biologics Evaluation and Research