ACRO
ASSOCIATION OF CLINICAL RESEARCH ORGANIZATIONS

June 9, 2017

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

RE: Comments on Docket No. FDA – 2017-N-0455, "Enhancing Patient Engagement Efforts across FDA: Establishment of a Public Docket: Request for Comments"

Dear Sir or Madam:

The Association of Clinical Research Organizations (ACRO) represents the world's leading, global clinical research organizations (CROs). Our member companies provide a wide range of specialized services across the entire spectrum of development for new drugs, biologics and medical devices – from discovery, pre-clinical, proof of concept and first-in-man studies through post-approval and pharmacovigilance research. With more than 130,000 employees engaged in research activities around the world, ACRO advances clinical outsourcing to improve the quality, efficiency and safety of biomedical research. Each year, ACRO member companies conduct more than 7,000 clinical trials involving 1.3 million research participants in over 100 countries. On average, each of our member companies works with more than 700 research sponsors annually. ACRO members contribute to the development of 95% of newly approved drugs, biologics, and biosimilars globally.[1] ACRO appreciates the opportunity to comment on "Enhancing Patient Engagement Efforts across FDA: Establishment of a Public Docket: Request for Comments."

ACRO welcomes the increasing and ongoing efforts by the Food and Drug Administration to engage patients and patient organizations and to incorporate the patient perspective into regulatory decision-making. Implementation of the Patient-Focused Drug Development program, supported by the fifth authorization of the Prescription Drug User Fee Act (PDUFA), has provided FDA and other stakeholders, including industry, a better understanding of patients' views of the impact of their diseases and conditions. Additional patient-focused activities planned under the upcoming PDUFA VI cycle and reinforced by the 21st Century Cures Act will take further needed steps to facilitate the development of approaches and methods to collect meaningful patient input in clinical trials and to measure, report and analyze patient impacts. These efforts will help ensure that medical product development is directly informed by patients' experiences of disease and perspectives on the appropriate balancing of benefits and risks, ultimately enhancing the quality and efficiency of clinical trials and improving outcomes for patients.

ACRO commends FDA for its proposal to further enhance patient engagement with the Agency through a new Office of Patient Affairs. The availability of a single point of entry for engagement with FDA through this Office may particularly useful for individuals and smaller patient organizations that may lack the resources or expertise to successfully navigate the Agency. ACRO also supports the proposal for the new Office to develop robust data management systems to incorporate and formalize knowledge shared with FDA by patient stakeholders. To the extent feasible and appropriate, ACRO suggests that mechanisms also be developed to share information derived through such interactions with stakeholders involved in medical product development. ACRO also supports the proposal for a regular evaluation of the new Office to ensure that it continues to further the goal of enhancing patient engagement.

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Clinical trials present patients the opportunity to not only contribute to medical research that helps spur the development of new medical products but also to play a more active role in their health care and access new treatments before they are widely available. Yet among the biggest challenges confronted in clinical research is the critical task of finding the right patients to become trial participants. According to Tufts Center for the Study of Drug Development 37% of clinical trial sites do not meet enrollment goals and 11% fail to enroll a single patient.[2] To the extent that the proposed Office of Patient Affairs receives requests for information regarding clinical trial enrollment, we would urge the Office to work with stakeholders in directing patients to clinical trial resources and to also consult with the FDA's Office of Minority Health and Office of Women's Health on best practices from their ongoing efforts to increase diversity in clinical trials.

Thank you again for the opportunity to comment on a new Office of Patient Affairs. We support the proposal as an important element in the Agency's continuing efforts to facilitate patient knowledge of and engagement with the medical product development process. Please do not hesitate to contact ACRO (knoonan@acrohealth.org) if we can provide additional information or details.

Respectfully submitted,

Karen A. Noonan

Karen A. Noonan
Vice President, Global Regulatory Policy

[1] ACRO Member Demographics Survey (2016). For further information on the role of ACRO members in advancing clinical research, please see "Clinical Research: A Legacy of Innovation, A Future of Transformed Medicine," available on the ACRO web site at: http://www.acrohealth.org/wp-content/uploads/2014/10/acro-white-paper-tah10.pdf

[2] "New Research from Tufts [CSDD] Characterizes Effectiveness and Variability of Patient Recruitment and Retention Practices," available on the Tufts web site at: http://csdd.tufts.edu/news/complete_story/pr_ir_jan-feb_2013