

April 16, 2018

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

RE: Docket No. FDA-2017-N-6607 for Oncology Center of Excellence Listening Session

To Whom It May Concern:

On behalf of the American Association for Cancer Research (AACR), the oldest and largest scientific organization in the world dedicated to the prevention and cure of cancer through research, education, communication, and collaboration, we sincerely thank the U.S. Food and Drug Administration (FDA) for the opportunity to provide comments in response to the Oncology Center of Excellence (OCE) Listening Session Public Meeting. Our membership includes more than 40,000 basic, translational, and clinical researchers; population scientists; other health care professionals; and patient advocates residing in 120 countries.

First, the AACR enthusiastically congratulates OCE Director Richard Pazdur, MD, and his staff for their steadfast leadership in improving cancer treatment and monumental success-to-date establishing the first cross-agency center of excellence. With approximately 30 percent of all new drugs approved by the FDA in 2017 being oncology products, the field is evolving rapidly. In 2017, the FDA approved 17 drug and biologic applications, 32 supplemental drug and biologic applications, and two biosimilar applications in oncology. In addition, in 2017 the OCE played a critical role in the coordinated review and subsequent approval of multiple breakthrough therapies including pembrolizumab, the first-ever tissue-agnostic approval of a cancer treatment based on a biomarker, and two CAR T-cell therapies that harness the power of the patient's own immune system to fight cancer (tisagenlecleucel and axicabtagene ciloleucel). We commend the FDA's expedited review programs that allow these cutting-edge therapies to reach patients with life-threatening and often rare cancers earlier in development while ensuring safety and efficacy standards are maintained.

Stakeholder engagement is an integral component central to the mission of the OCE and is perhaps best exemplified through their stakeholder meetings and workshops. These workshops have contributed to the advancement of new therapies by convening the FDA, industry, academia, and advocacy groups to consider how best to advance science and regulatory policy together. In 2017, the AACR cosponsored two workshops with the FDA including the FDA-AACR Oncology Dose Finding Workshop in July, and the FDA-AACR Liquid Biopsies in Oncology Drug and Device Development Workshop in October. Already in 2018, the FDA, the AACR, and the American Society of Radiation Oncology cosponsored a two-day workshop on Clinical Development of Drug-Radiotherapy Combinations. Additionally, the AACR Annual Meeting Regulatory Science and Policy Track assembles the foremost cancer scientists and FDA leaders to discuss the latest innovations and breakthroughs in cancer research. We look forward to continued partnership with OCE to provide a premier platform to convene academia, industry, and regulators. The AACR applauds the OCE for their commitment to engaging stakeholders across the oncology space.

Regarding the questions posed at the March 15th public meeting concerning the structure and function of the OCE, the AACR submits the following comments:

- 1) The OCE should have clear, final signoff authority for all product reviews associated with anti-cancer therapeutics, including drugs, biologics, and devices. While technical expertise can and should exist across the FDA, final evaluation and clearance should always come from the OCE.
- 2) All Office of Hematology and Oncology Products staff and any other oncology-focused staff from the FDA, specifically including clinical review staff from the Center for Biologics Evaluation and Research and Center for Devices and Radiological Health, should be folded under the purview of the OCE.
- 3) Patients are a critical part of our healthcare system and their engagement should remain a priority of the OCE and the FDA. The AACR congratulates the OCE for hosting the first annual education workshop for new cancer patient advocates, “Partners in Progress: Cancer Patient Advocates and FDA” in November 2017. The AACR ardently encourages and intends to support such initiatives.
- 4) The OCE should continue to maintain its high level of integrity in review processes while continuing to support innovation and approvals that deliver safe and effective cancer drugs to patients in a timely manner.

Finally, the AACR must call attention to the need for a fully-funded OCE. The important work and fast pace of approvals highlighted above cannot continue without proper resources. Appropriate funding will allow the OCE to respond quickly to rapidly advancing technology and to hire, develop, and retain expert staff. To this end, we encourage the OCE to develop and share a proposed budget of operation to better understand the scope of the investments needed. We deeply appreciate the FY18 Omnibus Appropriations Bill which provides \$15 million to the FDA OCE. We also support the President’s inclusion of \$20 million for the OCE in the FY19 budget. The AACR will continue urging Congress to provide this funding, because to keep pace with the rate of innovation in oncology the OCE also requires robust, predictable, and sustainable funding.

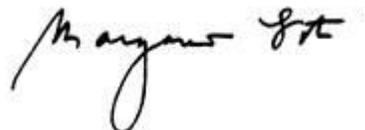
In conclusion, the AACR is encouraged by the accomplishments of the OCE thus far and will continue providing our support to ensure its success. The approvals outlined above show that this innovative inter-center, cross-cutting team is already streamlining the review process for oncology products. We hope that the comments laid out in this letter and from other stakeholders will help the OCE to refine this process and continue ensuring patients have access to the best oncology therapies available.

If you have further questions, please contact Jon Retzlaff, Chief Policy Officer, Science Policy and Government Affairs, at jon.retzlaff@aacr.org.

Sincerely,



George D. Demetri, MD
Chair, Science Policy and Government
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