

January 03, 2020

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

RE: Docket No. FDA-2019-N-3453 Promoting Effective Drug Development Programs: Opportunities and Priorities for the Food and Drug Administration's Office of New Drugs

To Whom It May Concern:

On behalf of the American Association for Cancer Research (AACR), the first 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 feedback in response to the request for comments on Opportunities and Priorities for the FDA's Office of New Drugs. The membership of the AACR includes more than 46,500 basic, translational, and clinical researchers working in both academia and industry; population scientists; other health care professionals; regulators; and patient advocates residing in 120 countries. Together we share a commitment to developing effective treatments that benefit cancer patients as quickly as possible. We appreciate the FDA's stated interest in ensuring that scientific and technological advances, many facilitated by our members, "reach patients through the development and dissemination of clear policies regarding our expectations and standards."

The AACR commends the FDA for its dedication to soliciting and incorporating stakeholder input in the development of its policies and initiatives. As demonstrated at the public meeting on November 7, 2019, that accompanied this request for comments, the drug development community, AACR included, stands ready to work with the FDA and the Office of New Drugs (OND). **Moving forward, continued stakeholder engagement will be integral to the OND achieving its goals of identifying areas in need of and strategies for providing regulatory clarity for the purpose of facilitating the development and review of safe and effective medical products.**

One mechanism for engagement that has proven beneficial to the FDA and its various stakeholders is public meetings on topics of interest to the broader community. The AACR has a long history of partnering with the FDA on such meetings, both public workshops and through the Regulatory Science and Policy Track at our Annual Meeting. These are excellent forums for discussion, learning, and the exchange of ideas among industry, academicians, patient advocates, and regulators. Specifically, the 2019 FDA-AACR Real-world Evidence Workshop garnered high praise from attendees for its content and format. Industry stakeholders presented pre- and post-market use cases in which real-world evidence was utilized to improve and accelerate treatment development; during panel discussions, FDA reviewers offered insights as to why, in each case, the use of real-world evidence was appropriate and facilitated regulatory decision-making.

In February 2020, the FDA and AACR will jointly host a workshop to address the under-representation of African Americans in multiple myeloma clinical trials compared to disease incidence. In advance of the

workshop, researchers, clinicians, physicians, patients and advocates, regulators, and representatives from industry are working together to deliver recommendations to improve representation of African Americans in all phases of clinical and post-marketing studies to better understand drug safety, efficacy, and outcomes in that population. The hope is that this initiative will lead to a more inclusive, “real-world” drug development paradigm. **OND should utilize similar, case study-focused workshops to discern stakeholders’ views and identify best practices regarding the use of novel trial designs (Topic 3), as well as to familiarize both stakeholders and the FDA with innovations in drug development as they arise (Topic 5).**

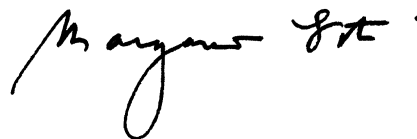
Finally, the FDA Oncology Center of Excellence (OCE) should serve as an exemplar for streamlining the development and review of effective drugs, biologics, and devices. In the two years since its inception, under the direction of Richard Pazdur, MD, the OCE has made phenomenal strides in improving cancer treatment by coordinating scientific activities and expertise across agency centers, making judicious use of expedited review pathways, and launching innovative initiatives. Medical Oncology Review and Evaluation teams unite medical oncology specialists with experts from the relevant center to expedite product review. Real-time Oncology Review and the Assessment Aid, two pilot programs implemented in 2018 to improve the process of data evaluation and benefit-risk assessment generation, have enabled faster review and approval of numerous products. Project Orbis, an international collaboration launched in 2019, facilitates concurrent submission and review of oncology products among partner regulatory agencies, leading to earlier, more uniform access to potentially life-saving therapies. **By implementing regulatory innovations proven effective by the OCE, the OND could achieve similar regulatory efficiencies for other therapeutic areas as those seen in oncology.**

The AACR is encouraged by the OND’s deliberate, proactive efforts to promote innovative and effective drug development as we share the goal of ensuring that patients have access to the best therapies available. We look forward to continued engagement of the community by OND as areas of policy and guidance development are identified. If you have further questions, please contact Sarah Martin, MS, PhD, Director, Regulatory Science and Policy, at sarah.martin@aacr.org.

Sincerely,



Kenneth C. Anderson, MD
Chair, Regulatory Science and Policy Subcommittee
American Association for Cancer Research



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