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August 13, 2024
Dockets Management Staff (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. FDA-2024-N-1809 — Optimizing FDA's Use of and Processes for Advisory Committees; Public Meeting

To Whom It May Concern:

The Pharmaceutical Research and Manufacturers of America ("PhRMA") is pleased to submit these comments in response to the Food and Drug Administration's ("FDA's" or "the Agency's") Public Meeting on Optimizing FDA's Use of and Processes for Advisory Committees ("Public Meeting").[1] PhRMA represents the country's leading innovative biopharmaceutical research companies, which are devoted to discovering and developing medicines that enable patients to live longer, healthier, and more productive lives. Over the last decade, PhRMA member companies have more than doubled their annual investment in the search for new treatments and cures, including nearly $101 billion in 2022 alone.

I. INTRODUCTION

PhRMA applauds FDA for convening this Listening Session on Optimizing FDA's Use of and Processes for Advisory Committees. PhRMA views Advisory Committees (ACs) as an important part of the regulatory process, providing the Agency with independent advice on a range of scientific, technical, and policy matters. We appreciate this workshop as a continuation of the Center for Drugs Evaluation and Research's (CDER) New Drugs Regulatory Advisory Committee workstream, established in 2019.[2] PhRMA welcomes the opportunity to provide feedback on the composition of ACs, the experience of Special Government Employees (SGE) serving on ACs, and the public perception and understanding of ACs.

II. GENERAL COMMENTS

A. Topic 1: Composition of Advisory Committees

[1] *See* 89 FR 34254: Listening Session: Optimizing the Food and Drug Administration's Use of and Processes for Advisory Committees; Public Meeting; Request for Comments, April 30, 2024; https://www.federalregister.gov/documents/2024/04/30/2024-09014/listening-session-optimizing-the-food-and-drug-administrations-use-of-and-processes-for-advisory.

[2] *See* FDA, "New Drugs Regulatory Program (NDRP) Advisory Committees;" (December 12, 2023); https://www.fda.gov/drugs/regulatory-science-research-and-education/new-drugs-regulatory-program-ndrp-advisory-committees.

PhRMA believes that is essential for FDA to appoint AC members who possess the requisite expertise to effectively consider the topics under discussion and provide valuable advice to the Agency. However, despite recent expansions in the number of AC members, there remains a shortage of experts in areas such as rare disease, clinical trial innovation, and emerging technologies who are either available or considered eligible to participate in an AC. Considering these restraints, PhRMA encourages FDA to exercise flexibility, when possible, to allow qualified individuals to serve on ACs as ad-hoc advisors, notwithstanding potential ties to industry. In general, PhRMA believes that disclosure of potential conflicts of interest can promote transparency and mitigate concerns while also allowing for participation by those with appropriate scientific expertise. In the meantime, to assist FDA in the recruitment of appropriate experts on ACs, we encourage FDA to continue the development of and share with other Centers the educational reference guide developed by CDER on recruiting experts.[3]

To encourage the widest participation possible, the Open Public Hearing (OPH) process should be consistent across ACs, with every effort made to extend the OPH time to provide ample speaking opportunities for registrants. More specifically, the time dedicated to OPH should reflect the duration of the entire AC meeting. Should there be overwhelming interest in participating in the OPH, FDA's May 2013 Guidance, "The Open Public Hearing at FDA Advisory Committee Meetings," states the Agency may, at the discretion of the committee chair, either extend the OPH time, or initiate a lottery to select the speakers.[4] However, there are seeming inconsistencies in establishing the OPH timeframe for CDER and CBER ACs. For example, in the past CDER has extended the 60-minute OPH to a 90-minute period before initiating a lottery process.[5] However, CBER's Cellular, Tissue, and Gene Therapies Advisory Committee (CTGTAC) uses a lottery process before extending the OPH beyond a 60-minute timeframe.[6] PhRMA suggest the OPH time frames and lottery processes should be consistent across the ACs for both Centers.

B. Topic 2: Service on an Advisory Committee as a Special Government Employee (SGE)

[3] Id.

[4] *See* FDA, "The Open Public Hearing at FDA Advisory Committee Meetings;" Final Guidance for the Public, FDA Advisory Committee Members, and FDA Staff; May2013; https://www.fda.gov/regulatory-information/search-fda-guidance-documents/open-public-hearing-fda-advisory-committee-meetings.

[5] *See* FDA, Joint Meeting of the Drug Safety and Risk Management Advisory Committee and the Dermatologic and Ophthalmic Drugs Advisory Committee Meeting Announcement; March 28-29, 2023; https://www.fda.gov/advisory-committees/advisory-committee-calendar/march-28-29-2023-joint-meeting-drug-safety-and-risk-management-advisory-committee-and-dermatologic#event-information.

[6] *See* FDA, Cellular, Tissue, and Gene Therapies Advisory Committee October 31, 2023 Meeting Announcement; October 31, 2023; https://www.fda.gov/advisory-committees/advisory-committee-calendar/cellular-tissue-and-gene-therapies-advisory-committee-october-31-2023-meeting-announcement-10312023.

Direct and transparent communication of administrative requirements and processes can mitigate the barriers that hinder service of and participation by SGEs on ACs. To improve the experience of AC members more broadly, PhRMA suggests FDA offer training on drug development and regulatory processes, thereby ensuring the meeting is focused on the questions at hand. Similarly, establishing a page limit for briefing documents would help AC members in their preparation for the meetings. PhRMA also encourages FDA to continue to provide a virtual participation option for all AC members.

C. Topic 3: Public Perception and Understanding of Advisory Committees

PhRMA encourages FDA to clearly communicate the purpose, timing, and recommendations of ACs through its website, social media, and other communication platforms. More specifically, PhRMA believes FDA should clarify that ACs provide expert advice on scientific, rather than regulatory matters. To further clarify this distinction, PhRMA suggests that before opening each committee meeting, the AC Chair describe the role of the AC and how FDA may use the discussion and recommendations in the regulatory decision-making process. The AC Chair can serve as a resource to public attendees to help explain the overall process.

III. CONCLUSION

PhRMA thanks the Agency for hosting the public meeting and appreciates the opportunity to comment on this important topic.

Respectfully submitted,

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