Alliance FOR AGING RESEARCH

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September 8, 2026

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

Re: [FDA-2026-N-8004] Molecular and Clinical Genetics Panel of the Medical Devices Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments—GRAIL, Inc. Galleri

Dear Members of the Molecular and Clinical Genetics Panel:

Thank you for the opportunity to provide comments on the Premarket Approval application for the Galleri multi-cancer early detection (MCED) test. The Alliance for Aging Research is the nation's leading nonprofit organization dedicated to changing the narrative to achieve healthy aging and equitable access to care. Critical to achieving this mission is making cancer a more survivable disease through advances in early detection.

While the Alliance for Aging Research does not take a position on the merits of the application for the FDA Premarket Approval application for the Galleri multi-cancer early detection (MCED) test, we urge the Advisory Committee to consider the importance of access to early detection across a broad range of cancers for which there are currently no screening options.

Older Americans have much at stake on this matter. Over half of all new cancer cases in the United States occur among those age 65 and older. As has been well documented across cancers, early detection can make a profound difference in making treatment more effective and less burdensome on patients, their families, and caregivers.

Available screenings for breast, cervical, colorectal, lung and prostate cancers are highly effective, but they leave many other lethal cancers without early detection options. We are encouraged that recent trial data indicates that adding Galleri to the current standard of care screenings increased the number of cancers detected by approximately threefold. Of those detected by Galleri, over 70% of cancers were types with no existing recommended screening test.

For older Americans, an early cancer diagnosis provides a greater opportunity to plan with family members and health care providers to consider all possible treatment options and develop a care plan. Waiting until symptoms have developed and the disease has advanced can deprive them of taking an active role in their own care decisions – and can mean significantly fewer treatment options.

We know the FDA will consider all available evidence and the potential impact on patients in evaluating Galleri. A significant and meaningful addition to our current cancer screening capabilities and the opportunity for more cancer patients to gain the health and quality-of-life benefits that come with early detection is long overdue.

Sincerely,

Sue Peschin
President & CEO
Alliance for Aging Research