Alliance for Women's Health & Prevention

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

September 8, 2026

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:

The Alliance for Women's Health and Prevention (AWHP) works to advance policies that prioritize prevention, support earlier detection, and expand access to high-quality healthcare for women. We believe women should have access to screening and preventive services that can help identify disease earlier, improve health outcomes, and reduce unnecessary suffering. We also support the responsible advancement of emerging technologies that may strengthen prevention and earlier detection, paired with clear information about their benefits, limitations, and appropriate use.

With that mission in mind, AWHP supports the FDA's careful consideration of the premarket approval application for the Galleri multi-cancer early detection (MCED) test. Galleri represents a promising innovation that could expand the reach of cancer screening, particularly for cancers that currently lack a recommended screening pathway.

Existing screening programs, including mammography and cervical cancer screening, have driven significant improvements in outcomes for certain cancers that affect women. However, recommended screening is available for only a limited number of cancers, and approximately 70% of cancer deaths are attributed to cancers without recommended screening. MCED tests may complement established screening by detecting cancer signals associated with a broader range of cancers. They should not replace proven screening tests or appropriate evaluation of symptoms.

This challenge is especially significant for cancers such as ovarian and pancreatic cancer, which are frequently diagnosed at later stages because no standard screening pathway exists. MCED technologies may help address this gap by detecting cancer-associated signals before symptoms emerge and predicting where a signal may have originated. A positive result is not a cancer diagnosis and must be followed by an appropriate diagnostic evaluation.

AWHP was a proud and longtime advocate of the Nancy Gardner Sewell Medicare Multi-Cancer Early Detection Screening Coverage Act, which became law earlier this year and creates a Medicare coverage pathway for FDA-approved MCED tests that are determined to be reasonable and necessary.

From our perspective, an important measure of a screening test's value is whether it can safely shift diagnosis toward earlier stages and ultimately improve health outcomes. Results from the randomized NHS-Galleri trial are encouraging but should be interpreted with appropriate caution.

AWHP supports approval of the Galleri MCED test if the FDA determines that the applicable standards for safety and effectiveness have been met. Innovative screening technologies like this present a path forward for cancer screening.

Thank you for your consideration.

Sincerely,

Millicent Gorham
CEO, Alliance for Women's Health and Prevention (AWHP)