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Testimony Before the Food and Drug Administration's Molecular and Clinical Genetics Panel of the Medical Devices Advisory Committee

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I am Nina Zeldes, a Senior Health Researcher at Public Citizen's Health Research Group. We have no financial or other conflicts of interest.

Public Citizen opposes the marketing authorization of the Galleri test because of the lack of data demonstrating that the test's benefits outweigh its risks. The lack of convincing data is of particular concern because the test is likely to become widely used if it receives marketing authorization.

Our first specific concern is about the trial design. Only one of the two trials (NHS-Galleri) supporting the safety and efficacy of the Galleri test was a randomized controlled study. The second trial (PATHFINDER 2) did not include a control group.[1]

The primary endpoint of the randomized controlled trial, reduction of stage III and IV cancers, has been criticized because it does not directly measure whether the Galleri test had a meaningful effect on the survival of cancer patients.[2,3] More importantly, however, the study did not even meet its prespecified primary endpoint.[4]

[1] Food and Drug Administration. FDA executive summary for Galleri (GRAIL, Inc.) prepared for the September 23, 2026 meeting of the Molecular and Clinical Genetics Panel of the Medical Devices Advisory Committee. https://www.fda.gov/media/194909/download. Accessed September 23, 2026.
[2] Sullivan R, Booth CM. Multicancer detection tests: Promise, hype, and reality. *JAMA*. 2026 May 30.
[3] Bermúdez-Guzmán L. Signal-to-care gap in multicancer early detection. *JAMA Intern Med*. 2026 Jul 20.
[4] Swanton RC, Johnson P, Round T, et al. NHS-Galleri: primary results from a randomised controlled trial to assess the clinical utility of a multi-cancer early detection (MCED) test in population screening. *J Clin Oncol*. 2026 Jun 10;44(17_suppl):LBA100-.

Our second specific concern is that between 81% (PATHFINDER 2) and 94% (NHS-Galleri) of trial participants were White and therefore not representative of the U.S. population,[5] which has a greater percentage of non-White individuals.

Our third specific concern is that the effectiveness of the Galleri test has not yet been established. Importantly, no follow-up data beyond several years are available. The Galleri test is proposed to be indicated for "the early detection of multiple cancers," yet the sensitivity for new cancers detected in stage I and II combined ranged only from 21% to 25% across both trials.[6] The test's sensitivity was also highly variable by cancer type, ranging across both trials from 1.6% for some skin cancers to 81% for liver and intrahepatic bile duct cancers.[7]

Based on the available data, it has not been established whether the benefits of the Galleri test outweigh its risks. False-positive results can lead to a cascade of unnecessary diagnostic tests and invasive procedures. Additional risks can include anxiety, delayed diagnosis and treatment, and other unintended harms. For instance, a higher demand for diagnostic testing can lead to increased wait times, additional time away from work, and increased out-of-pocket costs.[8, 9]

Importantly, there are currently no authorized devices indicated for the screening of multiple types of cancer. Granting marketing authorization to the Galleri test based on inadequate data is not in the best interest of patients and would establish a dangerously low bar for authorization for such devices going forward.

Given these important concerns, we urge the committee to vote "No" on all three voting questions.

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[5] Food and Drug Administration. FDA executive summary for Galleri (GRAIL, Inc.) prepared for the September 23, 2026 meeting of the Molecular and Clinical Genetics Panel of the Medical Devices Advisory Committee. https://www.fda.gov/media/194909/download. Accessed September 23, 2026.
[6] *Ibid.*
[7] Grail. Galleri multi-cancer early detection test. Sponsor executive summary. Molecular and clinical genetics panel. https://www.fda.gov/media/194910/download. Accessed September 23, 2026.
[8] McCartneyM, Cohen D. Galleri promises to detect multiple cancers—but new evidence casts doubt on this much hyped blood test. *BMJ*. 2024; 386:q1706.
[9] Bermúdez-Guzmán L. Signal-to-care gap in multicancer early detection. *JAMA Intern Med*. 2026 Jul 20.