No. 23-60167

IN THE

United States Court of Appeals

FOR THE FIFTH CIRCUIT

ILLUMINA, INC. AND GRAIL, INC.,

Petitioners-Appellants,

v.

FEDERAL TRADE COMMISSION,

Respondent-Appellee.

Petition for Review of an Order
of the Federal Trade Commission

BRIEF OF DR. GEORGE CHARAMES AND DR. ERIC DUNCAVAGE AS *AMICI CURIAE* SUPPORTING PETITIONERS AND REVERSAL

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Illumina Inc. v. Federal Trade Commission, No. 23-60167

The undersigned counsel of record certifies that the following listed persons and entities as described in the fourth sentence of Rule 28.2.1 have an interest in the outcome of this case. These representations are made in order that the judges of this Court may evaluate possible disqualification or recusal.

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TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

INTEREST OF *AMICI CURIAE*[1]

Amici curiae are leading medical professionals who have extensive experience researching and developing cancer tests and diagnostic tools. As a result, *amici* have a strong personal and professional interest in ensuring the development and widespread availability of effective early-stage cancer-screening tools that can save lives and reduce suffering.

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[1] No counsel for either party authored this brief in whole or in part, no party or party's counsel contributed money intended to fund the preparation or submission of the brief, and no one other than *amici* contributed money intended to fund the preparation or submission of the brief. All parties have consented to the filing of this brief.

received his medical degree from the University of Tennessee College of Medicine in Memphis, Tennessee.

Amici sign this brief in their individual capacities and not as an employee or agent of any institution. The positions taken in this brief are those of *amici* alone and should not be attributed to any institution with which *amici* are or have been affiliated.

INTRODUCTION

Cancer exacts a devastating toll on Americans. Currently the second-leading cause of death in this country, cancer will soon be the leading cause of death, overtaking any other cause of mortality. In 2023, two million people will be diagnosed with cancer for the first time; in that year alone, 600,000 will die of cancer.[2] Cancer does not merely inflict incalculable pain and suffering on its victims. It also leaves families shattered and friends grieving in its wake. As medical professionals, we see—first-hand—cancer's destructive toll.

Innovations like the one at issue in this case, however, provide reason for optimism. During the past decade, medical professionals have made progress in the battle against cancer. Improvements related to cancer screening and early detection have begun to show tremendous potential. When cancer is detected in its early

[2] *See* American Cancer Society, *Cancer Statistics Center: 2023 Estimates*, https://cancerstatisticscenter.cancer.org/#!/.

stages, it is more likely that the cancerous cells can be excised completely or treated through radiation or medication. But if the cancer is not detected until it has spread throughout the body or mutated, treatment is far less likely to lead to remission. Many cancers diagnosed in their late stages are more likely to be fatal. Early detection can save lives.

To significantly improve public health, early-stage detection must be accessible and avoid being unduly invasive or creating significant health risks. Over one-third of patients resist invasive screening techniques, such as colonoscopy, due to discomfort and risk of complications. Further, even non-invasive cancer screening methods, such as mammography, carry patient risks because (for example) they expose patients to radiation. Finally, effective cancer screening exists for only a small fraction of cancer types; for the majority of cancer types there are no effective cancer-screening programs.

Grail and its proprietary Galleri test promise an answer to those concerns. Galleri is a multi-cancer early detection ("MCED") test, aimed at detecting whether a patient has cancer even before the patient starts showing symptoms. Galleri is the first—and only—blood-based MCED test available to patients for cancer detection. Galleri screens for over 50 different types of cancers, including many for which there is no standard screening procedure. And the Galleri test can reveal the cancer's tissue of origin (*i.e.*, where the cancer is located in the body), which allows more

targeted follow-up screening, diagnosis, and treatment. Galleri has already demonstrated its potential as a lifesaving screening test. And it does that without the need for surgical procedures or x-rays. Detection is performed by drawing and examining a small quantity of the patient's blood, a standard process to which all of us have become accustomed.

But Galleri is not yet widely available. Significant additional investment is needed to secure FDA approval and make Galleri accessible to patients. By prohibiting Illumina from acquiring Grail, the Federal Trade Commission has delayed—and potentially prevented—that investment, jeopardizing Galleri's future. The Commission based its decision, in part, on concerns about hypothetical future competitors in the MCED market. But those competitors are nowhere near commercializing an MCED assay that would help save patient lives by screening for dozens of different cancers with a single test. The Commission's decision prioritizes hypothetical competition that does not yet exist over lifesaving innovation. If allowed to stand, the Commission's decision will harm patients. In this case, competition to develop and commercialize lifesaving technologies has yielded a revolutionary test. Concerns about hypothetical later-arriving technologies competing on price should not be allowed to delay or to deprive the public of the benefits of a revolutionary technology that, with Illumina's assistance, has the potential for widespread adoption.

ARGUMENT

I. THE COMMISSION'S DECISION THREATENS THE AVAILABILITY OF A LIFESAVING SCREENING TOOL

A. The Galleri Test Is a Revolutionary Screening Tool with the Potential To Dramatically Reduce Suffering and Mortality

Despite the importance of early detection, most cancer-screening tools available today suffer from serious deficiencies. Existing procedures are relatively narrow in scope: They can detect only a handful of cancers, such as breast, cervical, colorectal, lung, and prostate cancers.[3] But those cancers account only for approximately 30 percent of cancer-related deaths.[4] For the vast majority of cancers, ***there are no standard screening options at all***.[5]

As a result, many cancers can go undetected until the patient is symptomatic and the cancer has grown or spread to other parts of the body.[6] By that time, the

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[3] Allan Hackshaw *et al.*, *Estimating the Population Health Impact of a Multi-Cancer Early Detection Genomic Blood Test To Complement Existing Screening in the US and UK*, 125 Br. J. Cancer 1432, 1432 (2021), https://doi.org/10.1038/s41416-021-01498-4; *see also* Initial Decision of the Administrative Law Judge ("Initial Decision") ¶69.

[4] *See* Hackshaw, *supra* note 3, at 1432; s*ee also* Trial Transcript ("Trial Tr.") 3619:7-21.

[5] Currently, in the United States, there are "screening recommendations for only five cancers (breast, colorectal, cervical, lung, and prostate)." Patricia A. Deverka *et al.*, *Multicancer Screening Tests: Anticipating and Addressing Considerations for Payer Coverage and Patient Access*, 41 Health Affairs 383, 383 (2022). By contrast, "[t]here are no standard screening options for the majority of cancers today." Initial Decision ¶68.

[6] Cancer's "high mortality rate" is "mostly due to late detection, finding cancer when it has already progressed and metastasized, which significantly reduces effective

disease can become difficult—if not impossible—to cure.[7] Even apart from concerns about patient mortality rates, patient suffering increases as well. And as patients suffer, so do their families and friends.

The few standard screening tools in use today have serious drawbacks. For example, mammograms can be used to screen for breast cancer. But the required x-rays are correlated with increased risk of cancer, reducing the net public health benefit of regular screenings.[8] Regular colonoscopies are recommended for certain groups for early detection of colon cancer.[9] But colonoscopies carry the risk of adverse health consequences, including the potential for perforation of the bowel

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treatment options." Tiago Brito-Rocha *et al.*, *Shifting the Cancer Screening Paradigm: The Rising Potential of Blood-Based Multi-Cancer Early Detection Tests*, 12 Cells 935, 935 (2023); *see* Initial Decision ¶¶78-80 ("Most cancers are discovered after they have grown and spread in a person's body.").

[7] Brito-Rocha, *supra* note 6, at 935; David Crosby *et al.*, *Early Detection of Cancer*, Science, Mar. 2022, at 1, https://www.science.org/doi/epdf/10.1126/science.aay9040 ("When cancer is detected at the earliest stages, treatment is more effective and survival drastically improves."); Timothy P. Hanna *et al.*, *Mortality Due to Cancer Treatment Delay: Systematic Review and Meta-Analysis*, BMJ, at 4-5 (2020), http://dx.doi.org/10.1136/bmj.m4087; World Health Organization, *Early Cancer Diagnosis Saves Lives, Cuts Treatment Costs* (Feb. 3, 2017), https://www.who.int/news/item/03-02-2017-early-cancer-diagnosis-saves-lives-cuts-treatment-costs; *see also* Initial Decision ¶¶81-85.

[8] Martha S. Linet *et al.*, *Cancer Risks Associated with External Radiation from Diagnostic Imaging Procedures*, 62 CA Cancer J. Clin. 75, 76 (2012) ("From 1956 to the present, epidemiologic studies have also linked diagnostic x-rays with cancer increases in patients.").

[9] Centers for Disease Control and Prevention, *Colorectal Cancer Screening Tests* (Feb. 23, 2023), https://www.cdc.gov/cancer/colorectal/basic_info/screening/tests.htm.

during the procedure.[10] And the highly invasive nature of some procedures discourages patients from seeking them out.[11]

To overcome those obstacles, Grail set out to develop a blood-based multi-cancer early detection ("MCED") test. Grail's Galleri test can identify multiple cancer types from a single blood sample. Galleri leapfrogs existing screening methods in at least three important ways.

First, Galleri can detect cancers that evade current screening procedures, such as cancer of the pancreas, ovary, kidney, or liver.[12] Galleri is thus an enormous improvement over existing technologies, which often fail to detect those types of

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[10] Varut Lohsiriwat *et al.*, *What Are the Risk Factors of Colonoscopic Perforation?*, 9 BMC Gastroenterology 71, 71 (2009), http://www.biomedcentral.com/1471-230X/9/71 ("[E]ndoscopic perforation of the colon"—one "of the most serious complications of colonoscopy"—is "reported as between 0.03% and 0.7%."); Jung Yun Park *et al.*, *The Outcomes of Management for Colonoscopic Perforation: A 12-Year Experience at a Single Institute*, 32 Annals of Coloproctology 175, 175 (2016) ("Although colonoscopy is a safe procedure, lethal complications such as perforation and bleeding may occur during the procedure.").

[11] *See, e.g.*, Brito-Rocha, *supra* note 6, at 936 (recognizing that because a colonoscopy "is a rather invasive and uncomfortable procedure, requiring prior preparation," there is "low patient compliance"); *id.* (noting that existing screening procedures have "several drawbacks, leading to low patient compliance").

[12] *See* Candace Westgate *et al.*, Poster: *Early Real-World Experience with a Multi-Cancer Early Detection Test*, American Society of Clinical Oncology (June 2023), https://grail.com/wp-content/uploads/2023/06/Westgate_ASCO-2023_Clinical-Surveillance_Poster_FINAL.pdf; *see also* Trial Tr. 4000:15-17; Initial Decision ¶245 (citing results of PATHFINDER clinical study); Trial Tr. 3789:25-3796:9.

cancers until they have grown or spread throughout the body (and have become more difficult to cure).[13]

Second, Galleri has the potential to accurately detect the presence of a wide variety of cancer types with a single test.[14] Clinical trials have shown that Galleri can detect ***over 50 different types*** of cancer.[15] That improves upon existing screening methods, which aim to detect one type of cancer in a single organ.[16]

Third, Galleri is minimally invasive. The Galleri test requires only a blood draw, a common medical procedure that is well tolerated and already conducted at

[13] *See* Brito-Rocha, *supra* note 6, at 936 (opining that MCED tests "have the capacity to detect cancer even when symptoms are not present or tumor masses are not detectable by imaging techniques"); Deverka, *supra* note 5, at 384 ("Because multicancer early detection screening tests can identify signals from a variety of potentially lethal cancers that currently have no recommended screening tests, the cancer detection rate could increase significantly for cancers such as pancreatic, liver, and ovarian cancers."); *see also* Trial Tr. 3781:16-24.

[14] *See* Westgate, *supra* note 12 (showing Galleri's ability to simultaneously screen for several types of cancer).

[15] The "performance characteristics" of Galleri "indicate" that it would detect 50 types of cancer in a sufficiently large interventional trial. *See* Trial Tr. 3794:3-24. While Galleri has not yet been shown clinically to detect all of those 50 types of cancer, that is due to the size of the clinical trial sizes that would be required. Because of the relatively low incidence of certain cancer types, finding evidence for "all 50 cancers" would require trials involving "hundreds of thousands of people." *See id.* at 3298:12-13.

[16] *See* Deverka, *supra* note 5, at 383 ("[S]creening for evidence of diverse common and rare cancers in one blood test . . . will improve screening efficiencies over individual, organ-specific tests.").

many annual physicals.[17] Because the procedure is familiar and non-invasive, many more patients would proactively seek or tolerate early screening.[18] Drawing blood, moreover, is not associated with significant health risks.[19] The health risks involved in screening through Galleri—unlike most other techniques—are de minimis. "[T]he ability to add a simple blood draw to detect multiple cancers noninvasively" thus "would represent a major public health advance."[20]

Galleri also has an enormous advantage even over most other MCEDs reportedly under development. Even if those other tests become available to the public—an uncertain result that is years away at best—those tests would only identify the likelihood that cancer exists ***somewhere*** in the body. Positive results will mean that patients must undergo still more procedures to try to determine the cancer's location within the body. Even though Galleri detects cancer through a blood test, it also provides information about the cancer's origins. Over 90 percent of the time, the Galleri test can accurately determine not only the presence of cancer, but also where the cancerous cells are localized in the body.[21]

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[17] *See generally* Harold J. Galena, *Complications Occurring from Diagnostic Venipuncture*, 34 J. Fam. Pract. 582, 583 (May 1992).

[18] *See* Deverka, *supra* note 5, at 386 (highlighting "the ease of use of a single blood test for multiple cancers").

[19] Galena, *supra* note 17, at 583 (noting venipuncture is "reasonably safe" and "results in few complications").

[20] Deverka, *supra* note 5, at 384.

[21] *See* Westgate, *supra* note 12 (91% "prediction accuracy" of cancer-signal origin).

Those results are remarkable—potentially revolutionary. The vital information derived from the Galleri test can inform doctors and patients about whether and how to follow-up with additional screening, diagnosis, and treatment. Developing a minimally invasive broad-spectrum test that does not merely detect but also pinpoints the cancer's location—one that also has the potential to screen for dozens of potential cancer types—has long been considered the Holy Grail of cancer-detection research. Grail's Galleri test holds enormous promise for allowing doctors to detect cancers earlier and ensuring patients will get treatment sooner. Thousands of lives could be saved and incalculable suffering avoided.

B. The Galleri Test Resulted from Years of Costly Research and Development

The Galleri test relies on breakthrough proprietary developments in DNA screening that allow practitioners to detect and identify the origin of dozens of cancers. But developing Galleri was not easy. It did not merely require game-changing insights. It also required time- and resource-intensive efforts that are a prerequisite to developing an accurate blood-based MCED test.

First, test developers must undertake sample collection, research, and biomarker discovery. This requires collecting blood samples from thousands, if not tens of thousands, of people in order to identify which biomarkers can best predict whether an individual has cancer. The biomarkers must have the requisite sensitivity and specificity to detect both the presence of cancer and the tissue from which the

cancer originated. That research and discovery stage can take several years, if not longer. After selecting the appropriate biomarkers to use, the developer focuses on optimizing test performance, cost, and quality control. Finally, developers must clinically validate the test—through expensive, multi-year, large-scale studies on patients—to ensure that it can effectively detect cancer.[22] This final step alone could take five to seven years, even if the clinical studies succeed.

Significantly, a newly developed test could fail at any one of these steps.[23] New drugs, for example, fail to make it to market more than 95% of the time.[24] The test's designer thus pumps extraordinary resources into research and development without knowing if the test will work, gain regulatory approval, or achieve commercial success.

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[22] *See also* Initial Decision ¶186 ("MCED tests will require multi-year, large-scale clinical studies to receive FDA approval.").

[23] *See generally* Aleksandr Ivanov, *Barriers to the Introduction of New Medical Diagnostic Tests*, 44 Lab. Med. e132 (2013) (describing financial and regulatory hurdles to the development and adoption of new medical diagnostic tests).

[24] *See* Aroon D. Hingorani *et al.*, *Improving the Odds of Drug Development Success Through Human Genomics: Modelling Study*, 9 Sci. Rep. 18911 (2019), https://doi.org/10.1038/s41598-019-54849-w (noting overall drug failure rate of 96%, dropping to 90% for drugs that advance to clinical development); Duxin Sun *et al.*, *Why 90% of Clinical Drug Development Fails and How To Improve It?*, 12 Acta Pharmaceutica Sinica B 3049, 3050 (2022) (noting that nine of ten drug candidates entering clinical studies fail); *id.* ("Drug discovery and development is a long, costly, and high-risk process that takes over 10-15 years with an average cost of over $1-2 billion for each new drug to be approved for clinical use.").

In light of these challenges, it is unsurprising that, to date, only one MCED test—the Galleri test—has made it from proof-of-concept to actual use in practice. Achieving those breakthroughs required a tremendous investment of money and labor: It took over six years and inordinate investments to commercialize Galleri even on a limited basis.

Despite Grail's investment, Galleri has not yet achieved its full potential. Galleri has been commercially available since April 2021 as a laboratory developed test; it has yet to receive FDA approval.[25] Laboratory developed tests typically "have lower rates of adoption than FDA-approved tests," and FDA approval is generally necessary for a test to "gain widespread commercialization."[26] Obtaining FDA approval, however, is a "costly, lengthy, and uncertain process" that requires, among other things, expensive, "multi-year, large-scale clinical studies."[27] It will thus take enormous additional investment to perform the extensive clinical trials needed for eventual FDA approval. Refining the test's accuracy and expanding the range of cancers it can detect will take still more resources and expertise. Significant additional investment will thus be required to optimize Galleri's ability to save lives.

[25] Initial Decision ¶¶52, 165, 258.

[26] *Id.* ¶¶166, 169; *see id.* ¶¶198-200 (discussing necessity of FDA approval for securing payer coverage).

[27] *Id.* ¶¶177, 186.

C. The Acquisition of Grail by Illumina Is Necessary To Accelerate Galleri's Widespread Adoption

Despite its tremendous promise, Galleri's widespread availability is far from guaranteed. As discussed earlier, *see* pp. 10-12, *supra*, achieving widespread commercialization of a novel test is difficult, and it is far from clear that Grail has sufficient expertise and resources to make that happen. Grail is in its infancy. We understand that its resources are limited, and it has no experience in achieving regulatory approval for a cancer-detection test. Nor does Grail have the sophisticated manufacturing infrastructure or supply-chain relationships that would be required to satisfy demand for this game-changing technology.

Illumina, by contrast, is an established and well-recognized biotechnology company. It has vast experience and significant resources that can be devoted to shepherding novel technologies through clinical and regulatory approval. Compared to Grail, Illumina has vastly superior supply-chain relationships and operational capabilities. If Illumina acquires Grail, it can devote those resources, capabilities, and know-how to move the Galleri test through the process of clinical validation and regulatory approval; it can see to expanding the scope of Galleri's capabilities; and it can ensure the efficient manufacture and widespread distribution once the test is approved.[28]

[28] *See* Illumina/Grail Opening Br. 64-70 (detailing cost-saving, research and development, and operational efficiencies from proposed acquisition).

When potentially lifesaving technologies are at issue—ones that could prevent the unnecessary spread of cancers and avoid human suffering—time is of the essence. Delaying Galleri's widespread availability has the potential to deny many patients early detection, subjecting them to otherwise avoidable suffering and death. By accelerating Galleri's widespread availability, Illumina's acquisition of Grail—pairing Grail's novel technology with Illumina's capabilities and industry know-how—promises to provide more Americans more rapid access to this revolutionary cancer-detection tool.

II. THE COMMISSION'S DECISION PRIORITIZES HYPOTHETICAL COMPETITORS OVER HUMAN LIVES

The Commission's rationale for blocking the merger rests on a premise that, in our experience, is deeply flawed. The Commission posited that rival blood-based MCED tests to compete with Galleri will soon emerge. That blinks reality. No MCED tests rival Galleri. From the patient-care and physician's perspective, it makes little sense to risk delaying the widespread availability of lifesaving technologies based on the hypothetical hope that doing so will protect not-yet-existing rival technologies that may take years to materialize—if they materialize at all.

Galleri's efficacy is not disputed. Numerous clinical studies have proved Galleri's value.[29] Thousands of asymptomatic people have already benefitted from

[29] *See* Westgate, *supra* note 12; BBC, *Multi-Cancer Blood Test Shows Real Promise in NHS Study* (June 2, 2023), https://www.bbc.com/news/health-65775159. The

using a Galleri test to screen for dozens of different cancers.[30] And Galleri is currently undergoing large-scale prospective interventional trials, which are necessary to ultimately achieve regulatory approval.[31]

No potential rival technology we know of is even close to achieving that.[32] No other group or company is close to achieving commercialization of a competing MCED test capable of screening for so many different cancers. Competing developers remain stuck in the development phase and may never progress. Based on our experience, they appear to be lagging Grail by at least several years. Singlera, a supposed rival, has acknowledged that it is at least seven to ten years away from

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"PATHFINDER study" found "29 cancers," including "13 different types of cancer," "some in their early stages." Trial Tr. 3297:22-24; Initial Decision ¶¶215-255 (discussing results of Galleri's clinical studies).

[30] *See* Westgate, *supra* note 12; Meg Farris, *Test Can Detect 50 Types of Cancer Before You Have Symptoms and You Can Get It Locally*, WWL-TV (June 7, 2022), https://www.wwltv.com/article/news/health/galleri-blood-test-cancer-screening-ochsner-trial/289-17d296c9-ad16-4531-b7d5-6e533ea0ebd5 (reporting on patient whose pancreatic cancer was detected by Galleri); *see also* Initial Decision ¶¶215-255.

[31] One marquee trial is being conducted in partnership with the United Kingdom's National Health Service. Roughly 140,000 individuals have enrolled in that trial, and initial results are promising. *See* BBC, *supra* note 29; Bloomberg, *Grail and National Health Service (NHS) England Complete Enrollment of 140,000 Participants in Largest Study of Multi-Cancer* (July 18, 2022), https://www.bloomberg.com/press-releases/2022-07-18/grail-and-national-health-service-nhs-england-complete-enrollment-of-140-000-participants-in-largest-study-of-multi-cancer.

[32] *See* Initial Decision ¶¶202-203 (recognizing that most "MCED tests are still in the early stages of development" and that most developers "do not expect to launch a screening test for more than one cancer type for many years").

submitting an MCED for FDA approval.[33] Another so-called rival, Natera, has stated publicly that it is spending only "about $5 million of annual expense all in for early cancer detection," and is not yet planning to "pull the trigger on a stepped-up level of investment."[34] Indeed, in the ***two years*** since the trial underlying this appeal, ***none*** of Grail's rivals has released a comparable MCED test. Nor does any launch appear imminent. Nothing suggests that competitors have devoted nearly the same resources to research and development as Grail.

Even if these (or other) competitors redoubled their research and development efforts, it is far from certain that those efforts would produce an accurate MCED test. Developing an MCED test is an enormously complicated, expensive, time-consuming undertaking. It is also fraught with peril. From concept, to proof-of-concept, to clinical trials, to regulatory approval, to scaling up while maintaining reliability, are just a few of the numerous points at which the development effort can fail. *See* pp. 10-12 & nn.22-27, *supra*. There are no guarantees that these competitors' efforts will bear fruit in the near term or ever.

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[33] *See* Initial Decision at 144 (Singlera "believes it will take at least seven to ten years before its test is submitted to the FDA for approval").

[34] Natera, Inc., FQ4 2022 Earnings Call, at 4 (Feb. 28, 2023), https://s201.q4cdn.com/354493536/files/doc_financials/2022/q4/Natera_Q4_2023_Transcript.pdf.

None of Galleri's purported competitors, moreover, has produced any data suggesting that it is anywhere near being able to detect 50 types of cancer as Galleri can. Several tests in development, for instance, are focused on detecting only a ***single type*** of cancer.[35] Galleri, moreover, excels at identifying the cancer tissue of origin following a single blood draw. By contrast, at least one rival test under development requires subsequent full-body imaging PET-CT scans to attempt to localize the potential cancer.[36] Such scans are expensive, are "a recognized source of potential harm," and may not ultimately succeed in pinpointing the cancer.[37] From the physician's perspective, the patient perspective, the public health perspective, it makes little sense to risk delaying Galleri's widespread availability based on concerns about the acquisition's putative effects on speculated alternatives that do not exist and may never exist—the medical equivalent of vaporware.

The Commission nonetheless blocked Illumina's acquisition of Grail in the name of protecting such hypothetical competitors. The Commission may be concerned with ensuring that, someday, competition among multiple options will drive down prices. But competition to ***develop*** a new, revolutionary technology has done its work. Galleri exists and has the promise to save lives today. Whatever the value

[35] *See* Initial Decision at 145.

[36] *See id.* ¶¶293-294; *see id.* at 146 n.33.

[37] *See id.* at 146-47; *id.* ¶¶295-296; Linet, *supra* note 8, at 76 (recognizing scans are a source of radiation).

of future price competition generally, competing alternatives to Galleri do not currently exist, may be years away, and may never materialize at all. Delaying Galleri means denying Americans a revolutionary tool for detecting cancer at early stages. Myriad cancers will go undetected or will be detected too late, costing lives and imposing incalculable suffering. There is no reason to sacrifice lifesaving medical detection at the altar of protecting imagined—hoped for but wholly speculative—competing technologies.

CONCLUSION

The Commission's decision should be reversed.

Dated: June 12, 2023

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on June 12, 2023, I caused this document to be electronically filed with the Clerk of Court by using the Court's electronic filing system, which will effect service on all counsel of record.

/s/ Jeffrey A. Lamken
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CERTIFICATE OF COMPLIANCE

1. This *amicus* brief complies with the type-volume limit of Fed. R. App. P. 29(a)(5) and 5th Cir. Rule 29.3 because, excluding the parts of the document exempted by Fed. R. App. P. 32(f), this document contains 4,214 words.

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