

No. 23-60167

United States Court of Appeals for the Fifth Circuit

ILLUMINA, INC. AND GRAIL, INC.

Petitioners,

v.

FEDERAL TRADE COMMISSION

Respondent

Petition for Review of an Order of the Federal Trade Commission

**BRIEF FOR THE NATIONAL HISPANIC MEDICAL
ASSOCIATION ET AL. AS *AMICI CURIAE*
IN SUPPORT OF PETITIONERS**

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CERTIFICATE OF INTERESTED PERSONS

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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INTEREST OF *AMICI CURIAE*¹

Amici are non-profits, bipartisan members of Congress, and a medical professional, who are advocates for healthcare equality for people in underserved communities, and in particular for minority groups, underprivileged individuals, and people with disabilities.

The National Hispanic Medical Association (NHMA) is a non-profit association representing the interests of Hispanic physicians in the United States. The NMHA exists to improve the healthcare of Hispanic Americans and members of underserved communities.

Congresswoman Nanette Diaz Barragán (D-CA, 44th District) is Chair of the Congressional Hispanic Caucus and serves on the House Energy and Commerce Subcommittees on Health. Congressman Steven Horsford (D-NV, 4th District) is Chair of the Congressional Black Caucus. Congresswoman Terri Sewell (D-AL, 7th District) is a member of the Congressional Black Caucus and serves on the House Ways and Means Subcommittee on Health. Congresswoman Barbara Lee (D-CA, 12th District) is the Co-Chair of the Democratic Policy and Steering Committee, and serves on the House Budget and Appropriations Committees. Congresswoman Sheila Cherfilus-McCormick (D-FL, 20th District) serves on the

¹ All parties consented to the filing of this brief. No party's counsel authored any part of this brief. No one, apart from *amici* and their counsel, contributed money intended to fund the brief's preparation or submission.

Congressional Black Caucus. Congresswoman Lori Chavez-DeRemer (R-OR, 5th District) serves on the Congressional Hispanic Conference.

MANA, a National Latina Organization, represents the interests of Latina women, youth, and families on various issues that affect their communities, including health equity.

The Center for Black Health and Equity is a national nonprofit organization that facilitates public health programs and services that benefit communities and people of African descent.

SER Jobs for Progress National, Inc. is a national nonprofit organization that formulates and advocates initiatives resulting in the increased development and utilization of America's human resources, with emphasis on the needs of Hispanic Americans, in the areas of education, training, employment, business, and economic opportunity.

The National Hispanic Council on Aging (NHCOA) works to improve the lives of Hispanic older adults, their families, and caregivers, and is dedicated to promoting, educating, and advocating for research, policy, and practice in the areas of economic security, health, and housing.

Dr. Jose Morey is a medical professional and the CEO of Ad Astra Media, a minority-owned production company, which, among other things, works to provide information and awareness about the importance of vaccinations for Black and Brown patients.

Mobilizing Preachers and Communities (MPAC) is a Non-Profit Civil Rights and Faith Based organization, comprised of clergy and community united together for the purpose of impacting public policy through civic engagement, to ensure justice and equality for all people.

Amici have a substantial interest in this case because reuniting Illumina and Grail has the potential to reduce racial, ethnic, and socioeconomic disparities in cancer diagnosis and treatment. *Amici* and their members have deep experience relevant to these antitrust efficiencies of the Illumina-Grail merger. *Amici* respectfully submit that this Court should hold unlawful and set aside the Commission's order, which fails as a matter of law and will delay widespread adoption of Grail's Galleri test—accelerated by the Grail-Illumina merger—that would be a game-changer for members of underserved communities.

INTRODUCTION

Evidence from a weeks-long FTC evidentiary hearing established that the Illumina-Grail merger will facilitate distribution of Grail's Galleri cancer screening test by accelerating the path to FDA approval and payor reimbursement. By making cancer screening easier and cost-effective, the merger will save thousands of lives and prevent immeasurable suffering in the near term. *Amici* submit that the merger would improve rates of

cancer screening for underserved communities in particular, and thus has the potential to reduce inequality in cancer screening and care.

For years, cancer screening has been invasive, expensive, time-consuming, or limited in other ways. Typically, patients test for only one cancer at a time, and only after a referral from a primary care physician. Because of these limitations and others, the general public does not proactively and sufficiently screen for all cancers. Many diagnoses are missed at the point when intervention would be most effective. (**§ I.A**).

Within that broader context is another problem: disparities in cancer outcomes based on race, geography, and socioeconomics. Health inequality in the United States is well-documented and cancer is no different. Studies show that members of underserved communities are less likely to obtain cancer screening, in part because the costs and burdens are amplified for them. And the obstacles are more than just dollar and cents—they include problems such as difficulty accessing insurance, employer inflexibility to take time off from work, long distances to healthcare facilities, language barriers, and implicit biases, among others. (**§ I.B**). Research shows that members of underserved communities receive less effective and less frequent screening. (**§ I.C**). And research in turn shows that members of such communities bear the burdens of cancer disproportionately. They are often

diagnosed at later stages and often have worse outcomes—*i.e.*, higher mortality rates, more severe illnesses, and greater financial hardships. (§ I.D).

Widespread adoption of the Galleri test would be a game-changer. It is a technological break-through that can significantly reduce the many costs and obstacles that hinder screening, particularly for the underprivileged. Galleri tests for up to 50 types of cancer at once, in a single blood draw, at a time when there is no standard screening method for most cancers. The sooner the Galleri test can get to widespread adoption—and be covered by payors—the better. By saving lives in all communities, and by reducing the need for hospitalization and surgery, Galleri could also save billions of dollars in healthcare costs nationwide. (§ II).

The unrefuted evidence from the agency hearing shows that reuniting Illumina and Grail will make all of that happen faster. Thus, the Commission erred when it cast aside this conclusive evidence of economic efficiency and deemed the merger unlawful. For the first time in decades, an ALJ found in favor of a merger after an in-house adjudication. But the Commission made up its mind when it first brought the case as the prosecutor, and overrode the ALJ's extensive and well-supported findings. The Commission blocked the merger without solid reasoning and based on its unsubstantiated predictions about future market dynamics.

Amici submit that this case is about more than abstract theory and supposition. The merger would save thousands of lives, starting right now, and reduce longstanding inequalities in cancer care. The Commission’s Order is thus an obstruction to remarkable progress, with the Commission elevating its own vision of the market over the public welfare. This Court should hold that Order unlawful and set it aside. (§ III).

ARGUMENT

I. Underserved Communities Disproportionately Bear The Burdens Of Cancer, Due In Part To Gaps In Screening

A. Although cancer screening is critical for better outcomes, historically it has been costly and limited

1. Effective screening is a crucial first step for cancer treatment. *See* Paul Pinsky et al., *Putting Cancer Screening in Perspective*, Nat’l Insts. Health (Apr. 27, 2022).² As the Commission recognized, “[b]etter screening methods . . . have the potential to extend and improve many human lives.” Op. 3.³ If cancer is diagnosed at an early stage, treatments are often less aggressive—and more likely to succeed. Op. 2. As the disease progresses and cancer metastasizes, treatments become more painful, more invasive, and less effective. *Id.* at 2-3.

² <https://www.nih.gov/about-nih/what-we-do/science-health-public-trust/perspectives/science-health-public-trust/putting-cancer-screening-perspective>.

³ For record citation abbreviations, see Petitioners Br., Dkt. No. 96, at p.xiv.

Moreover, increased cancer screening would lead to savings in healthcare costs. Although studies differ in methodology for assessing the economic impacts of cancer, numerous researchers have found that cancer exerts a significant burden on the economy and that its costs will rise in the coming years. According to the American Cancer Society, “[a]pproximately \$183 billion was spent in the U.S. on cancer-related health care in 2015, and this amount is projected to grow to \$246 billion by 2030—an increase of 34%.” Am. Cancer Soc’y, *The Costs of Cancer*, at 3 (2020 ed.).⁴

In addition, there are other substantial losses to society—including the loss of economic productivity. One recent study found that “[c]ancer diagnosis was associated with a 6.8% higher risk of part-year non-employment and 4.1% higher risk of full-year non-employment.” Roni Nitecki et al., *Employment Outcomes Among Cancer Patients In the United States*, 76 *Cancer Epidemiology* 102059 (Feb. 2022).

2. Cancer screening in the United States is currently costly, burdensome, inefficient, and limited. No standard screening options exist for most cancers in asymptomatic individuals, and single-cancer screening exists for only breast, cervical, colon, lung, and prostate cancer. *See Op. 2. More-*

⁴ <https://www.fightcancer.org/sites/default/files/National%20Documents/Costs-of-Cancer-2020-10222020.pdf>.

over, screening can be time-consuming, difficult, and expensive, particularly if a patient's insurance provider does not cover it. *See* Am. Cancer Soc'y, *Costs and Ins. Coverage for Cancer Screening* (Apr. 20, 2021);⁵ Am. Cancer Soc'y, *Costs of Cancer*, *supra*, at 30 (describing unexpected costs for preventative care and screening services).

To begin, a patient typically needs a referral from a primary-care physician to see a specialist to screen for cancers for which the patient may be at risk. *See* Am. Cancer Soc'y, *Costs of Cancer*, *supra*, at 9-10. That means waiting (often weeks) for a primary-care appointment; securing transportation to the doctor's office; taking time off work; and paying a co-pay. *See* AMN Healthcare: *Survey of Physician Appointment Wait Times and Medicare and Medicaid Acceptance Rates*, at 4 (2022)⁶ (finding wait times for family physicians in metropolitan areas of 26 days on average, and up to 45 days in some cities).

If the physician determines that testing is appropriate, she typically refers the patient to a specialist. But that imposes additional costs and delays. *Id.* (showing specialist wait times increasing consistently over two decades in major cities); Am. Cancer Soc'y, *Costs of Cancer*, *supra*, at 9

⁵ <https://www.cancer.org/cancer/screening/cancer-screening-costs-insurance-coverage.html>.

⁶ https://www.merritthawkins.com/uploadedFiles/MerrittHawkins/Content/News_and_Insights/Articles/mha-2022-wait-time-survey.pdf

(“The complexity of cancer treatment and the necessity of multiple specialists are large drivers of cancer patient costs”). The patient needs to book yet another appointment with specialists who are often “in short supply” and farther away. *Id.* He must take time off work (again), and pay any co-pay or co-insurance (again). *Id.* And co-pays and co-insurance for specialists tend to be higher and their wait times longer. *Id.*

Many cancer tests are also invasive. “Typically, cancers are detected through a tissue biopsy or involve an invasive procedure,” such as a colonoscopy, radiological tests, pap smear, or prostate exam—which are unpleasant or risky in their own ways. Op. 26. Some of these methods involve exposure to radiation. IDF ¶ 75 (noting that whole-body PET/CT scans can be useful but are not recommended for early screening due in part to danger from radiation); CDC, *What Is Breast Cancer Screening?* (Sept. 26, 2022)⁷ (“[P]otential harms from breast cancer screening include pain during procedures and radiation exposure from the mammogram test itself.”). Others can lead to injury, such as bleeding and tearing. See Nat’l Cancer Inst., *Cancer Screening Overview (PDQ)-Patient Version* (Aug. 19, 2020)⁸ (noting that “[n]ot all screening tests are helpful and most have risks”).

⁷ https://www.cdc.gov/cancer/breast/basic_info/screening.htm.

⁸ <https://www.cancer.gov/about-cancer/screening/patient-screening-overview-pdq>.

And tests can be embarrassing or uncomfortable, thus causing hesitancy and anxiety. *See* Kathleen Hall, *What To Do About Pre-Colonoscopy Anxiety*, U.S. News & World Report (Oct. 10, 2017)⁹ (many patients fear colonoscopies); *see also* Chengyue Yang et al., *Anxiety Associated with Colonoscopy and Flexible Sigmoidoscopy: A Systematic Review*, 13(12) *Am. J. Gastroenterology* 1810, 1810-1818 (Dec. 15, 2018); Danielle J. O’Laughlin et al., *Addressing Anxiety and Fear during the Female Pelvic Examination*, 12 *J. Prim. Care & Cmty. Health* 1 (Feb. 1, 2021) (“[a]nxiety and fear are common before and during the pelvic examination” used for cervical cancer screening). Thus, as the Commission found, people tend to be more “comfortable and familiar with blood draws” than with procedures that have traditionally been used for cancer screening. Op. 3.

For these and many other reasons, the American Cancer Society has found that the “potential” of cancer screening is “unfulfilled due to lower than optimal uptake and quality issues.” *Am. Cancer Soc’y, Cancer Prevention & Early Detection: Facts & Figures*, at 51 (2023-2024).¹⁰ Quite simply, screening even for a single cancer can require substantial investment of time, money, and travel—all which can be even more difficult for

⁹ <https://health.usnews.com/health-care/patient-advice/articles/2017-10-10/what-to-do-about-pre-colonoscopy-anxiety>.

¹⁰ <https://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/cancer-prevention-and-early-detection-facts-and-figures/2023-cped-files/2023-cancer-prevention-and-early-detection.pdf>.

workers and parents who cannot afford the co-pays, time off from work, or child care. Testing can be intrusive, embarrassing, or painful. And screening for multiple cancers multiplies those burdens, as the patient would need to screen for each cancer, one at a time.

B. Members of underserved communities face cumulative barriers

Members of underserved communities are more likely to face these and other structural barriers to screening, resulting in “racial/ethnic and socioeconomic status (SES) disparities in receipt of screening services.” Am. Cancer Soc’y, *Cancer Prevention & Early Detection: Facts & Figures*, *supra*, at 51. As the CDC explains, “[a]cross the country, racial and ethnic minority populations experience higher rates of poor health and disease in a range of health conditions.” CDC, *Impact of Racisms on our Nation’s Health* (April 8, 2021).¹¹ Social determinants of healthcare outcomes include: social context and racism, healthcare access, physical environment, workplace conditions, education levels, and income. *See* CDC, *What is Health Equity?* (July 1, 2022).¹² While these factors are complex—and the literature on healthcare inequality is vast and developing—*amici* believe that the factors play a substantial role in creating or exacerbating gaps in cancer screening, treatment, and outcomes.

¹¹ <https://www.cdc.gov/minorityhealth/racism-disparities/impact-of-racism.html>

¹² <https://www.cdc.gov/healthequity/whatis/index.html>.

To begin, studies have found that people in underserved communities lack equal access to healthcare resources and facilities due to socioeconomic and geographical disadvantages. *See, e.g.,* Am. Cancer Soc’y, *Cancer Facts & Figures for African American/Black People*, at 4 (2022-2024).¹³ Fewer primary-care doctors in their neighborhoods, fewer appointments available, longer wait times, and more difficulty finding transit for appointments. *See Healthcare Access in Rural Communities*, Rural Health Info. Hub (Nov. 21, 2022);¹⁴ *see also* Nancy Krieger et al., *Cancer Stage at Diagnosis, Historical Redlining, and Current Neighborhood Characteristics: Breast, Cervical, Lung, and Colorectal Cancers, Massachusetts, 2001–2015*, 189(10) *Am. J. Epidemiology* 1065, 1066 (March 27, 2020) (“[C]urrent neighborhood factors, including inability to access health care and inadequate transportation, can affect stage at diagnosis”). Even when they have referrals, moreover, members of underserved communities typically have less access to specialists. *See* Am. Cancer Soc’y, *Facts & Figures*, *supra*, at 58.

Research has found that lack of access can be particularly problematic in rural communities, including in states within the Fifth Circuit’s jurisdiction. According to some studies, rural areas have approximately

¹³ <https://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/cancer-facts-and-figures-for-african-americans/2022-2024-cff-aa.pdf>.

¹⁴ <https://www.ruralhealthinfo.org/topics/healthcare-access>.

one-fifth the number of oncologists per capita compared to urban areas, and rural patients need to travel, on average, twice as far to see doctors. See Am. Cancer Soc’y, *Costs of Cancer*, *supra*, at 9 (collecting studies). Those barriers translate to reduced screening. For example, one study that surveyed hundreds of people in Texas found that patients often forgo cancer treatment due to problems with transportation, and that Black and Hispanic patients consistently reported that they faced barriers to treatment such as distance and transit. J.J. Guidry et al., *Transportation as a Barrier to Cancer Treatment*, 5(6) *Cancer Pract.* 361-66 (1997). Another concluded that “[r]ural residents frequently face fewer and more dispersed options for healthcare compared to urban and suburban residents,” and that there are fewer colonoscopy providers in rural areas, “meaning fewer choices and longer distances for patients.” Katherine M. N. Lee et al., *Distance and Transportation Barriers to Colorectal Cancer Screening in a Rural Community*, 14 *J. Prim. Care Cmty. Health* 1, 1-5 (Jan. 2023).¹⁵

Studies have also found that individuals with blue-collar jobs, in both urban and rural areas, may be less likely to obtain health care because of greater difficulty getting time off work and arranging childcare. See CDC, *Equity in Cancer Prevention and Control* (Dec. 16, 2021)¹⁶ (“People whose

¹⁵ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9829879/>.

¹⁶ <https://www.cdc.gov/cancer/health-equity/equity.htm>.

jobs don't provide sick leave, people who live in rural or remote areas, and people without reliable transportation may not be able to go to a doctor's office."); Lucy A. Peipins et al., *The Lack of Paid Sick Leave as a Barrier to Cancer Screening and Medical Care-Seeking: Results from the National Health Interview Survey*, 12 BMC Pub. Health 520 (Jul. 2012) ("Lack of paid sick leave appears to be a potential barrier to obtaining preventive medical care.").

Studies have also found that uninsured adults are less likely to test for cancer. See Am. Cancer Soc'y, *African American/Black People Facts & Figures*, *supra*, at 4, 8. Black and Hispanic Americans also have markedly lower health insurance coverage compared to Americans overall, *id.*, with Hispanic men and women being "the least likely to have health insurance of any major racial or ethnic group," Am. Cancer Soc'y, *Cancer Facts & Figures for Hispanic/Latino People*, at 4 (2021-2023).¹⁷ Without insurance coverage, individuals face higher out-of-pocket costs for testing and often forgo screening, particularly when the individuals have not yet shown symptoms. As one example, in 2017, only 30.2 percent of women without

¹⁷ <https://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/cancer-facts-and-figures-for-hispanics-and-latinos/hispanic-latino-2021-2023-cancer-facts-and-figures.pdf>.

health insurance were up to date with recommended breast cancer screening compared to 68.2 percent of women with private insurance. Am. Ass'n for Cancer Rsch., *Cancer Disparities Progress Report*, at 37 (2022).¹⁸

Research has also shown that language and cultural differences can contribute to cancer screening disparities. Simply scheduling a single test may involve making multiple phone calls and appointments, which is more difficult for non-native English speakers. See Kelly H. Bruce et al., *Barriers and Facilitators To Preventive Cancer Screening in Limited English Proficient (LEP) Patients: Physicians' Perspectives*, 11(3) Community Med. 235-47 (2014). Language barriers can also make it harder for doctors to communicate the need for preventative screening and the available options. See CDC Health Equity, *supra*. Studies show that recent immigrants in particular face these barriers. See Am. Cancer Soc'y, *Hispanic/Latino People Facts & Figures*, *supra*, at 5 (“[M]any immigrants face barriers such as less paid time off and access to employer-provided health insurance and transportation, ultimately reducing health care access”); Natalie Guerrero et al., *Cervical and Breast Cancer Screening Among Mexican Migrant Women, 2013*, 13 Preventing Chronic Disease 160036, CDC (Aug. 11, 2016) (“Latinos with high levels of acculturation

¹⁸ https://cancerprogressreport.aacr.org/wp-content/uploads/sites/2/2022/06/AACR_CDPR_2022.pdf.

use more health care services than Latinos with low levels of acculturation”).

Finally, the CDC has found that explicit and implicit racial biases “contribute[] to cancer health disparities by limiting the ability of people of racial and ethnic minority groups to prevent cancer, find cancer early, and get treatment.” CDC, *How Racism Leads to Cancer Health Disparities* (Dec. 16, 2021).¹⁹ For example, studies have found that men who reported having experienced racism in the healthcare system were also less likely to be up to date on their screening for prostate cancer. See Bryn Nelson, *How Structural Racism Can Kill Cancer Patients*, 128(2) *Am. Cancer Soc’y–Cancer Cytopathology* 83-84 (Feb. 2020). Additionally, studies show that African Americans’ mistrust of the health care industry, rooted in longstanding discrimination, can lead to underutilization of services, including less colorectal cancer screening. See Leslie B. Adams et al., *Medical Mistrust and Colorectal Cancer Screening Among African Americans: A Systematic Review*, 42(5) *J. Cmty. Health* 1044-61 (Oct. 2017); Thomas A. LaVeist et al., *Mistrust of Health Care Organizations Is Associated with Underutilization of Health Services*, 44(6) *Health Serv. Res.* 2093-2105 (Dec. 2009).

¹⁹ <https://www.cdc.gov/cancer/health-equity/racism-health-disparities.htm>.

C. Members of underserved communities receive less frequent and less effective cancer screening

1. Numerous studies have found that, because of these barriers, “cancer screening rates are substantially lower among those from racial/ethnic minorities compared to White individuals.” Am. Ass’n for Cancer Rsch., *supra*, at 74. For example, the CDC reports that non-Hispanic American Indian and Alaska Native people were less likely than non-Hispanic White people to be up to date on cancer screening tests in 2021. See CDC, *American Indian and Alaska Native People and Cancer* (Jan. 30, 2023). And according to the American Cancer Society, “Black people were the most likely of all races to have a late-stage diagnosis of cancers that have a recommended screening,” with the exception of prostate cancer. See Farhad Islami, Am. Cancer Soc’y, *The State of Cancer Disparities in the United States*.²⁰ Beyond race, studies find that socioeconomics and geography also play an outsized role in screening frequency and early detection: “People living in counties with the highest average household income and in more populated cities generally were more likely to have an early-stage diagnosis of cancer and less likely to have a late-stage diagnosis in the breast, cervix, or lung compared to people living in other counties.” *Id.*

²⁰ <https://www.cancer.org/research/acs-research-highlights/cancer-health-disparities-research/state-of-cancer-disparities-in-the-united-states.html> (last visited June 10, 2023).

Take breast cancer, as just one example. Breast cancer is the second leading cause of death for all women in the U.S. but can be mitigated by screening. *See* CDC, *Basic Information About Breast Cancer* (Sept. 26, 2022).²¹ One CDC study found that the rate of breast-cancer screening is directly associated with socioeconomic status: the poorer the individual, the less likely she is to be up-to-date on recommending testing. *See* Yelena Gorina & Nazik Elgaddal, *Patterns of Mammography: Pap Smear, and Colorectal Cancer Screening Services Among Women Aged 45 and Over*, 157 Nat'l Health Statistics Reports 1-18 (June 9, 2021).²²

Successful breast cancer screening also often depends on follow-up exams. Yet studies show that “women from racial and ethnic minorities and other medically underserved populations often do not receive follow up care.” Am. Ass'n for Cancer Rsch., *supra*, at 77. Further, research shows that women of color—even when they do receive some form testing—are nonetheless given “suboptimal methods of screening.” *Id.* For example, “compared to 60.5 percent of White women, only 44 percent of Black women were screened by digital breast tomosynthesis, considered to be technologically superior in identifying invasive breast cancer,” and

²¹ https://www.cdc.gov/cancer/breast/basic_info/index.htm.

²² <https://www.cdc.gov/nchs/data/nhsr/nhsr157-508.pdf>.

Black women are less likely to receive supplemental imaging to confirm results of initial tests. *Id.*

One case study describes how a 60-year old black woman living in Chicago, after seeing multiple doctors, was not properly informed of her breast cancer's stage or even referred to an oncologist. See Kristen Pallock et al., *Structural Racism—A 60-Year-Old Black Woman with Breast Cancer*, 380 N. Engl. J. Med. 1489 (2019). By the time she was referred, her cancer had already progressed to stage III. A task force found that “many safety-net hospitals in Chicago’s minority neighborhoods performed poorly on standardized measures of breast care.” *Id.* at 1490.

Another study found that breast cancer is the most common cancer and the leading cause of cancer deaths among Hispanic women—yet “incidence rates are rising faster and mortality declines are lower” compared to other groups—again, in large part from lack of screening. See Stella Winters et al., *Breast Cancer Screening Outcomes among Mexican-origin Hispanic Women Participating in a Breast Cancer Screening Program*, *Prev. Med. Rep.*, at 1 (Sept. 20, 2021).

According to the American Cancer Society, uninsured adults and recent immigrants are also less likely to screen for breast cancer—which disproportionately include black and Latina women. Am. Cancer Soc’y, *His-*

panic/Latino Facts & Figures, supra, at 2. As of 2021, only 29% of uninsured women over 45 are up-to-date on their breast cancer screening. Am. Cancer Soc’y, *Cancer Prevention & Early Detection, supra*, at 9; see also Adriana M. Reyes & Patricia Y. Miranda, *Trends In Cancer Screening By Citizenship and Health Insurance, 2000-2010*, 17 J Immigr. Minority Health 644 (2015).

2. Members of rural communities similarly screen for cancers less frequently. For example, a recent study across eleven states found that women living in rural areas were 19% less likely to be up to date with colorectal screening than women in urban areas. See Am. Ass’n for Cancer Rsch., *supra*, at 78, 80. For cervical cancer, women in rural areas were 34% less likely to be up to date. *Id.* at 79. Breast cancer screening rates are particularly low in Central Appalachia, where resources are limited and there are few doctors per capita. See Health Disparities in Appalachia, at 218, 270 (Aug. 2017).²³ Similarly, one study found that breast cancer testing was less common among women in the Mississippi Delta region than among women nationwide, and Black women in the Delta reported testing rates that were markedly lower. H. Irene Hall et al., *Breast and*

²³ https://www.arc.gov/wp-content/uploads/2020/06/Health_Disparities_in_Appalachia_August_2017.pdf

Cervical Cancer Screening Among Mississippi Delta Women, 15 J. Health Care for Poor & Underserved 375, 378 (2004).

D. Members of underserved communities suffer from higher mortality rates and worse outcomes

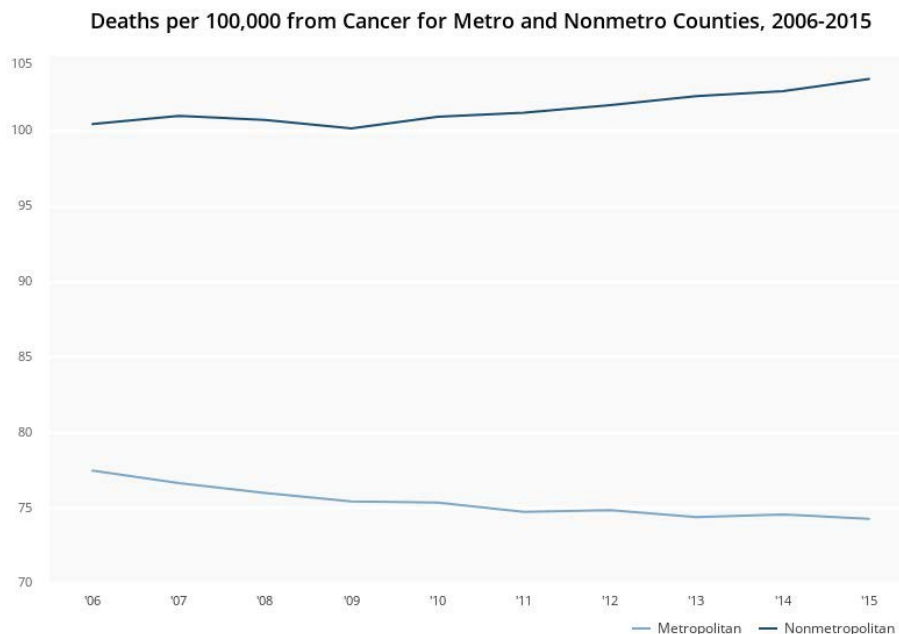
Reflecting these disparities in cancer testing, studies have consistently found that members of underserved communities have worse medical outcomes (and endure greater financial hardship) from cancer.

1. According to the American Association for Cancer Research, Black people have the “highest death rates ... of any racial/ethnic group ...for most cancers” and have the shortest survival rates in the country for most types of cancers. *Id.* at 1. “Black men have 6% higher cancer incidence but 19% higher cancer mortality than White men;” and “Black women have an 8% lower cancer incidence rate than White women, but 12% higher cancer mortality rate.” Am. Cancer Soc’y, *African American/Black People Facts & Figures*, *supra*, at 12. There are also disparities for specific cancers. For example, an NIH study found that Black men are twice as likely to die from prostate cancer as White men are. *See* Brandon A. Mahal et al., *Prostate Cancer-Specific Mortality Across Gleason Scores in Black vs Nonblack Men*, 320 JAMA 2480 (2018).

Studies have similarly found that cancer is the leading cause of death in the U.S. Hispanic population. *See* Am. Cancer Soc’y, *Hispanic/Latino People Facts & Figures*, *supra*, at 5. For example, the American Cancer

Society reports that Hispanic men and women are less likely to be diagnosed at early stages of cancer, when treatment is usually less intensive and more successful, with the largest gaps for melanoma and breast cancer. *Id.* at 9 (citing statistics from North American Association of Central Cancer Registries, 2021). While Hispanic Americans have lower mortality rates from cancer in general, they experience higher mortality rates from certain cancers, including liver, and stomach cancer. *Id.* at 14.

Last, as noted above, rural communities face added barriers to effective cancer screening. *See pp.12-13, supra.* The National Center for Health Statistics in turn has found that members of rural communities have substantially higher death rates than do individuals in urban settings.²⁴

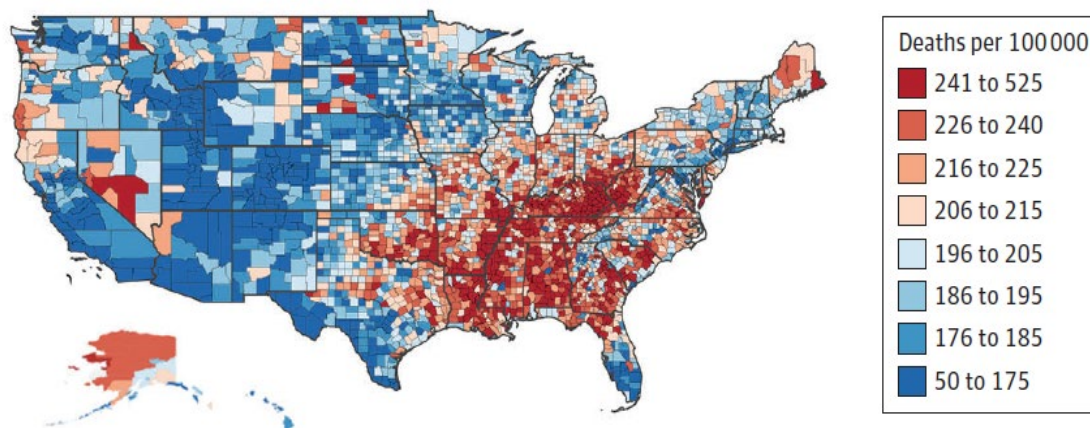


Source: National Center for Health Statistics, 2006-2015.

²⁴ <https://www.ruralhealthinfo.org/charts/46>

Those disparities are particularly stark in states and counties within the Fifth Circuit’s jurisdiction—in particular in the Mississippi delta.²⁵

A Rates of cancer deaths



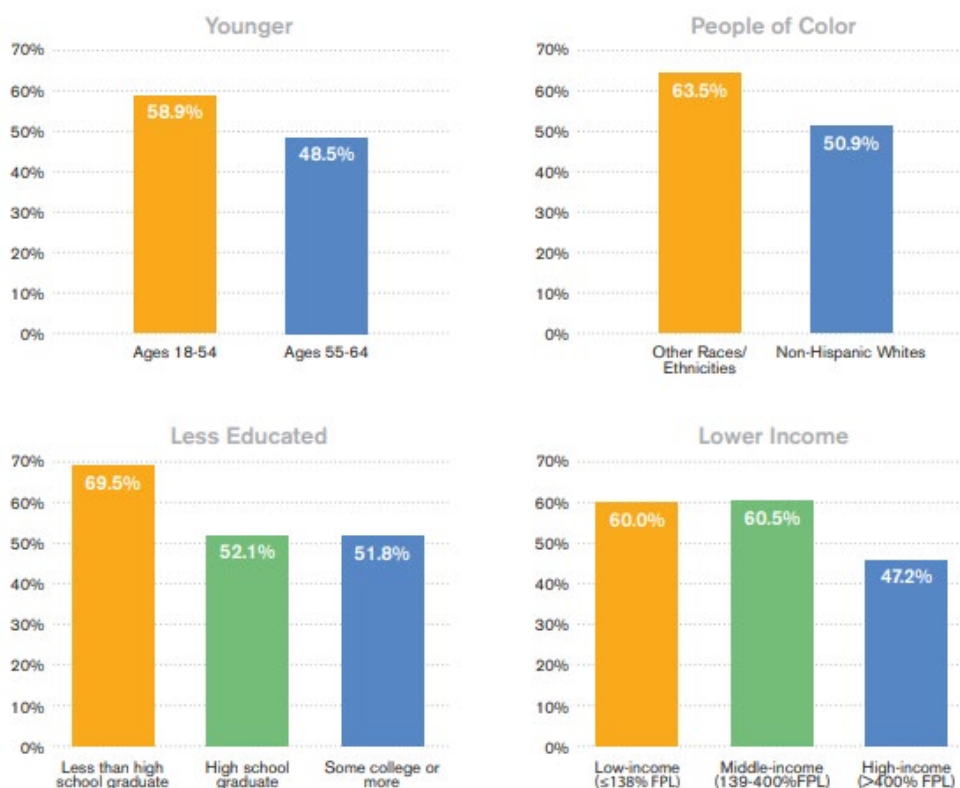
2. Studies also show that underprivileged individuals experience more severe illness and suffering from cancer—often because of late-stage diagnosis or disparities in treatment. For example, while many patients experience chronic pain after cancer treatments, studies have found that Black patients are less likely to have pain assessed or managed when compared to White patients, and often experience delays in treatment. See Kelly M. Hoffman et al., *Racial Bias in Pain Assessment and Treatment*

²⁵ Jeremy M. O'Connor et al., *Factors Associated With Cancer Disparities Among Low, Medium, and High-Income US Counties*, 1(6) JAMA Network Open, Oct. 2018, at 4, <https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2705856>.

Recommendations, and False Beliefs about Biological Differences between Blacks and Whites, 113(16) Proc. Nat'l Acad. Scis. 4296 (2016).²⁶

3. In addition to disparities in mortality rate and treatment, studies show that late-stage diagnoses are more likely to cause financial hardship for members of underserved communities. See Am. Cancer Soc'y, *Costs of Cancer, supra*, at 4 (financial hardships of cancer “do not impact all cancer

Cancer patients are more likely to experience financial hardship if they are:



% of Individuals with a History of Cancer Reporting at least 1 Type of Financial Hardship, Ages 18-64

*FPL = Federal Poverty Level
 Source: Han X, Zhao J, Zheng Z, de Moor JS, Virgo KS, Yabroff KR. Medical Financial Hardship Intensity and Financial Sacrifice Associated with Cancer in the United States. *Cancer Epidemiol Biomarkers Prev.* 2020;29(2):308-317. doi:10.1158/1055-9965.EPI-19-0460
 Note that similar patterns of disparities exist in the over-65 population.

²⁶ <https://www.pnas.org/doi/epdf/10.1073/pnas.1516047113>.

patients equally”). Race, education level, and income all have an impact on financial outcomes for cancer patients and their families. *Id.*

One reason is that workers in lower-wage jobs have less paid leave and employer flexibility, meaning they are less likely to retain jobs during periods of illness or treatment. *Id.* at 4, 41-42. The American Association for Cancer Research reports that “medically underserved groups including racial and ethnic minorities, those who live in rural areas, and/or those who are elderly are at a higher risk of experiencing financial toxicity as a result of a cancer diagnosis.” Am. Ass’n for Cancer Rsch., *supra*, at 122. Compared to 44.5 percent of Whites, 68 percent of African Americans and 58 percent of Hispanics reported experiencing financial hardships one year after cancer diagnosis. *Id.* And, “[a]mong rural populations, such as those residing in the Appalachian region of the eastern United States, two thirds of cancer survivors reported financial distress.” *Id.*

II. The Merger Can Improve Care And Significantly Reduce Cancer Inequality By Reducing Barriers To Screening

Widespread availability of the Galleri test would be a game-changer. That test is poised to dramatically improve cancer screening and care for members of underserved communities—and to reduce longstanding barriers and gaps. In particular, by combining multiple tests in a single non-intrusive blood draw that is easily administered, Galleri would eliminate

many of the barriers that prevent members of underserved communities from screening regularly.

A. Access to Galleri is currently limited to the economic elite

At the moment, Galleri is available only to the select few. Because it lacks FDA approval, it is not yet covered by Medicare, Medicaid, or most private insurers. IDF ¶¶ 169, 177, 258. The test costs about \$950 out of pocket and, at the time of the agency hearing, Grail had sold only about three thousand tests. IDF ¶¶ 55-56. As a practical matter, only wealthy patients currently use Galleri, often through concierge medicine practices, where they already pay substantial premiums for preventative tests. IDF ¶¶ 53-54. Thus, despite this scientific break-through, underserved communities cannot currently enjoy Galleri's benefits. Indeed, without Galleri, many people—and especially those in underserved groups—are not testing for cancers at all.

B. Widespread availability of the Galleri test would reduce inequality in cancer screening and outcomes

1. Once the Galleri test becomes FDA approved, however, access would increase dramatically: FDA approval would allow Galleri to obtain payor coverage and, in turn, be distributed in larger volume and at lower costs. Op. 12. Expert testimony shows that, with just a one-year acceleration in FDA approval and payor coverage—which would result from the merger—an additional 10 million tests would be performed in the U.S.

over a nine-year period (2022-2030). PFF ¶ 1123.2. That would cause a reduction of between 7,429 and 10,441 deaths in the United States. *Id.*

Based on their diverse expertise, and having reviewed the evidence from the evidentiary hearing, *amici* submit that such widespread use of the Galleri test would significantly improve cancer treatment and care for the underprivileged—and significantly reduce healthcare inequality in the process. Securing payor reimbursement is the fastest way to make Galleri cost-accessible and available for all.

First, a person could get tested when seeing their primary care physician for a routine exam. ID 146. This would greatly reduce the need for patients to see multiple specialists, just for initial testing. That means less time waiting for appointments and fewer follow-ups with specialists who are hard to find and book. *See* pp.8-9, 12-14, *supra*. Overall, there would be less need for travel and transportation. *Ibid.* Geographic barriers to cancer screening would be less of a problem, particularly in rural areas, where oncologists and other specialists are in short supply. *Ibid.*

Economic burdens would also be reduced. In addition to a reduction in transportation costs, there would be fewer co-pays and co-insurance costs. Patients would not have to worry as much about unexpected costs or expensive out-of-coverage procedures, as the Galleri screening would streamline follow-up care and testing. There would also less need to take

time off work—which can be especially difficult for working-class people, and can put them at risk of losing a job.

Likewise, doctors could more easily communicate, recommend, and administer screening. Rather than setting the patient down a lengthy and confusing path of multiple calls and appointments—a particular problem for non-native English speakers and immigrants, *see p.15, supra*—a doctor could make the test part of a routine checkup. And with test results, primary-care doctors will be in a better position to explain the need for follow-up and to direct their patients to the appropriate specialist. Patients will be less likely to get lost in the shuffle of multiple referrals and miscommunications, as in the case of the 60-year old Black woman in Chicago, described above. *See p.19, supra*.

There would also be less need for invasive or embarrassing procedures at the screening stage. *See pp.9-10, supra*. Indeed, the Commission itself accepted that people are more comfortable with blood draws than with other forms of cancer screening. Op. 3. Accordingly, if Galleri were distributed widely and were more affordable, screening rates would rise significantly for all groups, and fewer individuals would forego initial testing because of fear or anxiety.

Most importantly, a single blood draw would test for dozens of cancers *at once*. That alone would reduce barriers and gaps to screening, as the

current need to screen one cancer at a time means that the cumulative burdens are multiplied. With Galleri, it would all start with just a single test. And with the information from that test, the patient's primary care doctor could make much more tailored recommendations for follow-up screening or other courses of action, thereby simplifying and streamlining a complicated, expensive, and time-consuming process.

2. Unsurprisingly, studies have found that when medical tests and treatment become more widely available and easier to administer or access, the socioeconomic and racial gaps in healthcare can shrink.

In 2006, for example, a managed care consortium started a population-based colorectal cancer screening. *See* Chyke A. Doubeni et al., *Association between Improved Colorectal Screening and Racial Disparities*, 386 N. Engl. J. Med. 796 (2022). The program involved mailing at-home screening tests to various groups annually and allowing eligible individuals to obtain a colonoscopy during the course of the program. *Id.* The results are the rate of participants who are up-to-date on screening doubled for both White and Black recipients, at almost exactly the same clip. Colorectal cancer mortality among the two groups dropped. *Id.* And the disparity between the two groups was eliminated almost entirely—dropping from a difference of 21.6 cases per 100,000 people to only 1.6 cases. *Id.*; *see also, e.g.*, Christina A. Clarke et al., *Racial/Ethnic Differences in Cancer*

Diagnosed after Metastasis: Absolute Burden and Deaths Potentially Avoidable through Earlier Detection, 31 *Cancer Epidemiol Biomarkers Prev.* 521 (2022) (“[N]on-Hispanic Black males have the highest burden of stage IV cancer and would have the most deaths averted from improved detection of cancer before metastasis.”).

Widespread availability of the Galleri test would enable similar improvements in patient care and outcomes—and a similar reduction in gaps and inequalities—to potentially happen across the board, for dozens of cancers, all at once.

3. Finally, the Galleri test continues to improve with each iteration, in part because scientists have a larger set of genome data, and can make testing more accurate, as the volume of testing grows. RFF ¶ 1170.2; Tr. 2375-76. It is critical for this testing data to include the full spectrum of races and ethnicities. Otherwise, the test will be finely-tuned to detect cancers in certain groups but not others, potentially exacerbating health inequality.

III. The FTC Erroneously Discounted The Efficiencies Of The Merger And Missed The Broader Implications For Healthcare Equality And The Economy

At the hearing, Petitioners offered copious evidence of efficiencies that could be gained from the merger, including many lives saved in the near future. RFF ¶ 1106. Illumina brings significant regulatory experience and

a large team with knowledge of the FDA's processes. The unrebutted evidence shows the merger will hasten FDA approval and, in turn, accelerate payor coverage that is needed for widespread adoption. RFF ¶¶ 1121.10, 1326-34.

Complaint Counsel did not refute that evidence or rebut Petitioners' expert testimony. RFF ¶ 1175.4. Instead, the Commission labeled Petitioners' evidence "vague" and "self-serving," and claimed Petitioners did not sufficiently "quantify" the benefits. Op. 75, 77. And, ultimately, it assumed—based on abstract economic theory—that the merger *might* harm competition at some unidentified point in the future, *e.g.*, Op. 57-58—notwithstanding Illumina's Open Offer in which it committed to maintaining open access for its oncology customers for 12 years. IDF ¶¶ 888, 896-901.

The Commission's focus on what might happen in the distant future (notwithstanding that commitment) is no answer to members of underserved communities who need improved access to screening right now—and who would be able to get that testing today if Galleri were FDA approval and payor reimbursed. The Galleri test is currently available, just not for everyone. The faster the Galleri test can get to widespread market adoption, the better for all. The unrebutted evidence shows that the Illumina-Grail merger is the fastest way to make that happen. The Commission's Order will only hinder that outcome and its many economic benefits.

Courts have recognized that “[i]n the real world,” healthcare providers are “in the business of saving lives,” and that economic efficiency is often key to that mission. *See FTC v. Butterworth Health Corp.*, 946 F. Supp. 1285, 1302 (W.D. Mich. 1996), *aff’d*, 121 F.3d 708 (6th Cir. 1997); *United States v. Long Island Jewish Med. Ctr.*, 983 F. Supp. 121, 149 (E.D.N.Y. 1997) (cost savings from a hospital merger would be used “to fulfill [the defendants’] mission to provide high quality health care to economically disadvantaged and elderly members of the community”). Petitioners are no different. These companies have been working rigorously for years, and invested hundreds of millions of dollars, to get this remarkable test to market. The merger would make that test more widely available and at a lower cost. RFF ¶¶ 77.6, 1767.

Ultimately, the Commission’s focus on hypothetical conduct in the distant future loses sight of the forest for the trees. Diagnosing cancer at earlier stages will lead to benefits for the entire health system and economy. Treatment becomes much more complicated—and costly—after cancer has progressed. If cancer is diagnosed early, doctors can treat patients more effectively with less, and they are more likely to prevent expensive hospitalizations. Op. 2; *supra* § I. Making Galleri accessible and available on a large scale sooner, will accelerate cost savings for the entire health system. It will save lives and keep people healthy, active, and working for

years to come. And it will do so while knocking down longstanding and pervasive barriers to equal medical care for all.

CONCLUSION

For these reasons, the Court should hold unlawful and set aside the Commission's order.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

The undersigned counsel of record certifies pursuant to Fed. R. App. P. 32(g) that the Brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B)(i) because, excluding the parts of the Brief exempted by Fed. R. App. P. 32(f), this document contains 6,385 words.

This document complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type-style requirements of Fed. R. App. 32(a)(6) because this document has been prepared in a proportionally spaced typeface using Century Schoolbook font in 14 point size.

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CERTIFICATE OF SERVICE

I hereby certify that on June 12, 2023, I electronically filed the foregoing with the Clerk of the Court using the ECF system, which will send notification of such filing to all ECF participants.

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