

**No. 23-60167**

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IN THE  
United States Court of Appeals  
FOR THE FIFTH CIRCUIT

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ILLUMINA, INC. AND GRAIL, INC.,

*Petitioners,*

v.

FEDERAL TRADE COMMISSION,

*Respondent.*

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PETITION FOR REVIEW OF  
AN ORDER OF THE FEDERAL TRADE COMMISSION

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**BRIEF OF AMICI CURIAE  
MILITARY ORDER OF THE PURPLE HEART AND  
THE NATIONAL TRAUMA EDUCATION AND POLICY INSTITUTE  
IN SUPPORT OF PETITIONERS**

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**CERTIFICATE OF INTERESTED PERSONS**

*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 5th CIR. 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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The Military Order of the Purple Heart is a congressionally chartered United States war veterans organization headquartered in the District of Columbia. The Order has no parent corporation, and no publicly held company has 10% or greater ownership in the Order.

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**STATEMENT OF COMPLIANCE WITH  
FEDERAL RULE OF APPELLATE PROCEDURE 29**

All parties have consented to the filing of this brief. No counsel for a party authored any part of this brief. No party, party's counsel or any person other than the amici curiae or their counsel contributed money that was intended to finance the preparation or submission of this brief.

### **INTEREST OF AMICI CURIAE**

In 1782, then-General George Washington ordered the creation of a new military award. Fashioned in “the figure of a heart in purple cloth, or silk,” it was to be awarded to those who exhibited “unusual gallantry” in the field or rendered “extraordinary fidelity and essential service” to their country. U.S. Department of Veterans Affairs, *Celebrating America’s Freedoms: The Purple Heart*, <http://bit.ly/3JatlnI> (last accessed June 10, 2023) (quoting Washington’s 1782 order). After the Revolutionary War ended, the award fell into disuse for 150 years. Then, in 1932, President Franklin D. Roosevelt revived it. He ordered that the military bestow it upon those wounded or killed in combat. *Id.*

The Military Order of the Purple Heart was formed the same year that President Roosevelt revived the award. *Id.* Today, it is congressionally chartered. *See* 36 U.S.C. §140501 *et seq.* By statute, all members of the Order must have received the decoration, making it the only veteran service organization composed entirely of combat veterans. *Id.* §140503. The Order exists to protect the interests of all combat-wounded veterans by, among other things, “assisting, comforting, and aiding all needy and distressed members and their dependents” and “giving needed hospital and service work through its Department of Veterans Affairs certified service officers.” *Id.* §140502(b)(4), (5); *see also* The Military Order of the Purple

Heart, *About: The Purple Heart*, <http://bit.ly/3NmWxuo> (last accessed June 10, 2023).

The Order's interest in the Illumina-Grail vertical merger stems from the fact that tens of thousands of veterans, including many who have received the Purple Heart, are diagnosed with cancer every year. Their diagnoses often come too late for effective treatment. Grail's product, Galleri, promises to provide a non-invasive test for a host of the cancers from which these veterans suffer. And Illumina produces the inputs that the Galleri test uses. Their merger would speed up the widespread production, distribution, and use of the Galleri test. Once widely available, the test will help diagnose cancer in veterans early, saving or improving their lives. The Order thus has an interest in seeing Galleri sped to market because it will "assist[], comfort[], and aid[]" many "needy and distressed" veterans. *Id.*

The National Trauma Education and Policy Institute too has an interest in this case. Among other things, the Institute seeks to influence and improve how U.S. communities identify and treat trauma of all types, including the trauma suffered by veterans afflicted with cancer. *See* Empowerment Behavioral Services, *National Trauma Education and Policy Institute*, <https://bit.ly/461ZHv0> (last accessed June 10, 2023). Like the Order, the Institute expects that the Illumina-Grail vertical merger will speed up the widespread distribution and use of Galleri, which will help reduce the harm that cancer inflicts on the veteran community.

## **INTRODUCTION AND SUMMARY OF ARGUMENT**

The Illumina-Grail merger would significantly improve the lives of this Nation’s veterans, who disproportionately suffer from cancer and thus would acutely benefit from the early screening test that this merger would speed to market.

The merger would vertically integrate a producer of blood-based cancer tests with the company that supplies the inputs for the tests. Unlike horizontal mergers, which can in certain circumstances risk concentrating market power in few participants, vertical mergers typically benefit consumers. They “encourage product innovation, lower costs for businesses, and create efficiencies—and thus reduce prices and lead to better goods and services for consumers.” *Comcast Cable Commc’ns, LLC v. FCC*, 717 F.3d 982, 990 (D.C. Cir. 2013) (Kavanaugh, J., concurring). Consumers then enjoy cheaper, better products and services. *Id.*

The Illumina-Grail vertical merger would yield precisely those beneficial results. Illumina “is a global leader in next-generation sequencing (‘NGS’).” *Illumina Br.* at 5.<sup>1</sup> Grail makes a blood test, called Galleri, that uses NGS technology to “detect more than 50 cancer types in asymptomatic patients from a single blood draw.” *Id.* at 6. As Petitioners explain, the merger would spur innovation and reduce costs by enabling Galleri to be brought to market more efficiently. *See, e.g., id.* at 7–

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<sup>1</sup> Amici cites Petitioners’ brief filed on June 5, 2023. As of the time of this filing, Petitioners have not filed a subsequent brief.

8, 70–71. And that will accelerate Galleri’s widespread availability—which will save countless lives.

Veterans in particular stand to benefit. Military service calls on those who serve to hazard many dangers. Some of those dangers are familiar and tangible, such as those faced in combat. But other dangers are subtle and insidious. Millions of veterans answered the call to duty by serving in locales or aboard platforms rife with carcinogens. Today, those veterans face significantly higher cancer risks than their civilian peers, and they rely on the United States Department of Veterans Affairs (“VA”) to help them detect and then combat those cancers. But the VA’s resources are limited, and many cancers are difficult to detect until it is too late. By speeding Galleri to market, the Illumina-Grail merger promises both to help mitigate cancer risks through early detection and treatment *and* to save the VA resources that it could then use to improve veteran medical care generally.

## ARGUMENT

### **I. The Illumina-Grail Vertical Merger Will Save Veterans' Lives.**

#### **A. Veterans Face a Higher Rate of Cancer than Their Civilian Counterparts.**

Statistics show that cancer strikes veterans harder than their peers. For example, studies have shown breast cancer rates are 20% to 40% higher among veterans than among the general population. *See* Kangmin Zhu et al., *Cancer Incidence in the U.S. Military Population: Comparison with Rates from the SEER Program*, 18 *CANCER EPIDEMIOLOG. BIOMARKERS PREV.* 1740 (2009). Veteran prostate cancer rates have been found to be double those in the general population, with an estimated 1 in 5 male veterans expected to suffer from prostate cancer in their lifetime. *Id.*; *see also* News Release, *H.R. 6092, 116th Cong., Veterans Prostate Cancer Treatment and Research Act* (2020), H. Comm. on Veterans' Affairs, <https://bit.ly/3qALF34>. Overall, approximately 50,000 veterans are diagnosed with cancer every year. Department of Veterans Affairs, *Spotlight on Cancer Research* (Oct. 2021), <http://bit.ly/3Noy5Zz> (hereinafter "VA *Spotlight on Cancer Research*").

Veterans face these heightened cancer risks *because* they answered the call to safeguard our liberties wherever and whenever necessary. Often, their duties took them to inhospitable environments. Infantrymen advancing across burning Middle Eastern deserts, crewmen strapped to jumpseats of heavy-lift aircraft, and enginemen

sweating in the bowels of a ship's main space all endured heat, cold, fatigue, and extreme discomfort. And, too often, they endured exposure to hazards that permeated the environments in which they served.

As one example, consider the land force's exposure to Agent Orange during the Vietnam conflict. During that conflict, U.S. aircraft drenched the Vietnamese jungles in the defoliant Agent Orange to deprive enemy soldiers of cover. U.S. servicemembers inhaled it alongside their enemy. Today, the VA recognizes an association between exposure to Agent Orange and an increased risk of developing various types of cancer, including non-Hodgkin lymphoma, soft tissue sarcomas, and certain respiratory cancers. Department of Veterans Affairs, *Veterans' Diseases Associated with Agent Orange*, <http://bit.ly/43UYKm9> (last accessed June 3, 2023).

For another example, consider the air service's exposure to military chemicals. A comprehensive yearlong study conducted by the Pentagon examined 900,000 service members who either flew on or worked with military aircraft between 1992 and 2017. Department of Defense, *Study on the Incidence of Cancer Diagnosis and Mortality among Military Aviators and Aviation Support Personnel* (Feb. 8, 2023), <http://bit.ly/3p2v6fS>. The findings revealed that aircrew members experienced an 87% higher rate of melanoma and a 39% higher rate of thyroid cancer. Further, within this study, men exhibited a 16% higher rate of prostate cancer, while women showed a 16% higher rate of breast cancer. Overall, the study



concluded that veterans who served as aircrew members experienced a 24% increase in cancer diagnoses. *Id.* at 4, 16.

For a third example, take the sea service's exposure to asbestos. Navy ships employed asbestos to mitigate fire risks. *See* Mesothelioma Veterans Center, Asbestos on Frigates, <http://bit.ly/3N22j3g> (last accessed June 6, 2023). Studies link asbestos to higher cancer death rates among machinist's mates, boiler technicians, pipe fitters, and other ratings who worked in spaces containing asbestos. *See* John E. Till et al., *Asbestos Exposure and Mesothelioma Mortality among Atomic Veterans*, 98 INT'L J. RADIATION BIOLOGY 1 (Sept. 2018).

**B. By Enhancing Early Detection, Galleri Promises to Prolong and Improve Veterans' Lives.**

Needless to say, the "earlier a cancer is diagnosed, the better the outcome" for the cancer patient. *See* Courtney Franchio, *Cancer Screenings Save Lives*, VA News (Oct. 27, 2021), <http://bit.ly/3J8C2Px> (last accessed June 4, 2023). More patients live longer when doctors identify a cancer at an early, localized stage rather than at a later, regional/metastatic stage. *See* David Crosby et al., *Early Detection of Cancer*, 375 SCIENCE 1244 (Mar. 2022), available at <https://bit.ly/3CkZ41X>; *see also* Girish Putcha G. et al., *Multicancer Screening: One Size Does Not Fit All*, 5 JCO PRECIS. ONCOL. 574 (Nov. 2021). Unfortunately, for many cancers, physicians lack the tools to detect those diseases early. Thus, veterans, who

disproportionately suffer from cancer, stand to disproportionately benefit from advances in cancer detection tools.

As a result, the Galleri test promises to be a game-changer for veterans. As explained in Illumina's brief, Galleri would provide a non-invasive means to detect over 50 types of cancer early on, using a simple blood test. *See* Illumina Br. at 6. Those would include the cancers that often strike veterans, including non-Hodgkin lymphoma, melanoma, prostate cancer, and breast cancer. *See* Galleri, *Types of Cancer Detected*, <http://bit.ly/3X5W7M3> (last accessed June 7, 2023). While the VA cannot reverse the service-related exposures that cause veterans to suffer disproportionately from cancer, a test like Galleri could revolutionize how the VA catches and treats it.

Moreover, the very existence of an early detection test like Galleri would improve the lives of many veterans. In addition to the myriad cancers that arise from their service, veterans often suffer from mental health issues. If a veteran's cancer is caught early, physicians have time to integrate mental health and cancer care into a holistic care plan. Researchers have shown that doing so elevates patients' psychological well-being and overall satisfaction with care, potentially improving their overall prospect of achieving remission and returning to a normal life. *See* Hermann Faller et al., *Effects of Psycho-Oncologic Interventions on Emotional*

*Distress and Quality of Life in Adult Patients with Cancer: Systematic Review and Meta-Analysis*, 31 J. CLIN. ONCOL. 782 (Feb. 2013).

And the data collected from the early and widespread use of a test like Galleri could itself have a direct salutary effect on veterans. Psychiatrists and neuroscientists have recognized that it matters what a patient believes about a diagnosis and accompanying treatment. A patient is less likely to comply with cancer treatment requirements if he or she does not understand the illness's cause, the treatment's effects, or their connection. Leslie R. Martin et al., *The Challenge of Patient Adherence*, 1 THERAPEUTICS AND CLINICAL RISK MGMT. 189 (Oct. 2005). Access to the multi-cancer early detection tests—along with the better association between exposure and illness gleaned from widespread usage—can provide medical professionals with data needed to connect an illness to service, teach the veteran about that connection, and encourage the veteran to stick with proven treatments.

Comprehensive early screening would enhance the overall health and well-being of not only veterans, but their families as well. A cancer diagnosis can also have a devastating impact on the quality of life for those who live and care for the patient. *See, e.g.*, Patrick Richard et al., *The Financial Burden of Cancer on Families in the United States*, 18 INT'L J ENV'T'L RES. PUBLIC HEALTH 3790 (Apr. 2021). Early detection would promote positive treatment outcomes and minimize the financial, physical, and emotional toll on veterans and their loved ones.

Finally, Galleri tests would facilitate a veteran's return to work. Cancer levies a heavy toll on the U.S. economy by removing people from the workforce or, if they stay on the job, reducing their productivity. *See* K. Robin Yabroff et al., *Economic Burden of Cancer in the U.S.: Estimates, Projections, and Future Research*, 20 *CANCER EPIDEMIOLOG. BIOMARKERS & PREV.* 2006, 2008 (Oct. 2011). And it levies a heavy toll on individuals who derived a livelihood and sense of purpose from their work. Veterans are no exception. With multi-cancer early screening tests like Galleri, doctors would have a better chance of detecting cancer early, optimizing treatment outcomes, and minimizing the impact on veterans' ability to work, thus enhancing the overall quality of life for afflicted veterans. *See* Erika L. Sabbath et al., *Preventive Care Utilization: Association with Individual- and Workgroup-Level Policy and Practice Perceptions*, 111 *PREV. MED.* 235 (June 2018).

## **II. The Illumina-Grail Vertical Merger Will Improve the Department of Veterans Affairs' Overall Effectiveness.**

The benefits of Illumina-Grail merger will also improve the overall effectiveness of the VA by speeding the introduction of Galleri. Once in widespread use, this cancer-testing tool promises to improve the VA's ability to care for veterans, reduce costs, and further other VA policy goals.

**A. Access to the Galleri Test Will Improve the VA’s Ability to Care for Veterans.**

Early cancer screening would enable the VA to provide more and better care to veterans. Cancer treatment can be incredibly expensive—especially when detected at a later stage. The Agency for Healthcare Research and Quality’s Medical Expenditure Panel Survey estimates that, for 2019, the direct medical costs for cancer in the United States were \$172.1 billion. Agency for Healthcare Research and Quality. Agency for Healthcare Research and Quality, *Medical Expenditure Panel Survey (MEPS) Household Component (HC)*, available at <http://bit.ly/3qKCzRa>. And experts expect those costs to reach more than \$240 billion by 2030. Angela B. Mariotto et al., *Medical Care Costs Associated with Cancer Survivorship in the United States*, 29 *CANCER EPIDEMIOLOG. BIOMARKERS & PREV.* 1304 (July 2020).

The Veterans Health Administration operates the largest integrated healthcare system in the United States, serving more than 9 million veterans annually. Jerry SH Lee et al., *From Discovery to Practice and Survivorship: Building a National Real-World Data Learning Healthcare Framework for Military and Veteran Cancer Patients*, 6 *CLIN. PHARMACOL. THER.* 52 (Jul. 2019). Unsurprisingly, it is often overstretched. See, e.g., Dave Philipps, *For Suicidal Veterans, a Frayed Lifeline*, *N.Y. TIMES* (July 17, 2016), <https://nyti.ms/3J9k13L>.

The heavy cost of cancer care does not help. With 50,000 new diagnoses per year, cancer care absorbs a particularly significant portion VA resources. *See also, e.g.,* News Release, Department of Veterans Affairs, Secretary McDonough Statement on FY 2023 Budget (Mar. 28, 2022), <http://bit.ly/42uNk7y> (noting that the fiscal year 2023 budget included \$167 million in funds just for precision oncology). A rapid cancer screening test like Galleri would reduce the demand for intensive late-stage care among veterans, which would alleviate strain on the VA. VA hospitals and clinics could then provide more efficient and effective care for all veterans, enhancing the overall healthcare system for all those who have served our country.

Early cancer detection also leads to less emergency care. Emergency care is costly and often less effective than preventive care and early intervention. Increased access to preventive care services might prevent a significant proportion of emergency department visits by cancer patients. *See, e.g.,* Ady Oster & Andrew B. Bindman, *Emergency Department Visits for Ambulatory Care Sensitive Conditions: Insights into Preventable Hospitalizations*, 41 MED. CARE 198 (Feb. 2003). Indeed, a recent study identified 51.6% of emergency visits among patients with cancer as potentially preventable. Amir A. Tabriz A et al., *Trends and Characteristics of Potentially Preventable Emergency Department Visits Among Patients With Cancer in the US*, 6 JAMA NETW. OPEN e2250423 (Jan. 2023). By accelerating access to

multi-cancer screening tests, physicians could detect cancer earlier and reduce the need for emergency care later, helping to alleviate the strain on VA hospitals and clinics.

And early detection can help head off long-term disabilities that also result in significant additional costs. The VA pays disability compensation to veterans. The costs of that compensation have ballooned over the last several decades. *See* Presentation at the Military Manpower Round table by David Mosher, *Trends in DoD's and VA's Budgets for Military Compensation* (Mar. 22, 2023, Cong. Budget Office), *available at* <http://bit.ly/3P7Wxzt> (noting a 300% increase since 2000). Treating cancer early can help physicians address cancers before they progress far enough to cause permanent disability requiring long-term disability compensation. This not only bolsters the quality of life for veterans but also decreases the financial burden on the VA and the American taxpayer.

In addition, early cancer screening would enable the VA to focus more of its limited resources on studying and caring for cancer-stricken veteran populations. The VA has a unique role in providing healthcare to millions of veterans across the United States. As discussed above, veterans have a higher risk of developing several types of cancer, including lung, prostate, and breast cancers, compared to the general population. *See supra* I.A. Accelerating its access to the Galleri multi-cancer screening test would enable the VA to track and respond to emerging cancer trends

among the veteran population much earlier than it can now, improving health outcomes.

In particular, access to multi-cancer early screening tests would enhance the VA's ability to monitor and evaluate the effectiveness of the cancer care it provides to veterans. Clinical trials offer patients access to innovative treatments that may not yet be widely available. *See generally* National Cancer Inst., *Clinical Trials Information for Patients and Caregivers*, <http://bit.ly/3PfTvt0> (last accessed June 3, 2023). Providing veterans with early-stage cancer screening would identify cancers early enough to enable timely access to these trials, granting veterans the opportunity to benefit from the latest advances in cancer care. This access could be particularly important for veterans with rare or aggressive cancers, for whom standard treatments may be less effective.

This is no mere theoretical benefit. A study published in *Seminars in Oncology* journal found that over 90% of veterans diagnosed with cancer indicated they would take part in clinical trials, especially because they knew that their participation could help improve cancer care for fellow veterans. Grace C. Hillyer et al., *Positive Attitudes Toward Clinical Trials Among Military Veterans Leaves Unanswered Questions About Poor Trial Accrual*, 48 *SEMIN. ONCOL.* 130 (May 2021). By collecting data on cancer detection rates, treatment outcomes, and patient satisfaction, the VA can identify areas for improvement and implement evidence-



based strategies to enhance the quality of care. The Galleri multi-cancer screening test would thus enable the VA to collect valuable data to inform and fortify cancer care for veterans.

**B. Access to the Galleri Test Will Further VA Policy Goals.**

The rapid development, approval, and widespread distribution of the Galleri test would also be consistent with the VA's congressionally directed mission. Congress has made significant strides in recent years to restore the quality of care for veterans, including by passing the VA Maintaining Internal Systems and Strengthening Integrated Outside Networks (MISSION) Act of 2018 and the Veterans Appeals Improvement and Modernization Act of 2017. *See generally* Department of Veterans Affairs, *VA MISSION Act: What is the Latest on Community Care?* (Apr. 2019), <https://bit.ly/43zToNg>; Department of Veterans Affairs, Veterans Benefits Administration Reports, *Appeals Modernization Act Comprehensive Plan and Reporting*, <https://bit.ly/3oVSk7B> (last accessed June 3, 2023). And, through the recently enacted "Honoring Our PACT Act," Congress has sought to address the carcinogenic effects of exposure to environmental hazards. *See generally* Honoring Our PACT Act of 2022, Pub. L. No. 117-168, 136 Stat. 1789 (2022) [hereinafter PACT Act].

In particular, accelerating access to the Galleri test would serve the PACT Act's goal of improving healthcare for veterans. *See, e.g.*, PACT Act §§ 103, 604,

704, 902. This is especially true for veterans who were exposed to known cancer risks. See, e.g., National Academies of Sciences, Engineering, and Medicine, Committee to Review the Health Effect in Vietnam Veterans of Exposure to Herbicides, A Consensus Study Report, *Veterans and Agent Orange: Update 11 (2018)* (2018), <http://bit.ly/3N30dAb>. Accelerating access to the Galleri test would also further the VA's role in cancer research and the development of new treatments and technologies. See Lee et al., *supra*; see also Department of Veterans Affairs, *VA Research on Cancer*, <http://bit.ly/3X3Ckgn> (last accessed June 3, 2023) (describing past efforts). And enhanced cancer screening would help boost mental health outcomes by either providing peace of mind that a veteran is healthy (despite exposure) or, in the event of illness, by enabling life-saving early cancer care.

Finally, accelerating access to the Galleri early screening test would also increase trust in the VA—which could lead to a virtuous cycle of veterans taking advantage of early cancer screening. The VA has long suffered from a reputational crisis. It has faced criticism in the past for long wait times and inadequate care. VA access to the Galleri screening test would demonstrate a commitment to improving healthcare services for veterans, thereby enhancing the VA's reputation and public trust. A study published in the *American Journal of Public Health* found that trust in one's personal physician is associated with utilization of preventive health services. Donald Musa et al., *Trust in the Health Care System and the Use of*

*Preventive Health Services by Older Black and White Adults*, 99 AM. J. PUB. HEALTH 1293 (July 2009). Indeed, a strong relationship between veterans and the VA is essential for encouraging veterans to trust and utilize the VA's resources—which, if this merger is successful, would include the groundbreaking cancer screening that the Galleri test would provide.

\* \* \*

As a Nation, we have a moral obligation to provide the best possible care for our veterans—especially those who served in extreme environments contaminated with carcinogens. The Galleri test offers enormous promise for these heroes, potentially saving many thousands by identifying cancers at the earliest stages possible. And the Illumina-Grail vertical merger promises in turn to speed the test along toward approval and widespread distribution. The resulting access to these tests would strengthen the VA healthcare system, enhance resource management, strengthen the relationship between veterans and the VA, and fuel research, innovation, and technology in cancer care. These very real efficiencies far outweigh the FTC's unsupported competitive concerns. This Court should accordingly reverse the FTC's order.

**CONCLUSION**

For the foregoing reasons, the Military Order of the Purple Heart and the National Trauma Education and Policy Institute respectfully request that this Court reverse the Commission's decision and render judgment for Illumina and Grail.

Respectfully Submitted,

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I hereby certify that on June 12, 2023, I caused the foregoing *amici curiae* brief to be filed with the Clerk of the Court for the United States Court of Appeals for the Fifth Circuit. The Court's CM/ECF system was used to file the brief. All attorneys in this case are registered CM/ECF users and service will therefore be accomplished by the CM/ECF system.

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