

IN THE
Supreme Court of the United States

ROBERT F. KENNEDY, JR., SECRETARY
OF HEALTH AND HUMAN SERVICES, ET AL.,
Petitioners,

v.

BRAIDWOOD MANAGEMENT, INC., ET AL.,
Respondents.

**On Writ of Certiorari
to the United States Court of Appeals
for the Fifth Circuit**

**BRIEF OF THE SUSAN G. KOMEN
BREAST CANCER FOUNDATION, INC.
AS *AMICUS CURIAE*
IN SUPPORT OF PETITIONERS**

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INTEREST OF *AMICUS CURIAE*¹

The Susan G. Komen Breast Cancer Foundation, Inc. (“Komen”) is the world’s leading nonprofit breast cancer organization. Komen advocates on behalf of the millions of people who have been diagnosed with breast cancer, including more than 319,000 people in the United States who will be diagnosed with breast cancer and nearly 43,000 who are expected to die from the disease in 2025 alone.

Komen’s mission is to save lives by meeting the most critical needs in communities and investing in breakthrough research to prevent and cure breast cancer. To that end, Komen has an unmatched, comprehensive 360-degree approach to fighting breast cancer across all fronts, including by (1) advocating for patients; (2) driving research breakthroughs; (3) improving access to high-quality care; (4) offering direct patient support; and (5) empowering people with trustworthy information. Komen’s work has helped reduce the mortality rate from breast cancer by 44% since 1989.

However, not all people have benefited equally from progress against breast cancer. Thus, Komen is committed to achieving breast health equity so that all people have a fair and just opportunity to be as healthy as possible by breaking down the systemic and financial barriers that lead to poorer breast health outcomes through a variety of proven interventions.

¹ Pursuant to Supreme Court Rule 37.6, counsel for *amicus* represent that they authored this brief in its entirety and that none of the parties or their counsel, nor any other person or entity other than *amicus* or its counsel, made a monetary contribution intended to fund the preparation or submission of this brief.

Komen aims to assist the Court in understanding the importance of the Affordable Care Act's ("ACA") requirement that insurers cover certain breast-cancer-related preventive care measures – such as screenings, genetic testing, and preventive medications – and the consequences of the Fifth Circuit's decision striking these coverage requirements. Studies show that the ACA's elimination of cost-sharing for these types of services has had a profound impact on public health because such preventive care translates to earlier detection, earlier treatment, lower treatment costs, and fewer deaths from breast cancer. The costs of such preventive care – if not fully covered by insurance, which is the effect of the district court's decision – dissuade individuals from utilizing the services, and thus lead to later detection, later-stage diagnoses, more aggressive treatment plans, higher treatment costs, and more deaths. This is especially true among populations most at risk for disparities in breast cancer outcomes, including communities of color, those living in rural areas, and those under financial distress.

INTRODUCTION AND SUMMARY OF ARGUMENT

Breast cancer is the most common cancer among women in the United States, as well as the second most deadly. Fortunately, certain preventive care measures help identify and reduce one's risk of breast cancer, and detect the disease years before symptoms develop. Risk reduction and early detection measures enable individuals and their care providers to find breast cancer earlier, when more treatment options and better outcomes are possible. Such early efforts result in fewer breast-cancer-caused deaths and lower treatment costs. The ACA requires insurers to cover

these essential preventive care measures completely, with no cost-sharing for patients. By eliminating cost-sharing, the ACA's preventive care mandate ensures that everyone who needs access to such care has access.

The Fifth Circuit's affirmance of the district court's decision limits the preventive care to which individuals have access, and thus increases (1) the risk of breast cancer progressing to more advanced stages; (2) treatment costs; and (3) the risk of breast-cancer-related deaths. For that reason, Komen respectfully requests that the Court reverse the Fifth Circuit's decision.

ARGUMENT

I. THE ACA'S REQUIREMENT THAT INSURERS COVER PREVENTIVE SERVICES AIMED AT DETECTING BREAST CANCER EARLY REDUCES RISKS ASSOCIATED WITH LATE-STAGE BREAST CANCER, INCLUDING DEATH, AND LOWERS TREATMENT COSTS

Reliable access to affordable preventive care significantly reduces the risk of dying from breast cancer. Moreover, early detection can reduce the risk of being diagnosed with advanced cancer and can lower treatment costs.

A. Breast Cancer Diagnoses In The United States Are Prevalent And Often Fatal

Breast cancer is the most common type of cancer among women in the United States and the second most deadly.² As of 2024, there are more than

² See Nat'l Cancer Inst., *Common Cancer Types* (updated May 10, 2023), <https://www.cancer.gov/types/common-cancers#:~:text=>

4 million people in the United States that have been diagnosed with the disease. In 2025 alone, more than 319,000 additional people are likely to be diagnosed with invasive breast cancer in the United States, and the disease will cause nearly 43,000 deaths.³

Breast cancer affects not only the individual diagnosed, but also their families, caregivers, and loved ones. Given the prevalence of the disease and how devastating it can be, it has become part of daily life for far too many. Fortunately, preventive care measures can significantly reduce the risk of breast-cancer-caused deaths, as well as the risk that an early diagnosis advances to a more severe and costly stage.

B. Medical Professionals Recommend Various Preventive Care Measures That Are Proven To Save Lives And Reduce Treatment Costs

There are various preventive care measures providers recommend to identify both the risk associated with developing breast cancer and early signs of the disease, thereby positioning patients to treat the disease as early as possible. Early detection is crucial,

[The%20most%20common%20type%20of%20are%20combined%20for%20the%20list](https://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/cancer-treatment-and-survivorship-facts-and-figures/2022-cancer-treatment-and-survivorship-facts-and-figures-acs.pdf); see also Am. Cancer Soc'y, *Cancer Treatment & Survivorship Facts & Figures 2022-2024* (2022), <https://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/cancer-treatment-and-survivorship-facts-and-figures/2022-cancer-treatment-and-survivorship-facts-and-figures-acs.pdf>. For Black and Hispanic women in the United States, breast cancer is the most deadly cancer. See Am. Cancer Soc'y, *Breast Cancer Death Rates Are Highest for Black Women – Again* (Oct. 3, 2022), <https://www.cancer.org/research/acs-research-news/breast-cancer-death-rates-are-highest-for-black-women-again.html>.

³ See Am. Cancer Soc'y, *Cancer Facts & Figures 2025*, at 3 (2025), <https://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/annual-cancer-facts-and-figures/2025/2025-cancer-facts-and-figures-acs.pdf>.

as about 99% of women diagnosed with breast cancer at the earliest stage live for at least five years, compared to about 32% of those diagnosed at the most advanced stage.⁴

Early detection and treatment methods have improved over time. In fact, these improvements resulted in a 44% decline in the breast cancer death rate in the United States between 1989 and 2022,⁵ which prevented an estimated 517,900 breast cancer deaths during that time.⁶ Three of the most effective preventive care methods are (1) screening mammography; (2) genetic counseling and testing; and (3) preventive, risk-modifying medications. Each of these methods of care – if done early and as recommended by healthcare providers – is proven to significantly reduce the risk of breast cancer fatalities. In addition, these measures help to reduce treatment costs and prevent breast cancers from progressing to more advanced stages.

Screening Mammography. The most effective preventive care used to detect breast cancer in women of average risk is screening mammography, which is a test that uses X-rays to create images of the breast;

⁴ See U.S. Ctrs. for Disease Control & Prevention & Nat'l Cancer Inst., Cancer Statistics Working Grp., *United States Cancer Statistics: Data Visualizations Tool* (rel. June 2024) (based on 2022 submission data (1999-2020)), https://gis.cdc.gov/Cancer/USCS/?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fcancer%2Fdataviz%2Findex.htm#/SurvivalbyStage/.

⁵ See Am. Cancer Soc'y, *Cancer Facts & Figures 2025*, at 9 (2025), <https://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/annual-cancer-facts-and-figures/2025/2025-cancer-facts-and-figures-acf.pdf>.

⁶ See *id.*

the resulting image is referred to as a “mammogram.”⁷ Radiologists use mammograms to identify signs of breast cancer even when the cancer is at its earliest stages and thus when the individual’s chances of long-term survival are highest.⁸ Importantly, mammograms can reveal cancer before the individual experiences any symptoms.⁹

As the most effective screening test used to find breast cancer in women today, mammography is a powerful method that often leads to an early diagnosis, and thus early treatment.¹⁰ Indeed, a study showed women who participate in mammography screenings have a 41% reduction in their risk of dying of breast cancer within 10 years and a 25% reduction in the rate of advanced breast cancers.¹¹ Moreover, screening contributes to a 29% reduction in the number of women diagnosed with metastatic breast cancer that has spread to other parts of the body (which is the most advanced stage and is incurable).¹² Missing even one screen for breast cancer confers a significantly

⁷ See Susan G. Komen Found., *Mammography* (updated Dec. 27, 2023), <https://www.komen.org/breast-cancer/screening/mammography/>.

⁸ See *id.*

⁹ See *id.*

¹⁰ See *id.*

¹¹ See Stephen W. Duffy et al., *Mammography Screening Reduces Rates of Advanced and Fatal Breast Cancers: Results in 549,091 Women*, 126 *Cancer* 2971 (July 1, 2020).

¹² See Ronald E. Gangnon et al., *The Contribution of Mammography Screening to Breast Cancer Incidence Trends in the United States: An Updated Age-Period-Cohort Model*, 24 *Cancer Epidemiol. Biomarkers Prev.* 905, 905-06 (June 2015).

higher risk of breast cancer mortality within 10 years.¹³

Genetic Counseling and Testing. Another effective preventive measure is testing women who may be genetically predisposed to breast cancer. Such testing is important given that approximately 10% of breast cancers are related to the inheritance of mutated genes.¹⁴ Once it is determined that an individual has inherited particular gene mutations, the risk of developing breast cancer or other cancers can be as high as 85%.¹⁵

Genetic counseling and testing are currently recommended for individuals who have a personal or family history of breast, ovarian, tubal, or peritoneal cancer, or an ancestry associated with breast cancer susceptibility.¹⁶ Given the prevalence of breast cancer diagnoses in the United States, *see supra* pp. 3-4, many

¹³ See Stephen W. Duffy et al., *Beneficial Effect of Consecutive Screening Mammography Examinations on Mortality from Breast Cancer: A Prospective Study*, 299 *Radiology* 541 (June 2021).

¹⁴ See Anisha Ninan, Johns Hopkins Med., *Hereditary Breast Cancer*, <https://www.hopkinsmedicine.org/health/conditions-and-diseases/breast-cancer/hereditary-breast-cancer>.

¹⁵ Stacey Shiovitz & Larissa A. Korde, *Genetics of Breast Cancer: A Topic of Evolution*, 26 *Ann. Oncol.* 1291, 1291 (July 2015), <https://www.annalsofoncology.org/action/showPdf?pii=S0923-7534%2819%2934481-3>.

¹⁶ See U.S. Preventive Servs. Task Force, *BRCA-Related Cancer: Risk Assessment, Genetic Counseling, and Genetic Testing*, Final Recommendation Statement (Aug. 20, 2019), <https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/brca-related-cancer-risk-assessment-genetic-counseling-and-genetic-testing>. With respect to the risk of developing breast cancer, “the most important inherited gene changes are in the

people fall into this category. To identify whether an individual has potentially harmful mutations in breast cancer susceptibility genes (BRCA1 or BRCA2, among others), medical professionals first utilize risk-assessment tools designed to study the individual's family history.¹⁷ For example, doctors may employ mathematical models to analyze a patient's family history and other factors in order to determine the likelihood that the patient has a mutated gene.¹⁸ If such a risk is apparent, it is recommended that the individual receive genetic counseling¹⁹ and potentially BRCA testing.²⁰ BRCA testing itself uses DNA

BRCA1 and BRCA2 genes.” Am. Cancer Soc’y, *Breast Cancer Risk and Prevention* 30 (rev. Dec. 16, 2021), <https://www.cancer.org/content/dam/CRC/PDF/Public/8578.00.pdf>. Individuals with one of these genes have Hereditary Breast and Ovarian Cancer (“HBOC”) syndrome and have an increased risk of breast cancer. *See id.*

¹⁷ *See* U.S. Preventive Servs. Task Force, *BRCA-Related Cancer: Risk Assessment, Genetic Counseling, and Genetic Testing*, Final Recommendation Statement (Aug. 20, 2019), <https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/brca-related-cancer-risk-assessment-genetic-counseling-and-genetic-testing>.

¹⁸ *See* Am. Cancer Soc’y, *Genetic Counseling and Testing for Breast Cancer Risk* (rev. Dec. 16, 2021), <https://www.cancer.org/cancer/types/breast-cancer/risk-and-prevention/genetic-testing.html>.

¹⁹ “Genetic counseling can help you understand what the results could mean for your health. It also can help you decide whether genetic testing is right for you.” Mayo Clinic, *BRCA Gene Test for Breast and Ovarian Cancer Risk* (Oct. 21, 2023), <https://www.mayoclinic.org/tests-procedures/brca-gene-test/about/pac-20384815>.

²⁰ *See* U.S. Preventive Servs. Task Force, *BRCA-Related Cancer: Risk Assessment, Genetic Counseling, and Genetic Testing*,

analysis of a blood, saliva, or cheek cell sample to identify mutations in breast cancer-susceptible genes.²¹

Like screening mammography, screening for genetic mutations that make an individual more likely to develop breast cancer is an effective tool in the earlier detection of breast cancer, including before symptoms appear. Individuals who test positive for gene mutations that make them prone to breast cancer are recommended for more frequent breast imaging in order to identify symptoms early, in the event they do develop, and can even take affirmative steps to lower their risk of developing the disease. *See, e.g., infra* pp. 9-11 (describing medications that lower the risk of breast cancer).

Risk-Modifying Medications. Medical professionals may recommend that individuals with a high risk of breast cancer take preventive medications, such as tamoxifen, raloxifene, or certain aromatase inhibitors.²² Both tamoxifen and raloxifene are selective estrogen receptor modulators (“SERMs”), which are drugs that reduce the effects of estrogen in the breast. In doing so, these medications “depriv[e] breast cancer

Final Recommendation Statement (Aug. 20, 2019), <https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/brca-related-cancer-risk-assessment-genetic-counseling-and-genetic-testing>.

²¹ *See* Susan G. Komen Found., *Genetic Counseling For People Who Do Not Have Breast Cancer* (updated Dec. 16, 2024), <https://www.komen.org/breast-cancer/risk-factor/gene-mutations-genetic-testing/genetic-counseling-for-people-who-do-not-have-breast-cancer/>.

²² *See* Mayo Clinic, *Breast Cancer Chemoprevention: Drugs That Reduce Risk* (Oct. 28, 2023), <https://www.mayoclinic.org/diseases-conditions/breast-cancer/in-depth/breast-cancer/art-20045353>.

cells of the fuel they need to grow and thrive.”²³ Studies show that tamoxifen can lower the risk of invasive breast cancer by about 50% and that raloxifene can lower the risk of breast cancer by about 38%.²⁴

Aromatase inhibitors – such as anastrozole, exemestane, and letrozole – reduce the amount of estrogen in the body and are used to prevent breast cancer recurrence after menopause. Some studies show that “aromatase inhibitors are about 30% more effective in preventing breast cancer recurrence than tamoxifen or raloxifene.”²⁵

Preventive measures like mammography screenings, genetic testing, and risk-modifying medications save lives. Early detection that follows the use of these measures means lower costs of treatment, compared to those diagnosed at a later stage.²⁶ For

²³ *Id.*

²⁴ See Susan G. Komen Found., *Research Table: Tamoxifen and Raloxifene To Reduce Breast Cancer Risk* (updated June 6, 2024), <https://www.komen.org/breast-cancer/facts-statistics/research-studies/topics/use-of-tamoxifen-and-raloxifene-to-reduce-the-risk-of-breast-cancer/#:~:text=Both%20tamoxifen%20and%20raloxifene%20can,at%20high%20risk%20%5B1%5D>.

²⁵ Ronda Wendler, MD Anderson Cancer Ctr., *Diagnosed With Breast Cancer After Menopause? Aromatase Inhibitors Can Help* (Aug. 18, 2022), <https://www.mdanderson.org/cancerwise/diagnosed-with-breast-cancer-after-menopause--aromatase-inhibitors-can-help.h00-159542112.html#:~:text=Clinical%20trials%20have%20shown%20that,with%20estrogen%2Dfueled%20breast%20cancers>.

²⁶ See Helen Blumen et al., *Comparison of Treatment Costs for Breast Cancer, by Tumor Stage and Type of Service*, 9 Am. Health Drug Benefits 23, 23 (Feb. 2016) (concluding that “[t]reating advanced- versus early-stage breast cancer is associated with significant increases in incremental costs”); see also Jinani

example, one study showed that “[t]he average costs per patient allowed by the insurance company in the year after diagnosis” more than doubled for individuals diagnosed with Stage III or Stage IV cancer, as opposed to Stage 0 or Stage I cancer.²⁷ As a result, the researchers concluded that “[k]nowledge of the relevant stage-specific cost data provides support for strengthening programs, such as breast cancer screening, that are designed to shift breast cancer diagnosis to earlier disease stages.”²⁸

Ultimately, access to breast cancer preventive care measures results in more people living longer with lower costs of care.

C. The ACA’s Preventive Care Coverage Expands Access To Life Saving Care

Given the extraordinary benefits of preventive care, it is not surprising that the ACA includes a requirement obligating insurers and group health plans to cover certain breast-cancer-specific preventive care.²⁹

Jayasekera & Jeanne S. Mandelblatt, *Systematic Review of the Cost Effectiveness of Breast Cancer Prevention, Screening, and Treatment Interventions*, 38 J. Clin. Oncol. 332 (Feb. 2020) (concluding that preventive measures generally reduce the cost of treatment, especially when utilized by the groups of individuals who are most likely to benefit, such as those with genetic predispositions to breast cancer); Sujha Subramanian et al., *Cost of Breast Cancer Treatment in Medicaid: Implications for State Programs Providing Coverage for Low-Income Women*, 49 Med. Care 89 (Jan. 2011).

²⁷ Blumen, *Comparison of Treatment Costs for Breast Cancer, by Tumor Stage and Type of Service*, 9 Am. Health Drug Benefits at 23.

²⁸ *Id.*

²⁹ The ACA empowers certain agencies – including the Health Resources and Services Administration (“HRSA”) and the U.S.

Specifically, insurers must cover mammography screenings every one to two years for women aged 40 and older.³⁰ In addition, plans must cover risk assessment for individuals with ancestry associated with breast cancer susceptibility gene mutations, and, for those with a positive result, genetic counseling and testing.³¹ Finally, insurers must cover risk-reducing medications (such as tamoxifen, raloxifene, and aromatase inhibitors) for women who are at increased risk for breast cancer.³²

The ACA's requirement that insurers cover these preventive measures has had a profound impact, including by increasing access to care, reducing treatment costs, and, ultimately, saving lives. Indeed, since the ACA eliminated cost-sharing for certain

Preventive Services Task Force ("USPSTF") – to determine which preventive care services must be covered. Komen understands that the district court found unconstitutional USPSTF's authority to prepare such guidelines and recommendations and found constitutional HRSA's authority to prepare such guidelines and recommendations. *See* Pet. App. 85a-136a. Komen does not have a position on the constitutional questions before the Court and instead submits this brief to educate the Court on the benefits of preventive care for breast cancer and the consequences of the district court's decision.

³⁰ *See* Department of Health and Human Services Appropriations Act, 2024, Pub. L. No. 118-47, div. D, tit. II, § 223, 138 Stat. 460, 649, 677 (2024) (providing that any reference to USPSTF's breast cancer screening, mammography, and prevention be treated as referencing the pre-2009 breast cancer screening recommendations, including that women 40 and older receive screenings every one to two years are covered under the ACA until 2026).

³¹ *See* HealthCare.gov, *Preventive Care Benefits for Women*, <https://www.healthcare.gov/preventive-care-women/> (last visited Feb. 24, 2025).

³² *See id.*

preventive services, studies show increased utilization of breast cancer preventive services. Historically, marginalized populations in particular have benefited from the elimination of cost-sharing for certain preventive services. Since the ACA was enacted in 2010, researchers found that mammography screening among Black Americans has significantly increased.³³ Another study shows an improvement in mammography screening rates in lower-income women in Medicaid expansion States when compared with non-expansion States.³⁴

Furthermore, by removing cost-sharing for these preventive care measures, the passage of the ACA is associated with increases in both (a) genetic testing³⁵ and (b) access to Medicaid-financed prescriptions for breast cancer hormonal therapies (at least within Medicaid expansion States).³⁶ The ACA's preventive

³³ See Soudabeh Fazeli Dehkordy et al., *Breast Screening Utilization and Cost Sharing Among Employed Insured Women Following the Affordable Care Act: Impact of Race and Income*, 28 J. Women's Health 1529 (2019).

³⁴ See Yoshiko Toyoda et al., *Affordable Care Act State-Specific Medicaid Expansion: Impact on Health Insurance Coverage and Breast Cancer Screening Rates*, 230 J. Am. Coll. Surgeons 775 (May 2020). Not surprisingly, Medicaid expansion also increased the diagnosis of early-stage disease and increased access to treatment. See Quyen D. Chu et al., *Positive Impact of the Patient Protection and Affordable Care Act Medicaid Expansion on Louisiana Women With Breast Cancer*, 127 Cancer 688 (Mar. 2021).

³⁵ See Hope C. Norris et al., *Utilization Impact of Cost-Sharing Elimination for Preventive Care Services: A Rapid Review*, 79 Med. Care Res. & Rev. 175 (Apr. 2022).

³⁶ See Johanna C. Maclean et al., *The Effect of Medicaid Expansion on Prescriptions for Breast Cancer Hormonal Therapy Medications*, 55 Health Serv. Res. 399 (June 2020).

care coverage has even helped cancer survivors obtain necessary care.³⁷

II. THE FIFTH CIRCUIT’S DECISION WOULD LIMIT ACCESS TO CARE, HARM TREATMENT EFFORTS, INCREASE COSTS, AND RISK LIVES

It is undeniable that the preventive care covered by the ACA has made a meaningful difference in the lives of people throughout the country. The Fifth Circuit affirmance ensures that fewer people will have access to this care. As a direct result, more people will die from breast cancer.

The district court held unlawful “[a]ll agency action taken to implement or enforce the preventive care coverage requirements in response to an ‘A’ or ‘B’ recommendation by the [USPSTF] on or after March 23, 2010.” Pet. App. 83a. While the Fifth Circuit’s remedy is narrower than the remedy originally ordered by the district court – a nation-wide injunction – it still will have sweeping implications. Indeed, the circuit court’s decision prohibiting the government from enforcing the USPSTF coverage requirement now acts as binding precedent in Texas, Louisiana, and Mississippi, so it unlikely is to be enforced against any plans therein. And the enforceability of the USPSTF coverage requirement likely will be challenged in jurisdictions outside the Fifth Circuit. *See id.* at 47a. Pursuant to this ruling, insurers no longer may be required to fully cover the costs of certain preventive care measures recommended by the USPSTF. As discussed, *see supra* pp. 12-14, out-of-pocket expenses borne by

³⁷ *See* Maria Pisu et al., *Costs of Cancer Along the Care Continuum: What We Can Expect Based on Recent Literature*, 124 *Cancer* 4181 (Nov. 2018).

individuals directly impact their utilization of health-care services. Consequently, by striking the requirement that insurers cover certain preventive care measures, the district court's judgment ensures that fewer people will have access to these preventive care measures.

That outcome will be devastating. Preventive care measures covered by the ACA – including those recommended by both the USPSTF and the HRSA – are lifesaving. Those measures may be able to prevent breast cancer deaths or from being diagnosed at later stages and reduce the cost of treatment. By limiting access to those screening and treatment measures, the district court's ruling stifles these momentous benefits. Accordingly, Komen respectfully submits that the Court should overturn the circuit court's decision affirming the grant of summary judgment (in part) and the district court's conclusion that the USPSTF's preventive care recommendations are unlawful and unenforceable.

CONCLUSION

The judgment of the court of appeals should be reversed.

Respectfully submitted,

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