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The Broken Link: *Braidwood*, the United States Preventive Services Task Force (USPSTF), and the Health Equity Implications of Losing Free Access to Preventive Care

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Abstract

Braidwood Management, Inc. v. Becerra threatens the nationwide enforceability of the preventive care mandate of the Affordable Care Act (ACA) with respect to a variety of preventive health care services. The success of this lawsuit could have devastating repercussions. Not only would many current guidelines of the U.S. Preventive Services Task Force (USPSTF) be affected, but future preventive care recommendations would be as well, to the detriment of achieving health equity goals. This Article posits that the loss of guaranteed free preventive care could threaten current and future health equity gains. If preventive care is no longer offered without cost-sharing, research shows that many people, especially those with lower socioeconomic status, will not access the care. This decrease in access to recommended screenings and other preventive services would likely decrease uptake, over time impacting the stage at which diseases such as cancer are diagnosed, making late-stage diagnoses with poorer prognoses more common, and increasing transmission of other conditions such as HIV. At the population level, decreased access to free preventive care could hinder efforts to reduce entrenched inequalities associated with these conditions.

*Moreover, these effects will be amplified as insured people lose access to preventive care recommendations that evolve in response to new research findings. In the years since the ACA's passage, the USPSTF has brought a health equity lens to each step of its recommendation process, including how it chooses preventive services to study, how it designs and conducts its research plan, and its approach to issuing recommendations along with calls for more research. Although some have argued that the resulting shift in the USPSTF's recommendations has not happened fast enough, the way in which the USPSTF structures its evidentiary reviews — with a focus on high-level literature reviews of medical studies — suggests that over time, as individual studies continue to examine the effectiveness of interventions in different populations and publish their results, the shift will become more dramatic and the resulting recommendations will be more effective at combating health care disparities. If *Braidwood* is successful, no-cost insurance coverage for these more responsive recommended services could be undermined.*

*This Article explores the potential impact *Braidwood* could have on existing and anticipated advances in preventive care through a focus on two life-threatening conditions: cancer and HIV. Both cancer and HIV preventive care recommendations have undergone significant changes since the implementation of the preventive care mandate. While the resulting recommendations remain imperfect, the Article shows the important and evolving relationship between these recommendations and efforts to overcome pervasive and entrenched disparities in health outcomes related to these conditions. If *Braidwood* is upheld, ongoing efforts to reduce disparities in cancer and HIV will be stymied.*

Keywords: *Braidwood*; preventive care; health equity; USPSTF; cancer; HIV

I. Introduction

Preventive care has significant capacity to help individuals avoid disease or, if that is not possible, detect disease earlier, when there is a better chance for cure, making survival more likely and improving quality of life during treatment for patients and their families. In addition, recent and ongoing efforts to improve preventive care recommendations hold promise for a future where preventive care more effectively meets the needs of groups who are disproportionately burdened by disease. Increasing access to and use of preventive care can, therefore, be a powerful tool in addressing health disparities and improving health outcomes for systemically marginalized populations. While much work remains necessary to enable these individuals to access preventive care interventions, many of the innovative health initiatives of the last decade — such as those aimed at addressing the social determinants of health, a key to improving health equity — assume that preventive care itself will be free to the patient. Thus, ensuring that this remains so is also critical to equity.

In this Article, we will explore the link between the Affordable Care Act (ACA) preventive care mandate, which ensures that most individuals with private health insurance can access certain recommended preventive services without cost-sharing, and efforts to close health equity gaps. We will analyze why the mandate is so important to these efforts, especially in the context of innovative health care delivery and improved preventive care recommendations. We will then discuss these issues in the context of *Braidwood Management, Inc. v. Becerra* and the threat it poses to continued assurances that services recommended by the U.S. Preventive Services Task Force (USPSTF) will be covered without cost to patients. Specifically, we will focus on the USPSTF as a source of evidence-based standards for preventive care that considers the most up-to-date research and, especially in recent years, embraces a health equity lens.

To illustrate how the preventive care mandate may impact health equity, we focus on cancer and HIV. In Part IV.A, we highlight key disparities in incidence and mortality rates for colorectal, lung, cervical, and breast cancer, and explain how current and future USPSTF recommendations may help reduce those disparities if access to recommended preventive services remains assured. In Part IV.B, we highlight disparities in the U.S. HIV epidemic and explain how certain preventive services recommended by the USPSTF show significant promise for helping to end the epidemic if use of those services is increased rather than reduced. If *Braidwood* is upheld, affordable access to these preventive services will be jeopardized, threatening to reduce their use among populations that stand to benefit the most from them. This would set us back in the fight to reduce longstanding and entrenched disparities in cancer and HIV. Moreover, cancer and HIV are only two of many conditions that could be negatively impacted by *Braidwood*, the effects of which could reverberate broadly across the U.S. health care system.

II. Why Make Preventive Care Free?

Preventive care is defined as “[r]outine health care that includes screenings, check-ups, and patient counseling to prevent illnesses, disease, or other health problems.”¹ In other words, preventive care by its nature is for people who are asymptomatic and in many cases disease free, whereas diagnostic care is for patients who present with symptoms or other indications of disease that require investigation and possible diagnosis and treatment. Lack of access to preventive care can result in later diagnoses of adverse health conditions.² Diseases diagnosed later can lead to worse health outcomes, both because later diagnoses may have resulted in more advanced disease with worse prognoses (as with more advanced stages of cancer) and because diseases caught at a more advanced stage can require more complex

¹Preventive Services, HEALTHCARE.GOV, <https://www.healthcare.gov/glossary/preventive-services/> [https://perma.cc/HY72-RNED].

²See Paul Reed, *An Ounce of Prevention...Can Save a Person's Life*, HEALTH.GOV: HEALTH & WELL-BEING MATTER (Aug. 26, 2022), <https://health.gov/news/202208/ounce-prevention-can-save-persons-life> [https://perma.cc/K5JT-7LRF] (“Preventive services can ... identify health problems early ... when clinical interventions are most beneficial.”).

treatments. Complex treatments can lead to poor treatment adherence, further contributing to worse disease outcomes.³ Thus, the purposes behind preventive care, generally stated, are to avoid disease in the first place and, when that is not possible or unsuccessful, to catch diseases in their earlier stages, when treatment is more tolerable and positive health outcomes more likely.

Because preventive care is for people who are asymptomatic, the benefits of utilizing preventive care may not seem as obvious as when a person must pay out of pocket for tests and procedures to detect or treat symptomatic disease. Studies have shown that when people must pay for preventive services, even if that cost is low, they may forgo the services altogether.⁴ For example, one pre-ACA study found that imposing cost-sharing requirements on mammograms and Pap smears negatively impacted uptake of those services across a variety of health insurance plan types.⁵ A more recent survey showed that large percentages of U.S. adults would be unwilling to pay for certain preventive services that must be free under current ACA rules; for instance, 38% of those surveyed stated that they would not pay out of pocket for cancer screenings, while 60% said they would not pay out of pocket for tobacco smoking cessation services.⁶ These negative effects of cost-sharing requirements may be even more significant for people with lower incomes, who are both more likely to forgo recommended health care in general based on cost⁷ and more likely to experience chronic illnesses and other health challenges.⁸

These types of concerns were an animating force behind what would eventually become the ACA's preventive care mandate. On September 9, 2009, President Barack Obama, in a major address to Congress on health care reform, invoked what would become the basis of the mandate: "[t]here's no reason we shouldn't be catching diseases like breast and colon cancer before they get worse. That makes sense, it saves money, and it saves lives."⁹ To accomplish this goal of catching diseases before they become worse — and preventing other diseases from occurring — the ACA included a simple but broadly sweeping provision requiring most private health insurers to cover certain preventive services without cost-sharing.¹⁰ The preventive care mandate, codified in Section 2713 of the ACA, requires that private, non-grandfathered insurers cover, without copayments or cost-sharing, four sets of recommended preventive services: (1) services with an A or B grade from the USPSTF; (2) services recommended by the federal Advisory Committee on Immunization Practices (ACIP) and adopted by the Centers for Disease Control and Prevention (CDC); (3) additional women's preventive health services recommended by the federal Health Resources and Services Administration (HRSA); and (4) additional preventive services recommended by HRSA for children and youth.¹¹ This mandate helps accomplish a major purpose of the ACA: to incorporate a greater emphasis on prevention and

³See, e.g., Leslie R Martin et al., *The Challenge of Patient Adherence*, 1 THERAPEUTICS & CLINICAL RISK MGMT. 189, 190 (2005).

⁴*Clinical and Equity Implications of Braidwood v. Becerra*, CTR. FOR VALUE-BASED INS. DESIGN (June 2, 2023), <https://vbidcenter.org/clinical-and-equity-implications-of-braidwood-v-becerra> [<https://perma.cc/H35U-5BAZ>].

⁵Geetesh Solanki et al., *The Direct and Indirect Effects of Cost-Sharing on the Use of Preventive Services*, 34 HEALTH SERVS. RSCH. 1331, 1339-40, 1348 (2000).

⁶Ricky Zipp, *Many Americans Are Likely to Skip Preventive Care if ACA Coverage Falls Through*, MORNING CONSULT PRO (Mar. 8, 2023, 5:00 AM), <https://pro.morningconsult.com/trend-setters/affordable-care-act-polling-data> [<https://perma.cc/775B-QX9N>].

⁷See, e.g., Lunna Lopes et al., *Americans' Challenges with Health Care Costs*, KFF (March 1, 2024), <https://www.kff.org/health-costs/issue-brief/americans-challenges-with-health-care-costs/>.

⁸Dhruv Khullar & Dave A. Chokshi, *Health, Income, & Poverty: Where We Are & What Could Help*, HEALTH AFFS.: HEALTH POL'Y BRIEF, Oct. 4, 2018, at 2.

⁹*Obama's Health Care Speech to Congress*, N.Y. TIMES (Sept. 9, 2009), <https://www.nytimes.com/2009/09/10/us/politics/10obama.text.html> [<https://perma.cc/9YX6-TQGP>].

¹⁰Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 2713, 124 Stat. 119, 131-32 (2010) (codified as amended at 42 U.S.C. § 300gg-13).

¹¹*Id.*

maintaining population health into the U.S. health care system, which has historically focused mainly on treating disease.¹²

III. The Link Between Free Preventive Care and Addressing Health Disparities

Many of the conditions for which the USPSTF recommends preventive care have a disproportionate impact on people of color and other systemically marginalized populations.¹³ This is particularly apparent in the contexts of different types of cancer and HIV, the two focal points of this Article. For cancer, the disparities in mortality rates are stark — “Black people¹⁴ are at the highest risk of death from cancer, even though White people have the highest rate of new cancers.”¹⁵ In the HIV context, Black or African American and Latino or Hispanic communities experience HIV incidence and deaths at rates that substantially exceed these communities’ representation in the U.S. population generally.¹⁶

Lower socioeconomic status (SES), often quantified through educational attainment or household income relative to the poverty level, is also strongly linked to health disparities.¹⁷ This is true across many measures of health, including rates of chronic conditions such as heart disease and diabetes, which can be prevented or ameliorated through timely preventive care.¹⁸ For example, people with lower SES have higher lung cancer morbidity and mortality rates; early evidence also suggests that people with lower SES are less likely to participate in lung cancer screening, a disparity that could increase as screening rates rise overall.¹⁹ In the United States, vulnerability to HIV is also concentrated among those with lower SES,²⁰ with factors such as poverty, lack of stable housing, lack of access to health care infrastructure and insurance, and increased stigma and discrimination helping to drive the HIV epidemic.²¹

Health disparities based on SES intersect with those associated with race and other systemically marginalized identities, complicating and enhancing the impact of other disparities.²² For complex reasons reflecting the deep roots of systemic racism in the United States, certain racial and ethnic groups

¹²Background: *The Affordable Care Act’s New Rules on Preventive Care*, CTRS. FOR MEDICARE & MEDICAID SERVS. (July 14, 2010), <https://www.cms.gov/ccio/resources/fact-sheets-and-faqs/preventive-care-background> [<https://perma.cc/K27G-WK8X>].

¹³Matthew J. O’Brien et al., *Reducing Health Disparities Through Prevention: Role of the U.S. Preventive Services Task Force*, 68 AM. J. PREVENTIVE MED. 724, 724 (2020).

¹⁴We recognize that there are many ways of referring to different racial and ethnic groups. See, e.g., Catherine Lewis et al., *Race and Ethnic Categories: A Brief Review of Global Terms and Nomenclature*, CUREUS, July 1, 2023, at 1, *passim*. In this Article, we will aim to use consistent terminology recognized by the National Institutes of Health, see *id.* at 2 tbl.1, adjusted in individual circumstances as necessary to accurately reflect research data.

¹⁵Michelle Tong et al., *Racial Disparities in Cancer Outcomes, Screening, and Treatment*, KFF (Feb. 3, 2022), <https://www.kff.org/racial-equity-and-health-policy/issue-brief/racial-disparities-in-cancer-outcomes-screening-and-treatment/> [<https://perma.cc/QB7L-DWWP>].

¹⁶See *Impact on Racial and Ethnic Minorities*, HIV.GOV (Dec. 18, 2023), <https://www.hiv.gov/hiv-basics/overview/data-and-trends/impact-on-racial-and-ethnic-minorities/> [<https://perma.cc/Q5M6-GV9P>]; *Black Americans and HIV/AIDS: The Basics*, KFF (Feb. 7, 2020), <https://www.kff.org/hiv/aids/fact-sheet/black-americans-and-hiv-aids-the-basics/> [<https://perma.cc/6Y8N-AA6D>]; *HIV/AIDS and Hispanic Americans*, OFF. OF MINORITY HEALTH, U.S. DEP’T OF HEALTH & HUM. SERVS., <https://minorityhealth.hhs.gov/hiv-aids-and-hispanic-americans> [<https://perma.cc/S4T4-N4CR>].

¹⁷Eliseo J. Pérez-Stable & Monica Webb Hooper, *The Pillars of Health Disparities Science—Race, Ethnicity, and Socioeconomic Status*, JAMA HEALTH F., Dec. 21, 2023, at 1-2.

¹⁸See Dhruv Khullar & Dave A. Chokshi, *supra* note 8, at 2.

¹⁹Daniel Redondo-Sánchez et al., *Socio-Economic Inequalities in Lung Cancer Outcomes: An Overview of Systematic Reviews*, CANCERS, Jan. 13, 2022, at 2.

²⁰Jennifer A. Pellowski et al., *A Pandemic of the Poor: Social Disadvantage and the U.S. HIV Epidemic*, 68 AM. PSYCH. 197, *passim* (2013).

²¹See Maria De Jesus, *To End the HIV Epidemic, Addressing Poverty and Inequities One of Most Important Treatments*, CONVERSATION (Feb. 14, 2019, 6:48 AM), <https://theconversation.com/to-end-the-hiv-epidemic-addressing-poverty-and-inequities-one-of-most-important-treatments-111484> [<https://perma.cc/6CLD-TH8A>].

²²See Pérez-Stable & Webb Hooper, *supra* note 17, at 2; Khullar & Chokshi, *supra* note 8, at 3-4.

disproportionately experience lower SES.²³ For example, in 2022, the U.S. Census found that 9.5% of White people were living below the poverty line, lower than the poverty rates among American Indian and Alaska Native people (24.5%), Black people (21.4%), and Hispanic people (16.7%).²⁴ Lower SES is also more common among other minoritized groups, such as lesbian, gay, bisexual, and transgender people.²⁵ The often layered and intersecting nature of these disparities can dramatically affect population health, including for preventable conditions — for example, Black men who have sex with men (MSM) are particularly vulnerable to HIV.²⁶

While solutions to these disparities are challenging and multifaceted,²⁷ improving access to and uptake of effective preventive care is one important approach that can help improve the health of communities disproportionately burdened by disease. As discussed, preventive care represents an opportunity to help people avoid disease or to support earlier diagnosis, when treatment may be more tolerable and less disruptive, and positive health outcomes more likely. For example, increasing access to certain kinds of cancer screenings and improving the quality of screening techniques, while reducing delays in linkage to care, could help address racial disparities in stage of cancer diagnosis,²⁸ with later cancer stages being associated with higher likelihood of mortality and more difficult treatment regimens. Likewise, expanding HIV prevention through pre-exposure prophylaxis (PrEP) (prescription medication and related services that can protect users from acquiring HIV) among populations disproportionately impacted by HIV is considered critical to improving disparities in HIV transmission rates.²⁹ Because even low copayments can discourage individuals from receiving preventive care like cancer screenings and PrEP, particularly those with lower incomes, ensuring affordable access to preventive care is an essential component of increasing uptake of these services.

Moreover, research into strategies to reduce health disparities in cancer, HIV, and other preventable conditions often presumes that preventive services will be fully covered, at least for insured patients, once those who would benefit from these services are successfully linked to care. A 2020 review of studies that tested different methods of reducing disparities for cancer, diabetes, and cardiovascular disease found that most such trials focused on cancer. In most cases, the study found, care navigation and other types of “personal support for patients increased screening rates in populations facing disparities.”³⁰ Other interventions aimed at reducing cancer disparities have focused on overcoming health care deserts by bringing cancer screening tools directly into communities where they are most needed.³¹ In the HIV

²³David R. Williams et al., *Understanding Associations Among Race, Socioeconomic Status and Health: Patterns and Prospects*, 35 HEALTH PSYCH. 407, 408 (2016).

²⁴Poverty Rate by Race/Ethnicity, 2022, KFF, <https://www.kff.org/other/state-indicator/poverty-rate-by-raceethnicity/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D> [https://perma.cc/5CYJ-JKLG].

²⁵Stephanie M. Hernandez et al., *Sexual Orientation, Gender Expression and Socioeconomic Status in the National Longitudinal Study of Adolescent to Adult Health*, 78 J. EPIDEMIOLOGY & CMTY. HEALTH 121, 121 (2024).

²⁶HIV and African American Gay and Bisexual Men: Prevention Challenges, CTNS. FOR DISEASE CONTROL & PREVENTION, <https://www.cdc.gov/hiv/group/bmsm/prevention-challenges.html> [https://perma.cc/3VWE-NPC7] (last reviewed Sept. 14, 2022); see Brian Mustanski et al., *Individual and Network Factors Associated with Racial Disparities in HIV Among Young Men Who Have Sex with Men: Results from the RADAR Cohort Study*, 80 J. ACQUIRED IMMUNE DEFICIENCY SYNDROMES 24, 28-29 (2019).

²⁷See Nambi Ndugga & Samantha Artiga, *Disparities in Health and Health Care: 5 Key Questions and Answers*, KFF (Apr. 21, 2023), <https://www.kff.org/racial-equity-and-health-policy/issue-brief/disparities-in-health-and-health-care-5-key-questions-and-answers/> [https://perma.cc/UDD6-PM23] (“A broad array of factors within and beyond the health care system drive disparities in health and health care.” (citation omitted)).

²⁸Tong et al., *supra* note 15.

²⁹PrEP for HIV Prevention in the U.S., CTNS. FOR DISEASE CONTROL & PREVENTION (Sept. 29, 2023), <https://www.cdc.gov/nchhstp/newsroom/fact-sheets/hiv/PrEP-for-hiv-prevention-in-the-US-factsheet.html> [https://perma.cc/6N7U-VY69].

³⁰Timothy S. Carey et al., *National Institutes of Health Pathways to Prevention Workshop: Achieving Health Equity in Preventive Services*, ANNALS INTERNAL MED. 272, 276 (2020).

³¹For example, in western New York, which has high rates of lung cancer incidence and death — with the greatest impact in communities of color and rural areas — Roswell Park Comprehensive Cancer Center has designed a mobile screening and outreach program that brings lung cancer screening through low-dose computed tomography (“LCDT”) directly to high-need

context, researchers have investigated numerous strategies to increase PrEP uptake among disproportionately impacted populations, including awareness campaigns, navigation and peer support models, and efforts to expand the scope of who can deliver PrEP and where they can do it.³² These types of interventions are all built on the assumption that once patients overcome the often numerous non-financial barriers to preventive care — including knowledge of a service, understanding how it could benefit them, access to a geographically accessible and culturally competent provider, and linkage to any necessary follow-up care — cost-sharing requirements will not discourage insured individuals from accessing prevention.

Fortunately, the ACA has already eliminated cost-sharing for recommended preventive services for most people with private health insurance — the most common type of insurance, with more than 200 million members in 2022.³³ Moreover, although the rate of private health insurance is lower among racial and ethnic minorities than among White non-Hispanics, it remains a common source of insurance across demographic groups, including 56.6% of Black individuals and 49.4% of Hispanic individuals.³⁴ Even among adults living in poverty, sizable percentages are covered by private health insurance.³⁵ Thus, the ACA's preventive services mandate eliminates a known financial barrier to receiving preventive care for large portions of communities disproportionately vulnerable to conditions like cancer and HIV.³⁶

IV. *Braidwood's* Potential Impact on the USPSTF and Its Efforts to Improve Health Equity

The USPSTF uses a rigorous, methodical process for assessing the evidence of potential benefits and harms associated with preventive services, without political interference.³⁷ Moreover, as researchers and others have explored ways to improve use and efficacy of preventive services among populations associated with disparate health outcomes, especially racial and ethnic minorities, the USPSTF has also engaged in recent efforts to incorporate a focus on equity into its work. Recognizing the racial disparities in use of preventive services and the multiple ways in which systemic racism impacts the USPSTF's recommendations and their uptake, the USPSTF has pursued several strategies to mitigate the effects of racism in delivery of preventive care.³⁸ Given the USPSTF's process for developing recommendations (discussed further below), as well as the reality that improvements in preventive care recommendations

areas. *Fact Sheet: White House Details Progress from the Cancer Cabinet and Private Sector During Cancer Moonshot Week of Action*, WHITE HOUSE (Dec. 8, 2022) [hereinafter *White House Fact Sheet*], <https://www.whitehouse.gov/ostp/news-updates/2022/12/08/fact-sheet-white-house-details-progress-from-the-cancer-cabinet-and-private-sector-during-cancer-moonshot-week-of-action/> [<https://perma.cc/4XHF-RG2G>].

³²Robert A. Bonacci et al., *Toward Greater Pre-Exposure Prophylaxis Equity: Increasing Provision and Uptake for Black and Hispanic/Latino Individuals in the U.S.*, 61 AM. J. PREVENTIVE MED. (SPECIAL ARTICLE) S60, S62-65.

³³KATHERINE KEISLER-STARKEY ET AL., U.S. CENSUS BUREAU, P60-281, HEALTH INSURANCE COVERAGE IN THE UNITED STATES: 2022, at 1, 2 (2023), <https://www.census.gov/content/dam/Census/library/publications/2023/demo/p60-281.pdf> [<https://perma.cc/3WP6-SPPS>].

³⁴*Id.* at 12, 13 fig.8.

³⁵*Id.* at 11 fig.7 (reporting 28.7% of adults below 100% of poverty level and 62.8% of adults between 100% and 399% of poverty level with private insurance).

³⁶The preventive services mandate also impacts adults enrolled in Medicaid through Medicaid expansion, since these individuals are guaranteed access to essential health benefits, which includes preventive services. See Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 2001(a)(1), (c)(3), 124 Stat. 119, 271, 277 (codified as amended at 42 U.S.C. § 18001); see also 45 CFR §§ 147.130(a), 156.115(a)(4) (2024) (defining essential health benefits to include preventive services). While the potential impact of *Braidwood* on Medicaid enrollees is murkier, it suffices to say here that any impact on Medicaid enrollees would further hinder efforts to address health disparities.

³⁷USPSTF: WHO WE ARE & HOW WE WORK, U.S. PREVENTIVE SERVS. TASK FORCE 2 (2022), <https://www.uspreventiveservicestaskforce.org/uspstf/sites/default/files/inline-files/uspstf-who-we-are-how-we-work-2022.pdf> [<https://perma.cc/L3RD-LJA2>].

³⁸U.S. Preventive Servs. Task Force, *Actions to Transform the US Preventive Services Task Force Methods to Mitigate Systemic Racism in Clinical Preventive Services*, 326 JAMA 2405, 2405 (2021) [<https://perma.cc/5F9Y-75HR>].

and their use may take a long time to impact population health,³⁹ it will likely be years before the full effect of these changes becomes apparent. Left intact, the ACA preventive care mandate ensures affordable access to these services as the recommendations are updated — but the *Braidwood* decision, if affirmed, threatens to undercut this process and reverse existing gains.

A. USPSTF's Independence and *Braidwood*

The USPSTF's authorizing statute protects the USPSTF's work from political interference by indicating that it “shall be independent and, to the extent practicable, not subject to political pressure.”⁴⁰ This independence helps ensure that USPSTF's decisions are grounded in science, not ideology, but *Braidwood* threatens to undermine it.

In two federal district court decisions issued in *Braidwood*, Judge Reed O'Connor for the Northern District of Texas held, among other things, that the ACA mandate to cover recommended preventive services without cost-sharing was unconstitutional as to those services with a grade A or B from the USPSTF, and that the federal government could not enforce this mandate.⁴¹ In concluding that enforcing coverage of USPSTF-recommended services — but not those recommended by ACIP and HRSA — violated the Appointments Clause of the Constitution, Judge O'Connor specifically pointed to the USPSTF's independence.⁴² He distinguished the USPSTF from ACIP and HRSA because, unlike those agencies, no federal officer appointed consistent with the Appointments Clause ratifies the decisions of the USPSTF, making its recommendations unenforceable.⁴³

While the federal government attempted to resolve this issue on appeal to the Fifth Circuit Court of Appeals by arguing that the USPSTF members are inferior officers whose decisions could be ratified by the Secretary of the Department of Health and Human Services (Secretary),⁴⁴ this argument appears unlikely to succeed. Alternatively, the federal government argued that the Fifth Circuit could preserve the ACA's preventive care mandate by severing the portion of the statute that limits the Secretary's ability to review the USPSTF's work.⁴⁵ This argument is designed to protect access to the USPSTF-recommended services as much as possible, but if successful, it risks allowing political interference to undermine the scientific independence and evidence-based grounding of the USPSTF's recommendations.

B. The USPSTF's Process for Developing Recommendations

The USPSTF's structure and process also facilitate development of independent, evidence-based recommendations that evolve as research generates new data about the benefits and harms of preventive services. The USPSTF comprises an independent group of sixteen national experts in prevention, evidence-based medicine, and primary care who all come from fields relevant to preventive care, including behavioral health, family medicine, geriatrics, internal medicine, pediatrics, obstetrics and gynecology, and nursing.⁴⁶ They serve four-year terms, are appointed by the Secretary, and are screened

³⁹Aparna Soni et al., *How Have ACA Insurance Expansions Affected Health Outcomes? Findings from the Literature*, 39 HEALTH AFFS. 371, 375 (2020) (“[S]ome types of medical care, such as preventive care and chronic disease management, may take longer to improve health.”).

⁴⁰42 U.S.C. § 299b-4(a)(6).

⁴¹*Braidwood Mgmt. v. Becerra*, 627 F. Supp. 3d 624, 655 (N.D. Tex. 2022); *Braidwood Mgmt. v. Becerra*, 666 F. Supp. 3d 613, 633 (N.D. Tex., 2023).

⁴²*Braidwood Mgmt.*, 627 F. Supp. 3d at 645-46.

⁴³*Id.*

⁴⁴See Opening Brief for the Federal Defendants at 17-18, *Braidwood Mgmt. v. Becerra*, 666 F. Supp. 3d 613 (N.D. Tex. 2023) (No. 23-10326).

⁴⁵*Id.* at 35, 39.

⁴⁶*About the U.S. Preventive Services Task Force: Our Members*, U.S. PREVENTIVE SERVS. TASK FORCE, <https://www.uspreventiveservicestaskforce.org/uspstf/index.php/about-uspstf/current-members> [<https://perma.cc/RWF3-4G7C>].

for any “conflicts of interest that could impair the scientific integrity” of the USPSTF’s work.⁴⁷ In addition to developing and updating recommendations, they are statutorily required to submit a yearly report to Congress identifying gaps in research on preventive services and “recommending priority areas that deserve further examination, including areas related to populations and age groups not adequately addressed by current recommendations.”⁴⁸

Additionally, the USPSTF employs a rigorous scientific process that, while slow, adds force to its recommendations. The process begins with the nomination of topics for new or updated recommendations, which any group or individual can submit.⁴⁹ The USPSTF has a systematic process for prioritization of topics nominated, which includes consideration of the prevalence of a condition and its burden on Black and other racial and ethnic minority groups.⁵⁰ An Evidence-Based Practice Center (EPC) then develops a draft research plan in collaboration with the USPSTF, which is posted on the USPSTF website for public comment.⁵¹ After the comment period, the USPSTF and the EPC review the comments and update the research plan based on any major themes that emerge and help clarify the plan.⁵² The EPC then gathers, reviews, and analyzes evidence related to the topic from peer-reviewed studies published in scientific journals, and develops a draft evidence review summarizing the EPC’s research.⁵³ The USPSTF reviews these findings and issues a draft recommendation statement, which is posted on their website for another public comment period.⁵⁴ The USPSTF and the EPC then consider all public comments and finalize both the evidence review and the recommendation statement, which are subsequently published on the USPSTF website and in a peer-reviewed journal.⁵⁵ In conducting its evidence review, the USPSTF “considers randomized controlled trials and well-conducted systematic reviews and meta-analyses as methodologically strongest.”⁵⁶ The USPSTF recommendations thus provide a platform for independent expert review of findings “from thousands of scientific studies every year on a range of preventive services,” with opportunity for feedback from providers and other members of the public, resulting in publicly available information about which preventive care services are recommended and the reasoning behind the recommendations.⁵⁷

C. USPSTF’s Recent Work to Improve Health Equity

This long review process generates recommendations grounded in comprehensive research, to which the USPSTF now brings a health equity lens. In 2021, the USPSTF committed to addressing systemic racism and health equity in every step of its recommendation development process.⁵⁸ For example, recognizing that most randomized clinical trials have enrolled predominantly White people, the USPSTF considered various ways to counteract that trend as it conducts its evidence review, such as by including contextual questions in its research plan or considering “robust, nonrandomized studies with more representative

⁴⁷*Id.*; *Nominate a New U.S. Preventive Services Task Force Member*, AGENCY FOR HEALTHCARE RSCH. & QUALITY, <https://www.ahrq.gov/cpi/about/otherwebsites/uspstf/nominate.html> [<https://perma.cc/9FU9-QUAD>].

⁴⁸ 42 U.S.C. § 299b-4(a)(2)(F) (2022).

⁴⁹Michael J. Barry et al., *Putting Evidence into Practice: An Update on the US Preventive Services Task Force Methods for Developing Recommendations for Preventive Services*, 21 ANNALS FAM. MED. 165, 165 (2023).

⁵⁰*Id.* at 166.

⁵¹USPSTF *Recommendations Development Process*, U.S. PREVENTIVE SERVS. TASK FORCE (May 2021), <https://www.uspreventiveservicestaskforce.org/uspstf/about-uspstf/task-force-resources/uspstf-recommendations-development-process> [<https://perma.cc/7RR9-SC9V>].

⁵²*Id.*

⁵³*Id.*

⁵⁴*Id.*

⁵⁵*Id.*

⁵⁶Barry et al., *supra* note 49, at 166.

⁵⁷USPSTF: *The Primary Care Clinician’s Source for Prevention Recommendations*, U.S. PREVENTIVE SERVS. TASK FORCE (May 2021), <https://www.uspreventiveservicestaskforce.org/uspstf/about-uspstf/task-force-resources/primary-care-clinicians-source-factsheet> [<https://perma.cc/69CP-KFB2>]; *USPSTF Recommendations Development Process*, *supra* note 51.

⁵⁸U.S. Preventive Servs. Task Force, *supra* note 38, at 2405.

populations.”⁵⁹ Upon identifying research gaps that adversely affect people of color, the USPSTF also planned to call for more funding and additional research to address those gaps.⁶⁰ As noted above, the USPSTF proposed to give higher priority to topics that have a “high potential for advancing health equity or addressing systemic racism.”⁶¹ More recently, the USPSTF adopted a “health equity framework” to translate this lens into action, including a detailed checklist for how the USPSTF intends to incorporate health equity considerations into every step of its recommendations development, dissemination, and implementation processes.⁶²

These, admittedly, are imperfect solutions. In fact, some have criticized the USPSTF’s process as too slow and insufficiently responsive to current health equity issues.⁶³ Members of Congress, Representatives Anna Eshoo (D-CA) and Frank Pallone (D-NJ), issued a joint statement to Secretary Xavier Becerra, urging him to take steps to decrease the time taken between the USPSTF’s recommendations to account for new preventive care interventions and research evidence.⁶⁴ Professional medical organizations have also criticized the USPSTF for not being aggressive enough in their efforts, exemplified by the American College of Radiology and Society of Breast Imaging’s response to the draft updated recommendations for mammography.⁶⁵ However, the very nature of the USPSTF’s approach lends itself to a long review process, which leads to recommendations that may not address the most current health equity issues, in large part due to remaining research gaps.⁶⁶

If the USPSTF’s current process of identifying topics for research, reviewing the evidence, and issuing recommendations continues — with consideration for health equity implications at every step — and any newly recommended services must be covered without cost-sharing, we expect to see movement toward more comprehensive preventive care that considers and advances health equity over time and across conditions. Recent examples of this process are illustrated by the recommendations made in the cancer and HIV spaces, as discussed below. But if *Braidwood* undermines access to coverage of any newly recommended preventive services by allowing health plans to impose cost-sharing for these services, or by compromising the USPSTF’s ability to operate free of ideological interference, the impact of these new recommendations could be blunted.

⁵⁹*Id.* at 2407-08. Other federal agencies have also recognized the challenge of addressing health inequities when research involving diverse subjects is limited and are taking steps to try to address this. For example, the NIH and the FDA are also including the requirement of diversity in the studies they fund and use to address systemic racism and improve health equity. See Richardae Araujo et al., *FDA Addresses Health Disparities Through Communication, Research, and Collaboration*, U.S. FOOD & DRUG ADMIN.: FDA VOICES, <https://www.fda.gov/news-events/fda-voices/fda-addresses-health-disparities-through-communication-research-and-collaboration> (last reviewed Apr. 30, 2019); Kathy Etz et al., *Minority Health and Health Disparities Research: Running the Marathon, Maintaining the Momentum*, NAT’L INST. HEALTH (Sept. 12, 2023), <https://www.nih.gov/ending-structural-racism/minority-health-health-disparities-research-running-marathon-maintaining-momentum> [https://perma.cc/4TLP-RJXH].

⁶⁰U.S. Preventive Servs. Task Force, *supra* note 38, at 2409.

⁶¹*Id.* at 2407.

⁶²See JENNIFER LIN ET AL., U.S. PREVENTIVE SERVS. TASK FORCE, AGENCY FOR HEALTHCARE RSCH. & QUALITY, NO. 23-05311-EF-1, HEALTH EQUITY FRAMEWORK FOR THE U.S. PREVENTIVE SERVICES TASK FORCE 6 (2023), <https://www.uspreventiveservicestaskforce.org/uspstf/sites/default/files/2023-12/health-equity-framework-report.pdf> [https://perma.cc/2A29-LZNN].

⁶³See, e.g., Michael J. Rovito et al., *A Call to Action to Review the USPSTF’s Recommendation for Testicular Self-Examination*, AM. J. MEN’S HEALTH, Sept. 2022, at 4 (calling for USPSTF to review its testicular cancer self-examination recommendation and to take other action, including reviewing their methods for making recommendations); Andrew T. Chan, *Aspirin and the USPSTF—What About Cancer?*, 8 JAMA ONCOLOGY 1393, 1393 (2022) (criticizing USPSTF’s reversal on the use of aspirin to prevent colorectal cancer as insufficiently nuanced).

⁶⁴Press Release, U.S. Rep. Anna G. Eshoo, Eshoo & Pallone Urge HHS to Reevaluate USPSTF Processes to Better Serve Health Care Needs (July 13, 2022), <https://eshoo.house.gov/media/press-releases/eshoo-pallone-urge-hhs-reevaluate-uspstf-processes-better-serve-health-care> [https://perma.cc/7K3Y-HM4Y].

⁶⁵ACR/SBI Statement on New USPSTF Breast Cancer Screening Recommendations, AM. COLL. RADIOLOGY (May 9, 2023), <https://www.acr.org/Media-Center/ACR-News-Releases/2023/ACR-SBI-Statement-on-New-USPSTF-Breast-Cancer-Screening-Recommendations> [https://perma.cc/ACW5-A222].

⁶⁶See U.S. Preventive Servs. Task Force, *supra* note 38, at 2409.

V. Cancer and HIV: Windows into How Upholding *Braidwood* Would Undermine Existing and Future Health Equity Gains

Cancer and HIV illustrate both the significant disparities that exist in the United States for preventable conditions and the importance of access to evidence-based services that can prevent those conditions or catch them earlier when they are more treatable. Due to the ACA's preventive care mandate and new research advances, access to more effective cancer and HIV preventive care has markedly improved since March 2010, when the ACA preventive care mandate went into effect — and the date for which any subsequent USPSTF recommendations would become unenforceable under Judge O'Connor's ruling.⁶⁷ New screening modalities and recommendations in the cancer space are making earlier diagnoses possible and increasing survival rates, while FDA-approved and USPSTF-recommended therapies to prevent HIV show huge promise in decreasing transmission. If the *Braidwood* decision is upheld and affordable access to recommended preventive services is diminished, these services, and others still to be developed, may become out of reach for many people in communities that already experience disparate health outcomes, hampering efforts to improve health equity.

A. Changes in Preventive Care Related to Cancer

In 2019, the overall age-adjusted cancer death rate in the United States declined by 32% (to 146 cancer deaths per 100,000 people) from its peak in 1991 (215 cancer deaths per 100,000 people).⁶⁸ This decrease was largely due to advances in early detection and treatment for some cancers as well as reductions in smoking.⁶⁹ While some advances in screening may be due to increased use of preventive services that have long been recommended, there have also been numerous changes in the USPSTF's recommendations, including improved recommendations based on new evidence that helps ensure preventive services are accessible to the populations that stand to benefit from them, as well as recommendations that consider new screening modalities that may be more effective or less invasive. Of the fifty-four preventive services that have received an A or B rating from the USPSTF,⁷⁰ and hence are eligible for coverage without cost-sharing, at least forty are new or have been updated since 2010; of those, eight relate directly to cancer prevention.⁷¹ Alongside these advances are numerous public and private endeavors to reach more people with cancer screenings and linkage to care, such as President Joe Biden's Cancer Moonshot, which seeks to reduce the cancer death rate by 50% over the next twenty-five years.⁷² Such efforts will have less impact if people who might otherwise be linked to the most up-to-date screenings and care are instead discouraged from using these services due to cost.

1. Colorectal Cancer

Preventive care for colorectal cancer has made significant strides since the USPSTF first started making recommendations regarding the disease in 1996.⁷³ Simultaneously, the rates of advanced colorectal

⁶⁷*Braidwood Mgmt. v. Becerra*, 666 F. Supp. 3d 613, 614 (N.D. Tex. 2023).

⁶⁸*Cancer Facts & Figures 2022*, AM. CANCER SOC'Y 4 (2022), <https://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/annual-cancer-facts-and-figures/2022/2022-cancer-facts-and-figures.pdf> [<https://perma.cc/2GCB-CKEF>].

⁶⁹*Id.*

⁷⁰*A & B Recommendations*, U.S. PREVENTIVE SERVS. TASK FORCE, <https://www.uspreventiveservicestaskforce.org/uspstf/recommendation-topics/uspstf-a-and-b-recommendations> [<https://perma.cc/NN9X-AZXX>].

⁷¹*See id.*

⁷²*White House Fact Sheet*, *supra* note 31.

⁷³*Compare Final Recommendation Statement Colorectal Cancer: Screening*, U.S. PREVENTIVE SERVS. TASK FORCE (Jan. 1, 1996), <https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/colorectal-cancer-screening-1996> [<https://perma.cc/D6TJ-E8EP>], with *Final Recommendation Statement Colorectal Cancer: Screening*, U.S. PREVENTIVE SERVS. TASK FORCE (May 18, 2021) [hereinafter *2021 Colorectal Cancer Recommendation Statement*], <https://www.uspreventiveservices.taskforce.org/uspstf/recommendation/colorectal-cancer-screening> [<https://perma.cc/43SF-9SMZ>].

cancer in patients sixty-five and older have decreased.⁷⁴ However, recent trends show an alarming rise in incidence of advanced stage colorectal cancer in patients younger than fifty, and disparities persist in morbidity and mortality among different racial groups.⁷⁵ Addressing these disparities through preventive care can improve colorectal cancer survival rates among marginalized communities.

For colorectal cancer, both the population for whom screening is recommended and the recommended screening modalities have changed since 2010.⁷⁶ In 2021, the USPSTF changed its colorectal screening recommendation to include screening for average risk adults between forty-five and forty-nine years as a B recommendation.⁷⁷ The lowering of the age of commencement of colorectal cancer screening from fifty (as was recommended before 2021) to forty-five means that 20 million additional people now have access to no-cost colorectal cancer screening.⁷⁸ Further, in 2021, the USPSTF included new preventive care modalities, such as stool DNA testing and fecal immunochemical tests, both noninvasive ways to screen for colorectal cancer.⁷⁹ Adding these modalities may increase the number of people who successfully access colorectal cancer screening, especially given that many patients choose not to access screening through colonoscopy due to its invasive and time-consuming nature.⁸⁰ These new modalities may be cost prohibitive, especially for lower income patients, if the patient must pay for them out of pocket.⁸¹

Though rates of colorectal cancer have been falling in general, the disease still disproportionately affects certain populations. Colorectal cancer mortality data show that Black people have the highest mortality rate at 16.8 per 100,000 people and Native Americans have a rate of 14.0 per 100,000 people (compared to a White mortality rate of 12.9 per 100,000 people).⁸² Black patients are about 20% more likely to get colorectal cancer and 40% more likely to die from it than other groups.⁸³ And while the causes of these disparities are complex, “recent evidence points to inequities in the access to and utilization and quality of colorectal cancer screening and treatment.”⁸⁴

⁷⁴See Rebecca L. Siegel et al., *Colorectal Cancer Statistics, 2023*, 73 CA: CANCER J. FOR CLINICIANS 233, 236 (2023).

⁷⁵*Id.* at 244.

⁷⁶*Compare Final Recommendation Statement Colorectal Cancer: Screening*, U.S. PREVENTIVE SERVS. TASK FORCE (Oct. 15, 2008), <https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/colorectal-cancer-screening-2008> [<https://perma.cc/KN2H-RQM9>] (recommendations before the March 2010 effective date of the ACA preventive care mandate), with *2021 Colorectal Cancer Recommendation Statement*, *supra* note 73 (recommendations after the March 2010 effective date of the ACA preventive care mandate).

⁷⁷*2021 Colorectal Cancer Recommendation Statement*, *supra* note 73.

⁷⁸A. Mark Fendrick & Nicholas Bagley, *Michigan Professors Offer Insights into What Braidwood Ruling Could Mean for Preventive Screening in Cancer Care*, 28 AM. J. MANAGED CARE SP353, SP354 (2023).

⁷⁹*Recommendation Statement Colorectal Cancer: 2021*, *supra* note 73.

⁸⁰See Jaspreet Shergill et al., *Fecal Immunochemical Test (FIT) Versus Colonoscopy: Does Knowing That a Positive FIT Requires a Follow-Up Colonoscopy Affect Initial Decision Making in the US?*, 27 PREVENTIVE MED. REPS. 1, 3 (2022).

⁸¹Stool DNA testing can range from \$581 to \$681, depending on whether you are willing to pay for the entire test upfront (in which case you can get a \$100 discount). Fecal immunochemical tests range between \$25 and \$89 depending on the manufacturer. See Monique M. Johnson, *Does Insurance Cover At-Home Colon Cancer Screening Tests?*, GOODRX HEALTH (Mar. 23, 2022), <https://www.goodrx.com/conditions/colon-cancer/at-home-colon-cancer-test>. It is important to note, however, that for patients who choose to get an at-home screening test, if their test comes back positive, they will need to get a colonoscopy. This colonoscopy will no longer be considered screening and instead will be considered diagnostic, and hence potentially subject to cost-sharing. See Danielle Underferth, *Colorectal Cancer and Race: What Black Men and Women Need to Know*, MD ANDERSON CANCER CTR. (Dec. 14, 2020), <https://www.mdanderson.org/cancerwise/colorectal-cancer-and-race--what-black-men-and-women-need-to-know.h00-159387468.html> [<https://perma.cc/9STQ-B89K>].

⁸²John M. Carethers, *Racial and Ethnic Disparities in Colorectal Cancer Incidence and Mortality*, 151 ADVANCES CANCER RSCH. 197, 226 (2022).

⁸³Dan Lea, *Health Disparities in Preventive Screenings for African Americans*, MAYO CLINIC NEWS NETWORK, (Feb. 3, 2023), <https://newsnetwork.mayoclinic.org/discussion/health-disparities-in-preventive-screenings-for-african-americans/> [<https://perma.cc/GP8F-7MAN>].

⁸⁴*2021 Colorectal Cancer Recommendation Statement*, *supra* note 73.

Moreover, even as colorectal cancer mortality rates in general are falling, rates of new diagnoses among younger patients are on the rise.⁸⁵ Colorectal cancer diagnoses in adults younger than fifty now account for roughly 10% of new colorectal cancer cases in the United States.⁸⁶ Distant stage early onset colorectal cancer, meaning the cancer is diagnosed after it has spread to distant parts of the body, is also on the rise, with the greatest incidence increase among young (ages 20–39) non-Hispanic Black people and Hispanics.⁸⁷ The reasons for these trends are not yet fully understood; thus, any policy responses needed, including further updates to the USPSTF's recommendations, remain to be determined based on the results of new research.

Upholding *Braidwood* would thus jeopardize access to newer modalities of colorectal cancer screening, and may threaten access to affordable screening among younger people, whose risk appears to be rising. Although the exact relationship between screening and racial disparities as well as the reasons for new trends in age of diagnosis are still being determined, decreasing affordable access to newly recommended screenings would inhibit efforts to reverse these statistics.

2. Lung Cancer

Lung cancer is the second most common cancer and the leading cause of cancer death in the United States.⁸⁸ In general, lung cancer has a poor prognosis, with an overall five-year survival rate of 20.5%.⁸⁹ However, earlier diagnosis makes a significant difference: when lung cancer is diagnosed at an early stage, the survival rate is 63%, whereas for late-stage diagnoses the survival rate is only 8%.⁹⁰

More Americans are surviving lung cancer than ever before,⁹¹ but significant racial disparities in early diagnosis, surgical treatment, and survival rates remain.⁹² For example, Black individuals with lung cancer are less likely to be diagnosed early, more likely to face barriers to treatment, and less likely to survive.⁹³ Data show that Black patients get lung cancer at earlier ages and are more likely to present with later stage disease than White patients.⁹⁴ Additionally, studies have suggested that even among tobacco users who smoke similar numbers of cigarettes per day, the risk of developing lung cancer is higher in certain racial and ethnic minorities.⁹⁵

The USPSTF is addressing the adverse impact of these disparities on health equity through recommendations regarding lung cancer screening and services to support smoking cessation. In 2013, the USPSTF found for the first time that screening with low-dose computed tomography (LDCT) had

⁸⁵Michael Masciadrelli, *Why Are Colorectal Cancer Rates Rising Among Younger Adults?*, YALE SCH. MED. (Mar. 29, 2023), <https://medicine.yale.edu/news-article/with-colorectal-cancer-rates-rising-among-younger-adults-a-yale-cancer-center-expert-explains-there-may-be-more-factors-behind-this-worrisome-trend/> [<https://perma.cc/XWQ9-JD7J>].

⁸⁶Charles Muller et al., *Disparities in Early-Onset Colorectal Cancer*, CELLS, 2021, at 1, 1018, 1018 (2021), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8146231/pdf/cells-10-01018.pdf> [<https://perma.cc/4ZCP-VNLW>].

⁸⁷Eric M. Montminy et al., *Shift in the Proportion of Distant Stage Early-Onset Colorectal Adenocarcinoma in the United States*, 31 CANCER EPIDEMIOLOGY, BIOMARKERS & PREVENTION 334, 335-337 (2022).

⁸⁸Alex H. Krist et al., *Screening for Lung Cancer: US Preventive Services Task Force Recommendation Statement*, 325 JAMA 962, 962-63 (2021).

⁸⁹*Id.*

⁹⁰*State of Lung Cancer: Lung Cancer Key Findings*, AM. LUNG ASS'N, <https://www.lung.org/research/state-of-lung-cancer/key-findings> [<https://perma.cc/E7E3-QLUF>]; see Sean Blandin Knight et al., *Progress and Prospects of Early Detection in Lung Cancer*, OPEN BIOLOGY, July 27, 2017, at *passim* (2017).

⁹¹*State of Lung Cancer: Lung Cancer Key Findings*, *supra* note 90.

⁹²*State of Lung Cancer: Racial and Ethnic Disparities*, AM. LUNG ASS'N, <https://www.lung.org/research/state-of-lung-cancer/racial-and-ethnic-disparities> [<https://perma.cc/V65B-UZ4S>].

⁹³*Id.*

⁹⁴Lisa L. Dwyer et al., *Disparities in Lung Cancer: A Targeted Literature Review Examining Lung Cancer Screening, Diagnosis, Treatment, and Survival Outcomes in the United States*, J. RACIAL & ETHNIC HEALTH DISPARITIES, May 19, 2023, at 4.

⁹⁵Christopher A. Haiman et al., *Ethnic and Racial Differences in the Smoking-Related Risk of Lung Cancer*, 354 NEW ENG. J. MED. 333, 341 (2006).

sufficient sensitivity and specificity to detect early-stage lung cancer.⁹⁶ The USPSTF therefore gave LDCT a B recommendation, making it eligible for zero cost-sharing under the ACA preventive care mandate.⁹⁷ This change significantly increased access to LDCT, given that it may be prohibitively expensive for many if it is not covered by insurance or substantial cost-sharing is imposed.⁹⁸ That recommendation covered people ages 55–80 with a thirty pack-per-year smoking history who currently smoked or had quit within the past fifteen years.⁹⁹

More recently, the USPSTF revised its lung cancer screening recommendation, making more people eligible for LDCT scans without cost-sharing. In 2021, the USPSTF amended its recommendation to cover those ages 50–80 with a twenty pack-per-year smoking history who currently smoke or have quit in the past fifteen years.¹⁰⁰ Given evidence that Black people who smoke are at greater risk of lung cancer than White people who smoke, this change is one strategy to help ameliorate racial disparities in screening eligibility.¹⁰¹ It will also help more women qualify for lung cancer screening because they tend to accumulate fewer pack-years than men.¹⁰² Based on the strong link between earlier diagnosis and the likelihood of surviving lung cancer, increasing access to lung cancer screening is an important health equity goal — but this access could face substantial setbacks if *Braidwood* is affirmed, given the absence of any USPSTF recommendation for LDCT screening prior to 2010.

Due to the strong correlation between smoking and lung cancer, the USPSTF has also addressed tobacco cessation preventive care strategies in its recommendations. Although the USPSTF has recommended tobacco cessation counseling services since the 1990s, in 2015 it issued its first recommendation specifically directing clinicians to “provide FDA-approved pharmacotherapy for cessation to nonpregnant adults who use tobacco.”¹⁰³ A systematic review of 136 trials concluded that all forms of nicotine replacement therapies increase the chances of quitting successfully by 50–60%.¹⁰⁴ Given the success of these therapies, making them available without cost-sharing is another way of facilitating access to potentially life-saving care, which can help people avoid an often fatal disease that disproportionately burdens communities of color.

3. Cervical Cancer

Cervical cancer used to be the leading cause of death due to cancer for women in the United States.¹⁰⁵ But, in recent decades, cervical cancer morbidity and mortality rates have decreased more than 50%, due

⁹⁶*Lung Cancer: Screening*, U.S. PREVENTIVE SERVS. TASK FORCE (Dec. 31, 2013), <https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/lung-cancer-screening-december-2013> [<https://perma.cc/SVW7-HDYD>].

⁹⁷*Id.*

⁹⁸See *CT Test for Hidden Lung Cancer Is Cost-Effective but Not Covered for Many Likely to Benefit*, HARV. HEALTH PUBL'G: HARV. HEALTH BLOG (Nov. 6, 2014), <https://www.health.harvard.edu/blog/ct-tests-hidden-lung-cancer-cost-effective-covered-many-likely-benefit-201411067506> [<https://perma.cc/68LU-KZMN>] (discussing the Center for Medicare & Medicaid Services' decision, as of 2014, not to cover lung cancer screening).

⁹⁹Virginia A. Moyer, U.S. Preventive Servs. Task Force, *Screening for Lung Cancer: U.S. Preventive Services Task Force Recommendation Statement*, 160 ANNALS INT. MED. 330, 330 (2014).

¹⁰⁰*Lung Cancer: Screening*, U.S. PREVENTIVE SERVS. TASK FORCE (Mar. 9, 2021), <https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/lung-cancer-screening> [<https://perma.cc/B48T-GCNG>].

¹⁰¹Krist, *supra* note 88, at 964.

¹⁰²*Id.*

¹⁰³*Compare Tobacco Smoking Cessation in Adults, Including Pregnant Women: Behavioral and Pharmacotherapy Interventions*, U.S. PREVENTIVE SERVS. TASK FORCE (Sept. 21, 2015), <https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/tobacco-use-in-adults-and-pregnant-women-counseling-and-interventions-september-2015> [<https://perma.cc/FPZ2-ZFU2>], with *Tobacco Use in Adults and Pregnant Women: Counseling and Interventions*, U.S. PREVENTIVE SERVS. TASK FORCE (Apr. 15, 2009), <https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/tobacco-use-in-adults-and-pregnant-women-counseling-and-interventions-2009> [<https://perma.cc/Z2YA-LT9M>].

¹⁰⁴Jamie Hartmann-Boyce et al., *Nicotine Replacement Therapy Versus Control for Smoking Cessation*, COCHRANE DATABASE SYSTEMATIC REV., May 31, 2018, at 1.

¹⁰⁵*Key Statistics for Cervical Cancer*, AM. CANCER SOC'Y (Aug. 23, 2023), <https://www.cancer.org/content/dam/CRC/PDF/Public/8599.00.pdf> [<https://perma.cc/GU98-5JLY>]. People of other gender identities can get cervical cancer, such as

in large part to an increase in screening.¹⁰⁶ When diagnosed at an early stage, cervical cancer has a 91% survival rate, compared to a 19% survival rate when diagnosed after spreading to a distant part of the body.¹⁰⁷ Despite this significant progress, cervical cancer disproportionately affects women of color. Black women have higher rates of new diagnoses than other women and Hispanic women have a higher death rate from cervical cancer in comparison to non-Hispanic women.¹⁰⁸

The USPSTF has made important updates in its cervical cancer screening recommendations and has issued a draft research plan that could make even greater progress, especially for women of color. The most recent USPSTF cervical cancer recommendation, published prior to 2010, was highly generalized: it stated only that cervical screening with a Pap smear was recommended for women who have been sexually active and have a cervix.¹⁰⁹ In 2012, the USPSTF eliminated the requirement of sexual activity for screening and added guidance on the use of high-risk human papillomavirus (hrHPV) testing in conjunction with a Pap smear for cervical cancer screening.¹¹⁰ The USPSTF further refined these recommendations in 2018, adding guidance on using hrHPV testing alone.¹¹¹ Adding hrHPV testing — a more sensitive screening tool than Pap smear alone — as a screening method either by itself or in combination with a Pap smear allows for less frequent testing and higher sensitivity.¹¹²

Research has found that “Black women are 30% more likely to develop and 60% more likely to die from cervical cancer than non-Hispanic White women.”¹¹³ The disparity in Black women’s survival rates is due in part to the fact that Black women are more likely to be diagnosed with more advanced stage disease.¹¹⁴ Hispanic women are also more likely develop cervical cancer and more likely to die from it.¹¹⁵ These racial and ethnic disparities have been attributed to a variety of factors, including unequal access to preventive care and follow-up after abnormal screening results.¹¹⁶

Due, at least in part, to the substantial racial disparities in cervical cancer incidence and mortality, the USPSTF published a draft research plan on cervical cancer screening for public comment in October

transgender men, non-binary people, and other persons assigned female at birth, as the USPSTF’s 2018 cervical cancer screening recommendation implicitly recognizes. See U.S. Preventive Servs. Task Force, *Screening for Cervical Cancer: US Preventive Services Task Force Recommendation Statement*, 320 JAMA 674, 675 (2018) (“This recommendation statement applies to all asymptomatic individuals with a cervix.”) However, because the literature, including that of the USPSTF, predominantly discusses cervical cancer using the term “women,” and some sources address cervical cancer in the context of women’s health, this Article will refer to cervical cancer among persons described as “women.”

¹⁰⁶*Screening Leads to Cervical Cancer Decline in the United States*, AM. CANCER SOC’Y CANCER ACTION NETWORK (Jan. 2020), <https://www.fightcancer.org/sites/default/files/FINAL%20-%20Cervical%20Cancer%20General%20Factsheet%20201.08.20.pdf> [<https://perma.cc/RVM3-873B>].

¹⁰⁷*Cervical Cancer Prognosis and Survival Rates*, NAT’L INST. HEALTH (Apr. 27, 2023), <https://www.cancer.gov/types/cervical/survival> [<https://perma.cc/3393-J3HM>].

¹⁰⁸*Health and Economic Benefits of Cervical Cancer Interventions*, CTRS. FOR DISEASE CONTROL & PREVENTION (Dec. 21, 2022), <https://www.cdc.gov/chronicdisease/programs-impact/pop/cervical-cancer.htm> [<https://perma.cc/ZLR9-U4SX>].

¹⁰⁹*Final Recommendation Statement: Cervical Cancer: Screening*, U.S. PREVENTIVE SERVS. TASK FORCE (Jan. 7, 2003), <https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/cervical-cancer-screening-2003> [<https://perma.cc/L83G-2Y6Q>].

¹¹⁰*Final Recommendation Statement: Cervical Cancer: Screening*, U.S. PREVENTIVE SERVS. TASK FORCE (Mar. 15, 2012), <https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/cervical-cancer-screening-2012> [<https://perma.cc/E8HV-5PPA>].

¹¹¹U.S. Preventive Servs. Task Force, *Screening for Cervical Cancer: US Preventive Services Task Force Recommendation Statement*, 320 JAMA 674, 675 (2018).

¹¹²*Id.* at 676-79, 81 (recognizing that there is a balance of risks and benefits with the use of cotesting because it has the highest rate of false positives, but that rate falls for women older than 30).

¹¹³Jennifer C. Spencer et al., *Racial and Ethnic Disparities in Cervical Cancer Screening from Three U.S. Healthcare Settings*, 65 AM. J. PREVENTIVE MED. 667, 668 (2023); see also AM. CANCER SOC’Y, CANCER FACTS & FIGURES FOR AFRICAN AMERICAN/BLACK PEOPLE 2022-2024, at 21 (2022), <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> [<https://perma.cc/6QBJ-ASF3>].

¹¹⁴AM. CANCER SOC’Y, *supra* note 113, at 21.

¹¹⁵Spencer et al., *supra* note 113, at 668.

¹¹⁶See *id.* at 668, 674; AM. CANCER SOC’Y, *supra* note 113, at 14, 21.

2021.¹¹⁷ The USPSTF proposed to evaluate the comparative effectiveness of cervical cancer screening strategies, including whether effectiveness varies among different populations as well as the accuracy and adherence rates to self-collected hrHPV vaginal samples (which may make screening more accessible for people who lack access to a primary care provider with whom they feel comfortable).¹¹⁸ The USPSTF also proposed to consider contextual questions that may help improve health equity in cervical cancer, including how “racism and other factors contribute to inequities in cervical cancer incidence and health outcomes” and “[whether] there [are] effective interventions that could redress existing inequities in morbidity and mortality from cervical cancer, such as strategies to improve screening rates and follow up to abnormal screening results.”¹¹⁹

HRSA currently has a cervical cancer screening recommendation that is similar to the 2012 USPSTF recommendation.¹²⁰ The major difference between the HRSA and the USPSTF recommendations concerns women ages thirty to sixty-five. For this group, the USPSTF allows for hrHPV testing alone, whereas HRSA recommends conducting hrHPV testing in conjunction with a Pap smear.¹²¹ Because Judge O’Connor’s decision in *Braidwood* did not strike down the enforceability of HRSA’s recommendations, if the decision is affirmed exactly as O’Connor held, people who benefit from HRSA’s recommendations will still have access to similar screenings as covered under the current USPSTF recommendation.¹²² However, because the *Braidwood* plaintiffs are continuing to challenge the enforceability of the HRSA and ACIP recommendations on appeal, HRSA’s recommendations remain at risk.¹²³ Moreover, even if O’Connor’s ruling in *Braidwood* is upheld as is (and not expanded to include HRSA and ACIP), access to any more advanced or targeted cervical cancer screening strategies that the USPSTF recommends based on the results of its research plan would not be guaranteed.

4. Breast Cancer

In 2013, the USPSTF recommended clearly for the first time that clinicians offer to prescribe risk-reducing medication such as tamoxifen to women who are at increased risk for breast cancer and at low risk for adverse medication effects.¹²⁴ The USPSTF also recommended that women with a family history of breast, ovarian, tubal, or peritoneal cancer, who are identified following a positive screen with their primary provider, undergo genetic counseling, and if indicated after counseling, genetic testing for increased risk of breast cancer.¹²⁵ The USPSTF updated and fine-tuned these recommendations in 2019.¹²⁶ Additionally,

¹¹⁷*Draft Research Plan, Cervical Cancer: Screening*, U.S. PREVENTIVE SERVS. TASK FORCE (Oct. 28, 2021), <https://www.uspreventiveservicestaskforce.org/uspstf/document/draft-research-plan/cervical-cancer-screening-adults-adolescents> [<https://perma.cc/YZJ4-XX3N>].

¹¹⁸*Id.*

¹¹⁹*Id.*

¹²⁰*Women’s Preventive Services Guidelines*, HEALTH RES. & SERVS. ADMIN., <https://www.hrsa.gov/womens-guidelines> [<https://perma.cc/3Z37-797D>].

¹²¹*Compare id. with* U.S. Preventive Servs. Task Force, *supra* note 111, at 63.

¹²²*Braidwood Mgmt. v. Becerra*, 627 F. Supp. 3d 624, 640, 655 (N.D. Tex. 2022).

¹²³*See* Brief of Appellees/Cross-Appellants at 57-60, *Braidwood Mgmt. v. Becerra*, 666 F. Supp. 3d 613 (N.D. Tex., 2023) (No. 23-10326).

¹²⁴*Breast Cancer: Medications to Reduce Risk*, U.S. PREVENTIVE SERVS. TASK FORCE (Sept. 15, 2013), <https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/breast-cancer-medications-for-risk-reduction-2013> [<https://perma.cc/B2JE-RLJS>].

¹²⁵*BRCA-Related Cancer Risk Assessment, Genetic Counseling, and Genetic Testing*, U.S. PREVENTIVE SERVS. TASK FORCE (Dec. 24, 2013), <https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/brca-related-cancer-risk-assessment-genetic-counseling-and-genetic-testing-2013> [<https://perma.cc/JN8B-P3QU>].

¹²⁶U.S. Preventive Servs. Task Force, *Risk Assessment, Genetic Counseling, and Genetic Testing for BRCA-Related Cancer: US Preventive Services Task Force Recommendation*, 322 JAMA 652, 660 (2019) [hereinafter *2019 BRCA Risk Assessment Recommendation*]. As with cervical cancer, people with gender identities other than women can be at risk for breast cancer. The USPSTF began to recognize this in its 2019 changes to the BRCA Risk Assessment Recommendation, which included the following language: “While this recommendation applies to women, the net benefit estimates are driven by biological sex (ie, male/female) rather than gender identity. Persons should consider their sex at birth to determine which recommendation best

the USPSTF recently updated its mammography recommendations, which included lowering the age for recommended screening.¹²⁷

Women who carry harmful genetic mutations in their BRCA1 and 2 genes are at a substantially increased risk of breast cancer.¹²⁸ According to the CDC, about 50% of women with a mutation in either BRCA1 or 2 will get breast cancer by the time they are seventy, versus 7% of women without the mutation.¹²⁹ Thus, early detection of the mutation, along with counseling and affordable preventive care, are essential. If a person with a family history of breast or related cancers must pay out of pocket for genetic testing, the cost alone may inhibit them from accessing preventive care.¹³⁰ Risk-reducing interventions for patients at a high risk of breast cancer may include intensive screening, medications like tamoxifen, and preventive mastectomy and salpingo-oophorectomy.¹³¹

In the United States, Black women are 40% more likely to die from breast cancer than their White counterparts, and they tend to get more aggressive cancers at younger ages.¹³² The USPSTF has therefore called for further research to assess diagnostic modalities and different screening strategies that could potentially help move the needle toward more equitable preventive care for breast cancer.¹³³ For example, research has shown that decreasing the starting age of biennial breast cancer screening to forty or forty-five has a greater reduction in mortality per mammogram compared with screening modalities that start at age fifty.¹³⁴ Given this research, on April 30, 2024, the USPSTF published an updated recommendation lowering the age that women should start getting biennial mammograms from fifty to forty years of age.¹³⁵

Moreover, the screening modality that has been historically recommended for breast cancer is 2D traditional digital mammography (“2D DM”) imaging.¹³⁶ But this screening method has led to false

applies to them.” *Id.* For the reasons discussed in footnote 105, *supra*, this Article uses the terminology “women” in its subsequent discussion of breast cancer except where otherwise noted.

¹²⁷*Final Recommendation Statement: Breast Cancer: Screening*, U.S. PREVENTIVE SERVS. TASK FORCE (Apr. 30, 2024), <https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/breast-cancer-screening#beci-recommendation-title-area> [<https://perma.cc/P5W8-EJSM>] [hereinafter 2024 *Final Breast Cancer Screening Recommendation*].

¹²⁸2019 *BRCA Risk Assessment Recommendation*, *supra* note 126, at 653.

¹²⁹*BRCA Gene Mutations*, CTRES. FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/cancer/breast/young_women/bringyourbrave/hereditary_breast_cancer/brca_gene_mutations [<https://perma.cc/LS4A-LX7D>].

¹³⁰*See Genetic Testing for Breast Cancer*, BREASTCANCER.ORG (Nov. 9, 2023, 1:56 PM), <https://www.breastcancer.org/genetic-testing> [<https://perma.cc/D9DU-HQUT>] (stating that the cost of genetic testing “can range from \$300 to \$5,000, depending on the type of test[ing]”).

¹³¹2019 *BRCA Risk Assessment Recommendation*, *supra* note 126, at 656.

¹³²AM. CANCER SOC’Y, *supra* note 113, at 14-15.

¹³³U.S. PREVENTIVE SERVS. TASK FORCE, UNDERSTANDING TASK FORCE DRAFT RECOMMENDATIONS: SCREENING FOR BREAST CANCER 2 (2023), https://www.uspreventiveservicestaskforce.org/files/breast-cancer/Breast_Cancer_DRS_Consumer_Guide.pdf [<https://perma.cc/MFA7-VEB5>].

¹³⁴AMY TRENTHAM-DIETZ ET AL., BREAST CANCER WORKING GROUP, CANCER INTERVENTION & SURVEILLANCE MODELING NETWORK, BREAST CANCER SCREENING WITH MAMMOGRAPHY: AN UPDATED DECISION ANALYSIS FOR THE U.S. PREVENTIVE SERVICES TASK FORCE 38 (2023), https://uspreventiveservicestaskforce.org/home/getfilebytoken/uRwAnYAnc4HCNY3j3h5v_z [<https://perma.cc/K7HW-UZAM>].

¹³⁵2024 *Final Breast Cancer Screening Recommendation*, *supra* note 127. The 2024 final recommendation for breast cancer statement also shifted its language to describe the target population as “cisgender women and all other persons assigned female at birth (including transgender men and nonbinary persons) 40 years or older at average risk of breast cancer.” *Id.* Prior to this recommendation, the 2016 recommendation described the target population as “asymptomatic women aged 40 years or older.” Albert L. Siu, U.S. Preventive Servs. Task Force, *Screening for Breast Cancer: U.S. Preventive Services Task Force Recommendation Statement*, 164 *Annals Internal Med.* 279, 279 (2016). This shift, which is more explicit than the language in the 2019 *BRCA Risk Assessment Recommendation*, see *supra* note 126, also reflects a move toward equity, in that it will help facilitate access to appropriate breast cancer screening for people who are at risk for breast cancer due to their sex at birth, but who do not identify as women.

¹³⁶*See Breast Cancer Screening and Early Detection*, SUSAN G. KOMEN FOUND., <https://www.komen.org/breast-cancer/screening/> [<https://perma.cc/GB3Y-Y7MA>].

negatives in women with dense breast tissue.¹³⁷ Studies have shown that Black women have higher breast density than White women.¹³⁸ Given the disparities in breast cancer mortality, there is growing concern that traditional imaging may not be sufficient to detect breast cancer early in this cohort of patients.¹³⁹ Thus, in 2023, the USPSTF issued an urgent call for more studies to show how other screening modalities, such as breast ultrasound or magnetic resonance imaging (MRI), might better diagnose women with dense breasts and lead to fewer false negatives as compared to 2D DM imaging.¹⁴⁰

The USPSTF's 2024 final recommendation for breast cancer screening also added digital breast tomosynthesis (DBT or "3D mammography") as a screening modality as long as it is paired with 2D DM or synthetic digital mammography.¹⁴¹ Although the 2024 final recommendation stated that the USPSTF had "found insufficient evidence on the effects of supplemental screening on health outcomes," such that it could not recommend supplemental screening with other modalities such as ultrasound or MRI, it called for additional research to understand the benefits and harms of these screenings for women with dense breasts.¹⁴² The USPSTF also called for more research aimed at understanding the racial differences in breast cancer morbidity and mortality — specifically why Black women suffer from higher rates of negative biomarker breast cancers, which are generally harder to treat and associated with worse health outcomes.¹⁴³

Upholding *Braidwood* could not only affect access to genetic screening, risk reducing medications, and other screening modalities for breast cancer, but could also blunt any impact of new research to understand and better address racial differences in breast cancer outcomes.

The above examples of advances in cancer prevention and accompanying USPSTF recommendations are only a few among many that have the potential to improve population health and reduce health disparities over the long term. Moreover, as discussed in Section IV, the USPSTF has brought a more deliberate health equity lens to its work in recent years. This lens is already beginning to impact the USPSTF's approach to research, as is particularly apparent in the context of its draft research plan for cervical cancer and calls for more research into breast cancer prevention. If the ACA's preventive service mandate is allowed to continue intact, this new focus on health equity in the USPSTF's recommendations could lead to promising improvements in access to preventive services that serve racial and ethnic minorities more effectively. But if *Braidwood* interferes — and people with private insurance are no longer guaranteed affordable access to preventive services, or if the USPSTF's independence is undermined — access to preventive care that is appropriate based on race, gender, and age for all patients, particularly for those who have been historically marginalized, will be at risk.

B. Changes in Preventive Care Related to HIV

There are approximately 1.2 million people living with the HIV in the United States, and the epidemic has a vastly disproportionate impact on certain marginalized populations, namely racial and ethnic

¹³⁷Wendie A. Berg et al., *Screening Algorithms in Dense Breast: AJR Expert Panel Narrative Review*, 216 AM. J. ROENTGENOLOGY 275, 276 (2021).

¹³⁸Anne Marie McCarthy et al., *Racial Differences in Quantitative Measures of Area and Volumetric Breast Density*, 108 J. NAT'L CANCER INST., Apr. 29, 2016, at 5.

¹³⁹See TRENTHAM-DIETZ ET AL., *supra* note 134, at 18.

¹⁴⁰See *Draft Recommendation Statement: Breast Cancer: Screening*, U.S. PREVENTIVE SERVS. TASK FORCE (May 9, 2023), <https://www.uspreventiveservicestaskforce.org/uspstf/document/RecommendationStatementDraft/breast-cancer-screening> [<https://perma.cc/MS6S-QF4V>]; Carol M. Mangione, *What Our Patients with Dense Breasts Deserve to Know*, MEDPAGE TODAY (May 25, 2023), <https://www.medpagetoday.com/opinion/second-opinions/104695> [<https://perma.cc/D284-JZTS>].

¹⁴¹2024 *Final Breast Cancer Screening Recommendation*, *supra* note 127.

¹⁴²See *id.*

¹⁴³*Id.*

minorities, MSM, and transgender women.¹⁴⁴ In 2021, Black people made up 40% of new HIV acquisitions, though they account for only 12% of the U.S. population.¹⁴⁵ Similarly, people who identify as Hispanic or Latino accounted for 29% of new HIV diagnoses, though they make up 18% of the U.S. population.¹⁴⁶ Notably, “MSM accounted for 70%... [of] estimated new HIV infections in 2021 and 86% of estimated infections among all males.”¹⁴⁷ The American South also bears a disproportionate burden of the HIV epidemic, with 52% of new HIV infections in 2021.¹⁴⁸ Black individuals are also more likely to develop advanced disease (AIDS) and to die from causes related to HIV than White individuals.¹⁴⁹ This disproportionate impact is due to many complex factors, including access to affordable, culturally competent care, racial and other biases among health care providers and within health care systems, and stigma that can impact people’s ability to seek HIV care.

There are bright spots, however, within this sobering picture. New infections are estimated to have declined 12% from 2017 to 2021, down to 32,100 per year.¹⁵⁰ One reason for this has been the increased uptake of PrEP,¹⁵¹ which reduces the risk of getting HIV from sex by about 99% and from injection drug use by at least 74%.¹⁵² From 2020 to 2021, PrEP use in the United States increased by 23%.¹⁵³ The cornerstone of PrEP is prescription medications to prevent HIV acquisition, which can take the form of daily oral pills or long-acting injectables.¹⁵⁴ But PrEP also includes a wraparound suite of services, including testing for sexually transmitted infections (STIs), liver and kidney function tests, lipid profiles, sexual health counseling, and substance use counseling.¹⁵⁵ These additional clinical services and lab tests help ensure that the person is being treated with the appropriate medication, not experiencing adverse effects of treatment, not coinfecting with STIs that can increase their risk of HIV, and not experiencing breakthrough HIV infection.¹⁵⁶ PrEP use has also been found to be

¹⁴⁴U.S. Statistics, HIV.gov (Dec. 7, 2023), <https://www.hiv.gov/hiv-basics/overview/data-and-trends/statistics/> [<https://perma.cc/ZL5T-QVMK>]; *The HIV/AIDS Epidemic in the United States: The Basics*, KFF (June 7, 2021), <https://www.kff.org/hiv/aids/fact-sheet/the-hiv-aids-epidemic-in-the-united-states-the-basics/> [<https://perma.cc/M59P-V7E5>].

¹⁴⁵U.S. Statistics, *supra* note 144.

¹⁴⁶*Id.*

¹⁴⁷*Id.*

¹⁴⁸*Id.*

¹⁴⁹*HIV/AIDS and African Americans*, DEP’T OF HEALTH & HUM. SERVS., OFF. OF MINORITY HEALTH, <https://minorityhealth.hhs.gov/hiv-aids-and-african-americans> [<https://perma.cc/FPV5-HALT>]; *AtlasPlus Tables*, NAT’L CTR. FOR HIV, VIRAL HEPATITIS, STD, & TB PREVENTION, CTRS. FOR DISEASE CONTROL & PREVENTION, <https://gis.cdc.gov/grasp/nchhstpatlas/tables.html> [<https://perma.cc/57SX-Q342>] (check “AIDS Deaths” in the indicator step; check “National” from the geography step; check “2021” in the year step; check “ages 13 years and older,” “Black/African American,” and “White” in the demographic step; then click “Create my Table”) (stating rate of death due to AIDS was higher in 2021 for African Americans as compared to white Americans ages 13 or older).

¹⁵⁰Press Release, Nat’l. Ctr. for HIV, Viral Hepatitis, STD, & TB Prevention, Ctrs. for Disease Control & Prevention, HIV Declines Among Young People and Drives Overall Decrease in New HIV Infections (May 23, 2023), <https://www.cdc.gov/nchhstp/newsroom/2023/2021-hiv-incidence.html> [<https://perma.cc/YF3Z-3VJX>].

¹⁵¹*PrEP for HIV Prevention in the U.S.*, NAT’L. CTR. FOR HIV, VIRAL HEPATITIS, STD, & TB PREVENTION, CTRS. FOR DISEASE CONTROL & PREVENTION, <https://www.cdc.gov/nchhstp/newsroom/fact-sheets/hiv/PrEP-for-hiv-prevention-in-the-US-factsheet.html> [<https://perma.cc/M72Y-P8NW>] (last reviewed Sept. 29, 2023).

¹⁵²*Pre-Exposure Prophylaxis (PrEP)*, CTRS. FOR DISEASE CONTROL & PREVENTION, <https://www.cdc.gov/hiv/risk/prep/index.html> [<https://perma.cc/CT2Q-VNWM>].

¹⁵³*AIDSVu Releases New Data Showing Significant Inequities in PrEP Use Among Black and Hispanic Americans*, AIDSVu (July 29, 2022), <https://aidsvu.org/prep-use-race-ethnicity-launch-22/> [<https://perma.cc/FS5X-BRTG>].

¹⁵⁴*About PrEP*, CTRS. FOR DISEASE CONTROL & PREVENTION, <https://www.cdc.gov/hiv/basics/prep/about-prep.html> [<https://perma.cc/G5WY-WU2L>] (last reviewed June 30, 2022).

¹⁵⁵*See* U.S. PUB. HEALTH SERV., CTRS. FOR DISEASE CONTROL & PREVENTION, *PREEXPOSURE PROPHYLAXIS FOR THE PREVENTION OF HIV INFECTION IN THE UNITED STATES – 2021 UPDATE: CLINICAL PRACTICE GUIDELINE 28* (2021), <https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf> [<https://perma.cc/CHY3-8C8Z>]; *see also* U.S. DEP’T OF LAB., *FAQS ABOUT AFFORDABLE CARE ACT IMPLEMENTATION PART 47*, at 3-4 (2021), <https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-47.pdf> [<https://perma.cc/F2L4-F38K>] (clarifying that for purposes of the USPSTF’s PrEP coverage recommendation, PrEP includes a suite of baseline and monitoring services).

¹⁵⁶*See* CTRS. FOR DISEASE CONTROL & PREVENTION, *supra* note 155, at 28-34.

associated with increased contact with the health care system, access to comprehensive medical services, and patient empowerment.¹⁵⁷

Given the extraordinary effectiveness of PrEP, the Ending the HIV Epidemic in the U.S. (EHE) plan — a federal initiative to address the epidemic — includes a prominent role for PrEP and other proven HIV interventions.¹⁵⁸ The goal of the EHE is a 75% reduction in new HIV infections by 2025 and a 90% reduction in new infections by 2030, with the hope of averting approximately 250,000 new infections.¹⁵⁹

PrEP medication alone can be expensive, depending on the regimen.¹⁶⁰ Moreover, the costs of quarterly lab tests and office visits associated with PrEP can add up to \$15,000 per year.¹⁶¹ Thus, it was significant when in June 2019, the USPSTF first gave PrEP a grade A recommendation, thereby requiring most private insurers to cover it without cost-sharing under the ACA.¹⁶² It updated its recommendation in August 2023 — fast by the USPSTF's standards¹⁶³ — to maintain the A grade and extend it to two additional medication formulations with FDA approval.¹⁶⁴ The Departments of Labor, Health and Human Services, and Treasury — the three federal agencies that enforce the ACA preventive services mandate — have also issued guidance making clear that the ancillary clinical and laboratory services necessary for access to PrEP are encompassed within the USPSTF's grade A recommendation.¹⁶⁵

PrEP prescriptions have increased steadily in recent years,¹⁶⁶ and evidence suggests that the mandate to cover PrEP without cost-sharing has played a role in this rise. Researchers have found that the number of people for whom cost was a barrier to PrEP has been cut approximately in half in recent years, due in part to Medicaid expansion and the ACA preventive care mandate for PrEP coverage.¹⁶⁷ More recently, researchers have identified a link between increased out-of-pocket costs for PrEP and the likelihood that a patient will abandon their prescription.¹⁶⁸ The study found that even small increases in out-of-pocket costs were associated with increases in abandonment rates.¹⁶⁹ Where out-of-pocket costs were greater than \$500, the study found a 42% abandonment rate.¹⁷⁰ Additionally, the study found a link between

¹⁵⁷Whitney Sewell et al., *Brief Report: "I Didn't Really Have a Primary Care Provider Until I Got PrEP": Patients' Perspectives on HIV Preexposure Prophylaxis as a Gateway to Health Care*, 88 J. ACQUIRED IMMUNE DEFICIENCY SYNDROMES 31, 34 (2021); Julia L. Marcus et al., *HIV Preexposure Prophylaxis as a Gateway to Primary Care*, 108 AM. J. PUB. HEALTH 1418, 1419 (2018).

¹⁵⁸*What is Ending the HIV Epidemic in the U.S.?*, HIV.GOV (Dec. 4, 2023), <https://www.hiv.gov/federal-response/ending-the-hiv-epidemic/overview/> [<https://perma.cc/9XZX-RJN7>]; *Expanding the Reach of Pre-Exposure Prophylaxis to End the HIV Epidemic*, CAREACTION NEWSL. (Ryan White HIV/AIDS Program, Health Res. Servs. Admin., Rockville, MD), Sept. 2020, <https://ryanwhite.hrsa.gov/sites/default/files/ryanwhite/resources/careaction-prep-newsletter.pdf> [<https://perma.cc/R8S2-E7AH>].

¹⁵⁹*Expanding the Reach of Pre-Exposure Prophylaxis to End the HIV Epidemic*, *supra* note 158.

¹⁶⁰Sarah Varney, *HIV Preventive Care Is Supposed to Be Free in the U.S. So, Why Are Some Patients Still Paying?*, KFF HEALTH NEWS (Mar 3, 2022), <https://kffhealthnews.org/news/article/prep-hiv-prevention-costs-covered-problems-insurance> [<https://perma.cc/BSC7-9WAN>]; Amy Killelea et al., *Financing and Delivering Pre-Exposure Prophylaxis (PrEP) to End the HIV Epidemic*, 50 J.L. MED. & ETHICS 8, 10 (2022).

¹⁶¹Varney, *supra* note 160.

¹⁶²U.S. Preventive Servs. Task Force, *Preexposure Prophylaxis for the Prevention of HIV Infection: US Preventive Services Task Force Recommendation Statement*, 321 JAMA 2203, 2204 (2019).

¹⁶³*Cf. Final Recommendation Statement: Prevention of Human Immunodeficiency Virus (HIV) Infection: Screening*, U.S. PREVENTIVE SERVS. TASK FORCE (June 11, 2019), <https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/human-immunodeficiency-virus-hiv-infection-screening> [<https://perma.cc/CD4H-TKQT>] (for comparison, USPSTF has taken 6 to 9 years between issuing each of its updates on HIV screening).

¹⁶⁴U.S. Preventive Servs. Task Force, *Preexposure Prophylaxis to Prevent Acquisition of HIV: US Preventive Services Task Force Recommendation Statement*, 330 JAMA 736, 738 (2023).

¹⁶⁵*See* U.S. DEP'T. OF LAB., *supra* note 155, at 3.

¹⁶⁶*See* AIDS.VU, *Deeper Look: PrEP*, <https://aidsvu.org/resources/deeper-look-prep/> [hereinafter *Deeper Look: PrEP*] [<https://perma.cc/YP4V-LEEK>].

¹⁶⁷Robert A. Bonacci et al., *Estimated Uncovered Costs for HIV Preexposure Prophylaxis in the US, 2018*, 42 HEALTH AFFS. 546, 546, 551-52 (2023).

¹⁶⁸Lorraine T. Dean et al., *Estimating the Impact of Out-of-Pocket Cost Changes on Abandonment of HIV Pre-Exposure Prophylaxis*, 43 HEALTH AFFS. 36, 39 (2024).

¹⁶⁹*Id.* at 40-41.

¹⁷⁰*Id.* at 43.

PrEP abandonment and increased likelihood of new HIV diagnosis.¹⁷¹ Researchers at Harvard and Yale have also found, through modeling, that if implementing the *Braidwood* ruling led to a reduction in PrEP coverage among MSM from 28% to 10%, 2,083 new HIV infections could be expected in 2024 (a conservative estimate).¹⁷² Their research also suggested that for every 1% decrease in the number of eligible MSM receiving PrEP, 114 new HIV infections could be expected in 2024.¹⁷³

The PrEP coverage mandate alone clearly has not resolved entrenched disparities in the HIV epidemic, but it is a step in the right direction. PrEP prescriptions are rising among Black, Hispanic or Latino, and White users, as well as among both men and women — even as extreme disparities persist in access.¹⁷⁴ Addressing these disparities requires sustained, multifaceted efforts to address the social determinants of health and to close remaining coverage gaps, particularly for people in states that have not expanded Medicaid. Likewise, enforcing the PrEP coverage mandate, particularly as it applies to recommended ancillary services, has also proved challenging; this has led some individuals who would otherwise access PrEP to forgo it.¹⁷⁵ But these challenges do not negate the critical role that ensuring comprehensive coverage for PrEP plays in our national efforts to end the HIV epidemic. Rather, they are a call to expand coverage and to reach more individuals in geographically accessible, culturally appropriate, and non-stigmatizing ways — challenges that would only increase if the mandate to cover PrEP without cost-sharing were rolled back.

V. Conclusion

Cancer and HIV are dramatic examples of conditions that are associated with significant health disparities, and that can be mitigated or avoided through preventive care — but they are not the only examples. Many other conditions are also associated with substantial health disparities, such as cardiovascular disease¹⁷⁶ and preeclampsia in pregnant patients.¹⁷⁷ If *Braidwood* is upheld, zero-cost coverage of preventive services for these and many other conditions would be at risk.¹⁷⁸

The ACA's guarantee that most people with private health insurance can access these preventive services at no cost is not in and of itself a solution to these disparities, which are highly complex and intertwined with racism and socioeconomic inequality. Rather, the preventive services mandate is a floor upon which researchers seeking to address health disparities can build, including through innovative

¹⁷¹*Id.* at 42.

¹⁷²A. David Paltiel et al., *Increased HIV Transmissions with Reduced Insurance Coverage for HIV Preexposure Prophylaxis: Potential Consequences of Braidwood Management v. Becerra*, OPEN F. INFECTIOUS DISEASES, Mar. 2023, at 2.

¹⁷³*Id.* at 3.

¹⁷⁴See *Deeper Look: PrEP*, *supra* note 166. As more White people have been able to access PrEP, inequity in access has grown, as reflected in PrEP-to-Need Ratios (the number of PrEP users compared to the number of new HIV diagnoses, this measurement helps assess whether PrEP use is preventing new HIV infections) that are growing faster for White people than for Black or Hispanic people. See *id.* However, this statistic, rather than being an argument against no-cost PrEP, further reveals the need to remove other barriers to PrEP access, such as the Medicaid coverage gap, as discussed in the text *infra*.

¹⁷⁵Jessica Bartlett, *Despite Federal Rules, HIV Prevention Drug Still Comes with Costs*, BOS. GLOBE (Jan. 8, 2023, 4:58 PM), <https://www.bostonglobe.com/2023/01/08/metro/despite-federal-rules-hiv-prevention-drug-still-comes-with-costs/> [https://perma.cc/Y5WP-2VY7].

¹⁷⁶See U.S. Preventive Servs. Task Force, *Statin Use for the Primary Prevention of Cardiovascular Disease in Adults: US Preventive Services Task Force Recommendation*, 328 JAMA 746, 748 (2022) (noting that Black adults have the highest rate of cardiovascular disease and the lowest use of statins).

¹⁷⁷See U.S. Preventive Servs. Task Force, *Aspirin Use to Prevent Preeclampsia and Related Morbidity and Mortality, US Preventive Services Task Force Recommendation Statement*, 326 JAMA 1186, 1186, 1190 (2021) (noting that the rate of maternal death is higher among Black and Hispanic women, and that there is a lack of research cohorts that include women who are at the highest risk for preeclampsia namely Black and Hispanic women).

¹⁷⁸See *Preventive Services Impacted by Braidwood v. Becerra*, AM. LUNG ASS'N (June 23, 2023), <https://www.lung.org/getmedia/7ee72d9c-ee78-4a77-a419-9bfa87e69acd/Braidwood-Preventive-Services-Chart.pdf> [https://perma.cc/5LE6-MLCB] (identifying a range of conditions with USPSTF recommendations post-March 2010, such that their coverage may be impacted if *Braidwood* is affirmed).

strategies to reach and support systemically marginalized communities in accessing care, and through efforts to ensure that preventive services recommendations are responsive to the needs of populations disproportionately impacted by preventable conditions. As we have discussed, both types of innovations presume that individuals will not be discouraged from utilizing care that is recommended for them due to cost.

Much more work remains necessary to ensure that lifesaving preventive services for cancer, HIV, and other conditions reach the populations that stand to benefit the most from them. Affirming *Braidwood* — and setting federal regulation of coverage of preventive services back more than a decade — would likely impede that progress.

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