No. 24-316

In the Supreme Court of The United States

ROBERT F. KENNEDY, JR., SECRETARY OF HEALTH AND HUMAN SERVICES, *et al.*,

Petitioners,

v.

BRAIDWOOD MANAGEMENT, INC., *et al.,*

Respondents.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT

BRIEF OF *AMICI CURIAE* HIV AND HEPATITIS POLICY INSTITUTE, ADAP ADVOCACY ASSOCIATION, AIDS ALABAMA, INC., *et al.*, IN SUPPORT OF PETITIONERS

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AMERICAN ACADEMY OF HIV MEDICINE, CARING AMBASSADORS PROGRAM, INC., COMMUNITY ACCESS NATIONAL NETWORK, COMMUNITY LIVER ALLIANCE, COMMUNITY RESEARCH INITIATIVE OF NEW ENGLAND, INC. d/b/a COMMUNITY RESOURCE INITIATIVE, FAST-TRACK CITIES INSTITUTE, FRANNIE PEABODY CENTER, GEORGIA AIDS COALITION, GLOBAL LIVER INSTITUTE, HEP B UNITED, HEPATITIS B FOUNDATION, HOUSING WORKS, INC., INTERNATIONAL ASSOCIATION OF PROVIDERS OF AIDS CARE, LATINO COMMISSION ON AIDS, NATIONAL MINORITY AIDS COUNCIL, SEXUALITY INFORMATION AND EDUCATION COUNCIL OF THE UNITED STATES d/b/a SIECUS, AND VIVENT HEALTH

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

Cases

Statutes and Regulations

Other Authorities

STATEMENT OF INTEREST OF *AMICI CURIAE*

Amicus Curiae HIV and Hepatitis Policy Institute is a non-profit advocacy organization committed to advancing policies that support the prevention and treatment of human immunodeficiency virus ("HIV"), acquired immunodeficiency syndrome ("AIDS"), viral hepatitis and other health conditions. The Institute actively monitors policy developments that affect healthcare access, ensuring that individuals and communities affected by HIV and hepatitis are informed and engaged in discussions about policies impacting their well-being. Through education and advocacy, the organization works to inform policymakers and the media about efforts to end HIV and hepatitis in the United States while striving to improve access to high-quality, affordable healthcare for individuals living with or at risk of serious or chronic conditions. Additionally, the Institute focuses on securing necessary funding, promoting effective programs and shaping policies that drive meaningful progress in the fight against HIV and viral hepatitis.[1] The 19 other *amici*, listed in Appendix A, are organizations that work globally, nationally, regionally, state-wide and locally towards the elimination of HIV and/or viral hepatitis by providing or advocating for HIV testing,

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[1] No counsel for a party authored this brief in whole or in part, and no such counsel or party made a monetary contribution intended to fund the preparation or submission of this brief. No person other than amici curiae or their counsel made a monetary contribution to this brief's preparation or submission.

hepatitis B & C testing and/or HIV pre-exposure prophylaxis (PrEP) and advocating on behalf of people and communities affected by HIV and viral hepatitis. All share an interest in the provision of HIV and hepatitis preventive services affected by this case, including PrEP.

As such, *amicus* HIV and Hepatitis Policy Institute, together with these 19 other *amici*, have a crucial interest in maintaining patient access to clinical interventions that facilitate prevention and early detection of HIV, viral hepatitis and other health conditions.

SUMMARY OF ARGUMENT

The United States Preventive Services Task Force ("Task Force") and its recommendations have been essential to the prevention of HIV, hepatitis and many other infectious and chronic diseases for millions of Americans. After the passage of the Affordable Care Act ("ACA"), Task Force's recommendations became a critical first step in ensuring effective interventions are covered by health insurance. A wholesale invalidation of the coverage requirement for Task Force's recommendations would strike a critical, unnecessary and costly blow to the battle to end HIV, hepatitis and other infectious diseases.

This brief details the impact of HIV and hepatitis in the U.S., emphasizing that these are infectious diseases spread by viruses which can and will spread to any person unless prevented from doing so. Removing access to evidence-based preventive measures will have a devastating impact, not only on those at risk for acquiring HIV and hepatitis, but also the population at-large.

We then contend that the Fifth Circuit's decision relied on a fundamental misreading of the Task Force's enabling statute and a lack of understanding of how the executive branch has already carried out its oversight function over the recommendations of the Task Force. If properly understood, the Fifth Circuit could not have found that the members of the Task Force were principal officers in violation of the Appointments Clause. They are, in fact, inferior officers whose independence is

solely limited to the evidence-based process by which they make their recommendations. For these reasons, we urge this Court to reverse the lower court's decisions invalidating Task Force's recommendations.

ARGUMENT

I. HIV and Hepatitis Affect Millions of Americans of All Demographics, and Weakening Bipartisan Efforts to End Their Transmission Will Have Catastrophic Consequences.

The fight against HIV/AIDS is one of the most significant public health battles of the modern era. For decades, false assumptions about how the virus spread and who was at risk impeded efforts to prevent transmission and provide treatment. The devastating toll of this delay is evident in the 700,000 American lives lost and the 1.2 million people still living with HIV. *The HIV/AIDS Epidemic in the United States: The Basics*, KAISER FAM. FOUND. (Aug. 16, 2024), https://tinyurl.com/556bahnt.

Both Republican and Democratic presidential administrations and Congresses have prioritized HIV prevention, treatment and research through decades of bipartisan efforts. These collective efforts have produced scientific advancements in screening, treatment and prevention of this disease and simultaneously expanded access to the same.

These advancements have fundamentally changed the trajectory of HIV, with the evolution of

routine screening to enable early detection to the advent of pre-exposure prophylaxis (PrEP) which promises nearly 100% effectiveness in the prevention of HIV and is the central object of Respondents' complaint. Today, we are closer than ever to ending HIV's painful 44-year ordeal.

The Patient Protection and Affordable Care Act ("ACA") requires that insurers cover Task Force-recommended preventive services without cost-sharing. The Task Force, which has existed since 1984, made evidence-based preventive care recommendations before the enactment of the ACA. Congress incorporated the Task Force's recommendations into the ACA to ensure essential preventive services were covered. This requirement assures access to HIV screening and PrEP for millions of Americans at risk of acquiring HIV. Stripping away this access will undermine the decades-long, bipartisan fight against the epidemic.

Today, while HIV is at its lowest ebb in the United States, there still are 32,000 new transmissions and 13,000 deaths annually. *Id.* This is unacceptable in our modern era. Without continued access to the no-cost prevention assured under the ACA and consequent new transmissions, our nation will witness a reversal of decades of progress as HIV resurges.

Viral hepatitis stands alongside HIV/AIDS as one of our nation's most critical and under-addressed public health challenges. Historical misconceptions about transmission routes and affected populations have significantly impeded prevention and treatment

efforts, resulting in approximately 3.3 million Americans living with chronic hepatitis B or C. HHS, VIRAL HEPATITIS: NATIONAL STRATEGIC PLAN 1 (2020), https://tinyurl.com/3mrtejzw. While implementation of the bipartisan Viral Hepatitis National Strategic Plan has driven meaningful progress, hepatitis B ("HBV") and hepatitis C ("HCV") still claim roughly 14,500 American lives each year. *Hepatitis B Surveillance*, CDC (Apr. 4, 2024), https://tinyurl.com/msnj6nav; *Hepatitis C Surveillance*, CDC (Apr. 4, 2024), https://tinyurl.com/6rspxpy4. The scientific community has achieved remarkable breakthroughs, developing curative treatments for hepatitis C and a highly effective vaccine and treatment for hepatitis B. HHS, VIRAL HEPATITIS: NATIONAL STRATEGIC PLAN 1 (2020), https://tinyurl.com/3mrtejzw.

The ACA's preventive services coverage requirement has dramatically expanded access to hepatitis screening and vaccination. Early diagnosis through screening is crucial, given that new hepatitis C infections have nearly tripled in the past decade. A. Blythe Ryerson, et al., *Vital Signs: Newly Reported Acute and Chronic Hepatitis Cases – United States, 2009-2018,* 69 MMWR 399 (2020). Removing these coverage guarantees would severely compromise efforts to eliminate viral hepatitis as a public health threat.

A. HIV Is a Public Health Crisis that Transcends All Demographics and Affects Millions of Americans.

More than 700,000 lives have been lost to HIV/AIDS and 1.2 million people are living with HIV in the United States, highlighting that the fight against the disease is one of the most significant public health battles of the modern era. *The HIV/AIDS Epidemic in the United States: The Basics*, KAISER FAM. FOUND. (Aug. 16, 2024), https://tinyurl.com/556bahnt. For years, false assumptions about how the virus spread and who was at risk impeded efforts to prevent transmission and provide treatment.

First identified in 1981, HIV initially appeared in a cluster of patients experiencing rare diseases such as pneumocystis pneumonia and Kaposi's sarcoma. M.S. Gottlieb, et al., *Pneumocystis Pneumonia - Los Angeles*, 30 MMWR 250, 250 (1981); CDC, *A Cluster of Kaposi's Sarcoma and Pneumocystis carinii Pneumonia Among Homosexual Male Residents of Los Angeles and range* [sic] *Counties, California*, 31 MMWR 305, 305 (1982). These were the consequences of opportunistic infections that were attacking the patients' immune systems.[2] Before it was well understood, the virus

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[2] Opportunistic infections are illnesses that occur more frequently or become more severe in people with HIV due to their weakened immune systems. *What is an Opportunistic Infection?*, HIV.GOV (Aug. 16, 2021), https://https://tinyurl.com/4m2pd9ap.

spread uncontrollably. Jacqueline Ortiz, *Silence from the Great Communicator: The Early Years of the AIDS Epidemic Under the Reagan Administration*, 4 SWARTHMORE UNDERGRADUATE HIST. J. 76, 81 (2023). Early attempts at treatment were ineffective and death was an inevitability for its sufferers. Within the first ten years of the epidemic, HIV/AIDS was transmitted to one million people and claimed over 100,000 lives. CDC, *Current Trends Mortality Attributable to HIV Infection/AIDS -- United States, 1981-1990*, 40 MMWR 41, 41 (1991).

In the early days of the epidemic, HIV was unfortunately termed "Gay-Related Immune Deficiency" ("GRID"), creating a misconception that HIV was confined to the gay community and that sexual orientation was a root cause. *A Timeline of HIV and AIDS: 1982*, HIV.GOV, https://tinyurl.com/4sfcxhmx (last accessed Feb. 24, 2025). This misclassification obscured the reality that HIV can infect anyone, regardless of sexual orientation. This framing established a lasting connection between people living with HIV and other stigmatized populations, which continues to hinder efforts to expand testing, prevention and treatment against the virus.

As more HIV/AIDS cases surfaced—especially among hemophiliacs, infants and women—it became clearer that HIV was a public health crisis affecting a

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See AIDS-Defining Illnesses, MERCK MANUAL, https://tinyurl.com/5fnnmu2j (last visited Feb. 24, 2025).

broad swath of society. Indeed, the disease we would come to term HIV/AIDS would choose casualties of all genders, sexual orientations, ages, races, religions and political persuasions. It has taken the lives of authors, poets, actors, doctors, nurses, elected officials, lawyers and judges. Thessaly La Force, *Those We Lost to the AIDS Epidemic*, N.Y. TIMES STYLE MAG. (Apr. 14, 2018), https://tinyurl.com/2bm2euwp; The Associated Press, *Jon Hinson, 53, Congressman and Then Gay-Rights Advocate*, N.Y. TIMES (July 26, 1995), https://tinyurl.com/4hadeex9.

Hemophiliacs were among the hardest hit, as many received contaminated blood through regular transfusions before the threat was fully understood. CDC, *Update: Acquired Immunodeficiency Syndrome (AIDS) in Persons with Hemophilia*, 33 MMWR 589, 589 (1984), https://tinyurl.com/3aba6bbn. The most prominent of these victims was Ryan White, a teenager from Indiana who became a national symbol for HIV/AIDS awareness. *Who Was Ryan White?*, HRSA (Feb. 2022), https://tinyurl.com/4zexpkm8. Diagnosed at age 13 in 1984, he fought against discrimination after being barred from school. *Id.* His struggle helped shift public perception and paved the way for national policies to provide critical medical support to people living with HIV. *Id.*

Other stories—from a Catholic nun who became infected after a surgery to high-profile figures like NBA star Magic Johnson, who publicly disclosed his HIV diagnosis in 1991—further shattered the myth that HIV was limited to certain communities. Dan Morain, *'It Was So Unnecessary': S.F. Nun*

Succumbs After Contracting AIDS from a Blood Transfusion, L.A. TIMES (Feb. 14, 1985), https://tinyurl.com/w7k32t8w; Richard Stevenson, *BASKETBALL; Magic Johnson Ends His Career, Saying He Has AIDS Infection*, N.Y. TIMES (Nov. 8, 1991), https://tinyurl.com/5n6jtbad.

The misconception that HIV transmission is confined to certain "high-risk" activities is not only flawed but dangerously misleading, failing to recognize the virus's ability to affect Americans across all demographics. Lisa A. Eaton, et al., *Stigma and Conspiracy Beliefs Related to Pre-exposure Prophylaxis (PrEP) and Interest in Using PrEP Among Black and White Men and Transgender Women Who Have Sex with Men*, 21 AIDS BEHAV. 1236, 1244 (2017). The Respondents' claims perpetuate a fundamental misunderstanding of HIV transmission. Despite their contentions, HIV transmission can occur in heterosexual marriages, and it can spread from mother to child during pregnancy, childbirth or breastfeeding. Nicole Crepaz, et al., *Examination of HIV Infection Through Heterosexual Contact with Partners Who Are Known to be HIV Infected in the United States, 2010–2015*, 31 AIDS 1641, 1642 (2017); *Preventing Perinatal Transmission of HIV*, HIV.GOV (Feb. 13, 2025), https://tinyurl.com/yc56s975. HIV continues to affect a broad spectrum of Americans, including young people and heterosexual women and men who never considered themselves as "at risk." In 2022, young people aged 13 to 24 made up 20% of new infections, while heterosexual women accounted for about 15% of new HIV diagnoses in the U.S. *U.S. Statistics*, HIV.GOV (Feb. 14, 2025),

https://tinyurl.com/y5ycs3t8. That same year, heterosexual men accounted for 6% of new HIV transmissions—approximately 2,100 cases. *Id.*

B. Bipartisan Commitments Have Driven Advancements in HIV Screening, Treatment and Prevention and Continued Access Is Essential to Sustain Progress.

HIV prevention and treatment have long been bipartisan priorities in the United States, with federal initiatives spanning multiple administrations and Congresses. These initiatives began in the Ronald Reagan administration and have continued and expanded in scope.

The Ryan White CARE Act, signed by President George H.W. Bush, established the largest federally funded program for low-income Americans with HIV. President Bill Clinton's administration continued to expand federal initiatives related to HIV/AIDS-related research. President George W. Bush launched PEPFAR in 2003, the largest single-nation commitment to fighting HIV globally. The National HIV/AIDS Strategy, first developed under President Barack Obama, continued under subsequent administrations. In 2019, President Donald J. Trump launched the Ending the HIV Epidemic ("EHE") initiative. In 2023, Congress reenacted PEPFAR. Under President Trump's second term, Secretary of State Marco Rubio upheld access to HIV care globally. Most recently, Secretary of Health and Human Services Robert F. Kennedy Jr. pledged continued support for HIV prevention, including

PrEP, and treatment, reinforcing the bipartisan commitment to ending the epidemic.

Taken together, these efforts underscore a longstanding tradition of bipartisan cooperation to combat HIV/AIDS, ensuring that prevention, testing, treatment and support services remain a national priority.

In the 44 years since HIV was identified, near-miraculous scientific advancements have dramatically reduced deaths, symptom severity and transmission associated with HIV/AIDS. Today, HIV screening, treatment and prevention form a continuum of care. *HIV Care Continuum*, HIV.GOV (Oct. 27, 2022), https://tinyurl.com/mr24sbz6. Comprehensive access to all parts of the continuum is essential to reducing HIV transmission—screening ensures HIV is detected as early as possible; treatment suppresses HIV infection to reduce risk of onward transmission; and PrEP lowers the risk of acquiring HIV. Zihao Li, et al., *Vital Signs: HIV Transmission Along the Continuum of Care—United States, 2016*, 68 MMWR 267, 269 (2019); Sagar Kumar, et al., *Reviewing PrEP's Effect on STI Incidence Among Men Who Have Sex with Men—Balancing Increased STI Screening and Potential Behavioral Sexual Risk Compensation*, 25 AIDS BEHAV. 1810, 1810 (2021).

Recognizing the importance of early detection, the Task Force recommended HIV screening for at-risk groups, including pregnant women, in 1996. *Human Immunodeficiency Virus (HIV) Infection: Screening, 1996*, USPSTF (Jan. 1, 1996),

https://tinyurl.com/43rb6muy. In 2013, it expanded screening to all individuals aged 15 to 65 and those at higher risk, ensuring health plan coverage and broader access to testing. Screening is the only way to confirm HIV status, and, therefore, the essential gateway to treatment and long-term health. Without it, individuals cannot access life-saving antiretroviral therapy or take prophylactic medication to prevent transmission. Among those who do get tested and receive a positive diagnosis, 80% are connected to care within one month. *National HIV Prevention and Care Outcomes*, CDC (Feb. 7, 2025), https://tinyurl.com/2cd3awp4.

Regular testing is essential for early diagnosis, as undiagnosed individuals are more likely to transmit HIV. *HIV Testing*, HIVINFO.NIH.GOV (May 24, 2024), https://tinyurl.com/3pxdd9yw. Studies show that those aware of their HIV-positive status take proactive steps to prevent further transmission of the virus. *HIV Testing in the United States*, KAISER FAM. FOUND. (June 24, 2022), https://tinyurl.com/bd9pfumc. Screening of sexually transmitted infections is also mutually beneficial in the prevention of HIV. A person with a sexually transmitted infection is up to five times more likely to acquire HIV and is at increased risk of transmitting HIV to others. CDC, *Reversing the Rise in STIs: Integrating Services to Address the Syndemic of STIs, HIV, Substance Use, and Viral Hepatitis* (Mar. 22, 2023), https://tinyurl.com/ywkrvsjs.

Despite the Task Force's recommendations and strengthened health insurance coverage of screening, 13% of people with HIV remain undiagnosed. *HIV*

Declines Among Young People and Drives Overall Decrease in New HIV Infections, CDC (May 23, 2023), https://tinyurl.com/3fh55vut.

Should this Court remove the requirement that health insurance cover Task Force-recommended HIV screening, the number of undiagnosed individuals—who will not know to seek treatment and will, therefore, unknowingly transmit the virus—will inevitably increase.

While there is still no cure for HIV, the path to today's highly effective treatments and preventive interventions has been marked by decades of steady, incremental progress. *Id.* Advancements in HIV treatment paved the way for revolutionary methods for preventing the infection altogether. Today, there are more than fifty approved HIV medications and three approved PrEP products, with several more in the drug development pipeline. *FDA-Approved HIV Medicines*, HIVINFO.NIH.GOV (July 31, 2024), https://tinyurl.com/3yspja69; *Pre-Exposure Prophylaxis*, HIV.GOV (Feb. 7, 2025), https://tinyurl.com/y2v499un.

The realization that viral suppression could prevent onward transmission sparked the prophylactic use of ART for HIV-negative individuals to preempt infection altogether. Known as PrEP, this has become one of the most effective and widely accepted tools for HIV prevention, making HIV more preventable than ever before. *Reducing New HIV Infections*, HIV.GOV (Jan. 31, 2025), https://tinyurl.com/3udk2cuj.

Since FDA approval of the first daily oral PrEP regimen in 2012, the range of available PrEP delivery methods has expanded. Building on the success of the daily oral pill, the FDA recently approved a long-acting injectable option administered every eight weeks. *FDA Approves First Injectable Treatment for HIV Pre-Exposure Prevention*, FDA (Dec. 20, 2021), https://tinyurl.com/327k34de. PrEP's effectiveness is deeply tied to adherence: when taken as prescribed, PrEP is nearly guaranteed to prevent HIV, reducing the risk of acquiring the virus by 99%. *Pre-Exposure Prophylaxis*, HIV.GOV (Feb. 7, 2025), https://tinyurl.com/y2v499un. Therefore, by eliminating the need for daily adherence, injectable PrEP provides longer-lasting protection, reducing the risk of missed doses and enhancing overall effectiveness in preventing HIV transmission. Emerging options like lenacapavir, a twice-yearly injectable currently pending approval at the FDA, have shown 100% effectiveness in preventing HIV, signaling a promising future for even more durable and accessible prevention methods—should access to PrEP remain unfettered. *Gilead's Twice-Yearly Lenacapavir Demonstrated 100% Efficacy and Superiority to Daily Truvada for HIV Prevention*, GILEAD (June 20, 2024), https://tinyurl.com/ycycb5ck. Seven years after the first FDA approval of PrEP, the Task Force issued its highest endorsement for oral PrEP in 2019, awarding a Grade A recommendation for the intervention. U.S. Preventive Servs. Task Force, *Preexposure Prophylaxis to Prevent Acquisition of HIV*, 330 JAMA 736, 736 (2023). The recommendation was for individuals at increased risk, including men who have sex with men,

heterosexually active men and women and others based on specific risk factors. *Id.* As awareness and access expanded, PrEP usage increased significantly, with approximately 31.4% of those recommended for PrEP receiving a prescription in 2022—up from just 3% in 2015. *Charts*, CDC, https://tinyurl.com/yp25hsb4 (last visited Feb. 24, 2025).

In 2023, the Task Force reaffirmed its support for PrEP, expanding its recommendation to include new options, specifically the injectable form. *Prevention of Human Immunodeficiency Virus (HIV) Infection: Preexposure Prophylaxis*, USPSTF (June 11, 2019), https://tinyurl.com/4r9k78jv.

PrEP not only prevents individual infections but also helps curb the spread of HIV at a population level. The widespread adoption of PrEP has already had a significant impact on reducing HIV transmission and overall incidence rates. Patrick Sullivan, et al., *Association of State-Level PrEP Coverage and State-Level HIV Diagnoses, US, 2012-2021*, CONF. ON RETROVIRUSES AND OPPORTUNISTIC INFECTIONS, https://tinyurl.com/53u55zb9 (last accessed Feb. 24, 2025). Studies have shown that in communities with high PrEP uptake, new HIV diagnoses have declined substantially. *Id.*

With continued PrEP innovation—enhancing adherence and further reducing HIV transmission—alongside continued access to all forms of PrEP, this intervention has brought the goal of ending the epidemic within reach. According to CDC data, if 50% of eligible individuals used PrEP, as envisioned by the

EHE initiative, HIV incidence could be reduced by half by 2030. *Reducing New HIV Infections*, HIV.GOV (Jan. 31, 2025), https://tinyurl.com/3udk2cuj.

C. USPSTF-Recommended Screening Is Essential for Prevention, Early Detection and Timely Treatment of Viral Hepatitis.

Hepatitis B (HBV) and Hepatitis C (HCV) offer parallel examples of how public health efforts—including widespread screening—can successfully control the transmission of a life-threatening infectious disease. Hepatitis, an inflammation of the liver, affects Americans from all walks of life. Like HIV, hepatitis affects individuals of all ages, genders and ethnicities, though it disproportionately impacts those with underlying health conditions. *Viral Hepatitis Basics*, CDC (July 30, 2024), https://tinyurl.com/f7x2abrm. HBV and HCV are leading causes of liver disease, affecting millions of Americans and often remaining asymptomatic until life-threatening complications, such as cirrhosis, liver failure or cancer, arise. *Id.*

In the 1960s and 1970s, researchers began distinguishing different strains of hepatitis. The discovery of HBV, and identification of an HBV antigen, paved the way for development of a safe and effective HBV vaccine. *Id.* Widespread attention to HBV in subsequent decades culminated in significant declines in new infections among vaccinated populations. Said A. Al-Busafi & Ahmed Alwassief, *Global Perspectives on the Hepatitis B Vaccination: Challenges, Achievements, and the Road to*

Elimination by 2030, 12 VACCINES 1, 17 (2024). Screening plays a crucial role in identifying individuals with HBV, enabling early intervention and access to treatment. Erin E. Conners, et al., *Screening and Testing for Hepatitis B Virus Infection: CDC Recommendations — United States, 2023*, 72 MMWR 1,1 (2023). While there is no cure for HBV, antiviral therapies can help suppress the virus, reduce liver damage and lower the risk of transmission. Hans L. Tillmann, *Antiviral Therapy and Resistance with Hepatitis B Virus Infection*, 13 WORLD J. GASTROENTEROL 125, 126 (2007). Building on this earlier research, HCV was discovered in 1989. Christian Trepo, *A Brief History of Hepatitis Milestones*, 34 LIVER INT'L 29, 29 (2014).

Initially, few treatment options existed, and many individuals infected with the virus were diagnosed only after considerable liver damage had already occurred. Advances in screening technology and more effective therapies in the 1990s and 2000s made it possible to detect hepatitis sooner and manage its progression. By the 2010s, direct-acting antiviral treatments for HCV emerged, offering cure rates of approximately 95 percent when administered early, a remarkable achievement that transformed the clinical outlook for HCV-infected patients. *Viral Hepatitis Basics*, CDC (July 30, 2024), https://tinyurl.com/f7x2abrm. While a vaccine exists for HBV, there is no vaccine to prevent HCV, making early detection and treatment the only effective means of preventing its devastating complications.

Despite these advancements, as of 2020, approximately 880,000 U.S. adults are living with

chronic HBV, and an estimated 14,000 new infections occur each year. *Id.* Since 2012, HCV has led to more deaths than all other reportable infectious diseases (except COVID-19) combined. Approximately 15-30% of individuals living with HIV in the United States are co-infected with HCV. David H. Spach, *Hepatitis C Coinfection*, NAT'L HIV CURRICULUM (Feb. 3, 2025), https://tinyurl.com/3whbwm2v.

The Task Force recognizes the urgency of addressing undiagnosed HCV infections and recommends universal, one-time screening for all adults aged 18 to 79, regardless of risk factors. *Hepatitis C Virus Infection in Adolescents and Adults: Screening*, USPSTF (Mar. 2, 2020), https://tinyurl.com/52zdsc69. Such broad screening is critical given that almost 40% of people with HCV are uninformed of their serostatus, meaning that thousands of Americans remain undiagnosed, vulnerable to severe liver disease and unknowingly contribute to further transmission of the virus. *Id.*

The indispensable role of early detection parallels the experience with HIV, where routine testing has been essential to achieving significant reductions in morbidity and mortality. For both HIV and hepatitis, widespread screening, coupled with prompt and appropriate therapeutic interventions, not only saves lives but also yields significant cost savings for both the health care system and affected individuals.

D. The Viability of the ACA Framework Is Dependent on Its Preventive Services Coverage Requirement.

Congress passed the ACA "in order to improve health insurance markets." *Nat'l Fed'n of Indep. Bus. v. Sebelius*, 567 U.S. 519, 521-22 (2012). The ACA's structure has been referred to as a "three-legged stool": (1) the individual mandate and minimum essential coverage; (2) guaranteed issue; and (3) subsidies to ensure access. Sabrina Corlette, et al., *The ACA's Effect on the Individual Insurance Market*, 39 HEALTH AFFAIRS 436, 437 (2020). The first leg of the stool was intended to promote good health outcomes and reduce health care costs by ensuring that the vast majority of Americans receive high quality health insurance that includes first-dollar coverage of preventive care.

The ACA intended for the Task Force to recommend those preventive services that were so essential to the public's health that they should be available without cost-sharing for Americans with insurance coverage. For example, under this framework, the Task Force undertook a rigorous evaluation of HIV testing, PrEP and hepatitis preventive services, awarding Grade A and Grade B ratings on such services and interventions. Subsequent health insurer coverage has allowed for Americans to access such services and interventions without cost-sharing.

If the Court were to whittle away the first leg of the ACA's stool by voiding the only mechanism the

ACA has contemplated to mandate most preventive services be available without cost-sharing, fewer people will have access to preventive services, including PrEP and screenings for HIV and hepatitis. This will undermine the ACA's strategy to balance risk pools by ensuring a floor of covered benefits and a strengthened primary care ecosystem. It would uproot the intentional design of the ACA and may begin to destabilize the insurance market, as plans' risk pools will be sicker, and, therefore, costlier.

Stripping the Task Force of its role will result in dire consequences for the insurance market and also for public health. The first-dollar coverage of preventive services is imperative in promoting access to PrEP and screenings for HIV and hepatitis. When patients are forced to bear the cost of preventive services, they are less likely to utilize such services; in fact, research has demonstrated that a copayment as low as $5 will lower utilization. Brian Schilling, *Hitting the Copay Sweet Spot*, THE COMMONWEALTH FUND, https://tinyurl.com/ywuh826f (last visited Feb. 24, 2025). Eliminating cost-free PrEP coverage would also undermine decades of progress in HIV prevention. Recent research underscores the devastating consequences of introducing financial barriers to essential preventive care. A 2024 study found that even a small increase in out-of-pocket costs from $0 to $10 doubled PrEP abandonment rates, while costs exceeding $500 resulted in abandonment rates of over 40%. Lorraine T. Dean, et al., *Estimating the Impact of Out-of-Pocket Cost Changes on Abandonment of HIV Pre-Exposure Prophylaxis*, 43 HEALTH AFFAIRS 36, 37 (2024). Alarmingly, HIV diagnoses were two to three times higher among

individuals who abandoned PrEP prescriptions compared to those who filled them. Another study from the Yale School of Public Health, conducted in response to the Fifth Circuit's ruling in *Braidwood*, estimates that for every 10% reduction in PrEP coverage, the U.S. could see more than 1,100 additional HIV infections annually—a lower-bound estimate given the limited study population. A. David Paltiel, et al., *Increased HIV Transmissions with Reduced Insurance Coverage for HIV Pre-Exposure Prophylaxis: Potential Consequences of Braidwood Management v. Becerra* 4 (Oxford Univ. Press 2023). This data suggests that any rollback of mandatory coverage will force some current PrEP users to discontinue treatment, placing them at immediate risk of acquiring or transmitting HIV.

Access to Task Force-recommended HIV and hepatitis screening without cost-sharing is a critical lifeline for all Americans. Full coverage of screening enables individuals who might otherwise never pursue testing to discover their serostatus early and receive timely, effective treatment. Imposing cost barriers would deter many from undergoing screening, jeopardizing early detection and undermining broader public health efforts to stop transmission of these viruses. Rolling back these measures would risk a resurgence of undetected hepatitis infections, leading to increased hospitalizations and costly liver transplants.

Similarly, full coverage of PrEP products fosters continuous and widespread use of these life-saving drugs, thereby enhancing its effectiveness and reducing HIV transmission rates. Introducing out-of-

pocket costs for PrEP would undercut its widespread use, affecting far more than individual health outcomes. It would lead to a cascade of public health challenges, such as delayed diagnoses, new infections and the emergence of treatment-resistant strains, that are difficult to reverse. *Early HIV Diagnosis and Treatment Important for Better Long-term Health Outcomes*, HIV.GOV (Nov. 2, 2022), https://tinyurl.com/4z2mxdvm.

Endorsing the Respondents' misguided logic and permitting the rollback of first-dollar PrEP coverage would perpetuate the harmful stigma associated with HIV and directly undermine bipartisan public health efforts to combat these diseases, triggering a significant backslide in our country's efforts to end the HIV epidemic, erasing decades of progress and placing countless lives at unnecessary risk.

II. Task Force Members are Inferior Officers Whose Recommendations Must Be Approved by Principal Officers Under the Affordable Care Act.

The design of the ACA entails a two-part process in order to execute the preventive services coverage mandate: 1) that the independent Task Force would use evidence-based criteria to determine whether a preventive service met the clinical threshold for a Grade A or Grade B rating and 2) that federal agency officials make policy decisions concerning insurance coverage requirements with respect to Task Force recommendations.

This hierarchy establishes that principal officers supervise the determination of insurance coverage requirement. The Task Force takes no part in the second step, rendering it no more than a collection of inferior officers for constitutional purposes.

Under *Morrison*, the court found that the Independent Counsel Act of 1978 was constitutional, despite the fact that the entity at issue was referred to as "independent," due to several factors, including whether it has the "authority to formulate policy for the Government or the Executive Branch." *Morrison v. Olson*, 487 U.S. 654, 671 (1988). Similarly, the Task Force statute entrusts seasoned experts to apply their individual expertise in making evidence-based determinations to recommend preventive care services, but only to formulate recommendations. Use of the word "independent" within the statute refers to and preserves the evidence-based scientific process, allowing the members of the Task Force to independently apply their expertise to formulate recommendations.

Even if this were not true, the inquiry into whether an officer is inferior must go beyond the language of the statute to look at the practical nature of how the role is carried out. *Morrison*, 487 U.S. at 672-73 (finding that "independent counsel" were nevertheless inferior officers). Here, myriad indicators show that the Task Force's role is carried out in a manner consistent with that of inferior officers.

The Task Force has carried out its responsibilities since 1984 and has long been understood as an independent body. *Procedure Manual*, USPSTF (Apr. 2023), https://tinyurl.com/2mmfc98v. However, its independence and freedom from political influence does not equate a lack of political accountability for its recommendations. Instead, only its process of reviewing evidence and making recommendations for clinical preventive services are cordoned off by the enabling statute. This process and its resulting recommendations are distinct from and only serve to inform the policymaking function delegated to the executive branch under health insurance law.

Similarly, freedom from "political pressure" is not freedom from oversight or accountability. Rather, it is further evidence that this provision is meant to protect the integrity of the evidence-based recommendation process. Otherwise, the output — the recommendations themselves — might be influenced to conform to political whims rather than evidence.

The word "independent" also does not foreclose oversight of the utilization of Task Force recommendations by the Secretary of HHS, who retains sole authority to accept any recommendation for purposes of determining those services which health insurers must cover.

This degree of oversight is sufficient for our purposes, as the Appointments Clause does not require that an inferior officer's superior be involved in every level of decision making, just direction and

supervision at "some level." *Edmond v. United States*, 520 U.S. 651, 663 (1997). Such is the case here, where superiors are involved not in the evidence review and recommendation processes, but in the subsequent policymaking utilized to effectuate the ACA's coverage requirement.

A. Task Force Members are Inferior Officers Who Develop Evidence-Based Recommendations, Not Policy.

Since 1989, the Task Force has published its Guide to Clinical Preventive Services. *Guide to Clinical Preventive Services: An Assessment of the Effectiveness of 169 Interventions*, USPSTF (1989). Since at least 1996, this guide has included the explicit statement that its recommendations "are independent of the U.S. Government. They should not be construed as an official position of the Agency for Healthcare Research and Quality ("AHRQ") or the U.S. Department of Health and Human Services." *Guide to Clinical Preventive Services*, USPSTF (1996).

The Task Force's distance from policymaking has been consistently demonstrated by the executive branch, even predating the passage of the ACA. In 2009, HHS Secretary Kathleen Sebelius rejected a Task Force recommendation that women ages 40-49 not receive mammograms, stressing that the recommendation was issued by "an outside independent panel of doctors and scientists who . . . do not set federal policy and . . . don't determine what services are covered by the federal government." Rob Stein & Dan Eggen, *White House Backs Off Cancer*

Test Guidelines, WASH. POST (Nov. 19, 2009), https://tinyurl.com/3c8h8zue.

Thus, its "independent charge to focus on the science of prevention" long preceded the ACA and remained intact following its enactment. Gregory Curfman & Kirsten Bibbins-Domingo, *US Preventive Services Task Force Challenged in Federal Court*, 329 JAMA 1743, 1743 (2023). In carrying out this charge, the Task Force engages in a substantial and complex undertaking. Its evidence review process prior to issuing its recommendations is notable in its thoroughness and consistency, entailing at least eight distinct steps, including:

1. Consideration of topics submitted for its consideration by the general public;
2. Development of a research plan;
3. Receipt and review of public comments on the research plan;
4. Review of peer-reviewed evidence;
5. Development of a draft recommendation;
6. Receipt and review of public comments on the draft recommendation;
7. Finalization of the recommendation; and

8. Vote on the recommendation.[3]

None of these steps involve promulgating a regulation or mandating a course of action. This process and the resulting recommendations are distinct from and only serve to inform the policymaking function delegated to the executive branch under health insurance law.

When amending the enabling statute and adopting the ACA's requirement to cover Task Force recommendations, Congress was presumably aware of these processes given the Task Force's existence for 26 years prior to the ACA's enactment. In doing so, it cordoned off as independent its process of reviewing evidence and making recommendations for clinical preventive services.

In reinforcing this independence, Congress and the executive branch did not push the Task Force across the threshold into a policymaking function. Instead, the Task Force has explicitly distanced itself from the complexities of determining insurance coverage requirements and is solely a body to provide recommendations based on the most current scientific and medical literature. Gregory Curfman & Kirsten Bibbins-Domingo, *US Preventive Services Task Force Challenged in Federal Court*, 329 JAMA 1743, 1743 (2023).

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[3] *Task Force Recommendations Development Process: A Graphic Overview*, USPSTF (May 2021), https://tinyurl.com/zs3a7wfv.

B. Under Longstanding U.S. Health Insurance Law, Multiple Agencies Determine Coverage Requirements.

Although the ACA explicitly linked insurance coverage to Task Force recommendations, it did not delegate to the Task Force the role of deciding and effectuating insurance coverage. Rather, that role is reserved under Title XXVII of the Public Health Service Act (PHSA) to three agencies – the United States Departments of Health and Human Services, Labor, and Treasury – known as "the tri-agencies." 42 U.S.C. §§ 300gg, *et seq*. This has been the case since the enactment of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), which established Title XXVII. Thus, when Congress enacted the ACA and its preventive services coverage framework, it amended a preexisting health insurance regulatory framework administered by the tri-agencies.

This oversight function alone satisfies the required Appointments Clause analysis as, once recommendations are made, politically accountable officials are free to circumscribe the recommendations in the course of implementing the ACA's preventive services coverage requirement.

Stated plainly, if the Secretary of HHS determines he does not wish to cover a Task Force-recommended item or service, he maintains the discretion to override the recommendations for purposes of determining which of those must be covered by health insurers.

In carrying out their responsibilities to effectuate insurance coverage under 42 U.S.C. § 300gg-13, 29 U.S.C. § 1185d, and 26 U.S.C. § 9815, the tri-agencies promulgated implementing rules. 45 CFR § 147.130; 29 CFR § 2590.715-2713; 26 CFR § 54.9815-2713. The very first subsection of these rules delineate a policy that requires group health plans or health insurance issuers to cover A- and B-rated Task Force recommendations without cost-sharing requirements. 45 CFR § 147.130(a)(1)(i); 29 CFR § 2590.715-2713(a)(1)(i); 26 CFR § 54.9815-2713(a)(1)(i). For the sake of expediency, the tri-agencies issued this policy via an interim final rule. 75 Fed. Reg. 41726 (July 19, 2010). It was subsequently codified following notice and comment rulemaking. 80 Fed. Reg. 41318 (July 14, 2015). The tri-agencies also explicitly stated the timeline for implementation of such Task Force recommendations and did not link that timing to any additional action undertaken by the tri-agencies. In other words, the tri-agencies decided, using their rulemaking authority, to make the Task Force's Grade A and Grade B ratings self-effectuating with respect to mandatory first-dollar coverage, while still allowing for the tri-agencies to review and accept the recommendations as evidenced in the below list of actions. 45 CFR § 147.130(b)(1); 29 CFR § 2590.715-2713(b)(1); 26 CFR § 54.9815-2713(b)(1).

The tri-agencies were not thoughtlessly deferential, reflexively outsourcing the responsibility of determining health insurance coverage requirements to the Task Force. Rather, the tri-agencies meticulously promulgated various rules and guidance that demonstrate it carried out its

responsibility to effectuate the Task Force recommendations as required by Congress. This is evidenced by myriad actions taken by the tri-agencies, including the following:

> 1. In the preamble to the first interim final rule, the tri-agencies delineated their approach to incorporating the Task Force recommendations into health insurance coverage:
>
> > The preventive services given a grade of A or B by the Task Force have been determined by the Task Force to have at least fair or good evidence that the preventive service improves important health outcomes and that benefits outweigh harms in the judgment of an independent panel of private sector experts in primary care and prevention; 75 Fed. Reg. 41726 (July 19, 2010).
>
> 2. The preamble further specified the timing of a recommendation's effectiveness, "which is considered to be issued on the last day of the month on which the Task Force publishes or otherwise releases the recommendation"; 75 Fed. Reg. 41726 (July 19, 2010).

3. As codified, the rules begin by cabining required coverage of USPSTF-recommended services as "with respect to the individual involved"; 45 CFR 147.130(a)(1)(i); 29 CFR § 2590.715-2713(a)(1)(i); 26 CFR § 54.9815-2713(a)(1)(i).

4. The rules outlined the circumstances under which patients are entitled to coverage without cost-sharing, including whether the recommended service is "the primary purpose" of an office visit with a provider and whether the provider who delivered a service was in network with a health plan; 45 CFR 147.130(a)(2) - (3); 29 CFR § 2590.715-2713(2) - (3); 26 CFR § 54.9815-2713(2) - (3).

5. The rules outlined the parameters under which a health insurer must cover a USPSTF-recommended preventive service, including the application of "reasonable medical management" and the date on which coverage must begin; 45 CFR 147.130(a)(4) - (b)(1); 29 CFR § 2590.715-2713(a)(4) - (b)(1); 26 CFR § 54.9815-2713(a)(4) - (b)(1).

6. The rules explicitly provide that health insurers are not required to cover services that are not described within a Task Force recommendation; 45 CFR 147.130(a)(5) - (b); 29 CFR § 2590.715-2713(a)(5) - (b); 26 CFR § 54.9815-2713(a)(5) - (b).

7. The rules specify the obligations of health insurers when the Task Force alters a

recommendation; 45 CFR 147.130(b)(2); 29 CFR § 2590.715-2713 (b)(2); 26 CFR § 54.9815-2713(b)(2).

8. Its "Frequently Asked Questions" ("FAQs"), issued for some recommendations over the course of a 14-year period, have included the following guidance, extensively interpreting and guiding implementation of coverage for Task Force recommendations, including:

> I. Required coverage of Task Force recommendations when a recommendation "do[es] not definitively state the scope, setting, or frequency of the items or services to be covered." *Affordable Care Act Implementation FAQs – Set 2*, CMS (Sept. 10, 2024), https://tinyurl.com/mucs47zd.
>
> II. Required coverage for aspirin following its recommendation by the Task Force to reduce the risk of myocardial infarction; *Affordable Care Act Implementation FAQs – Set 12*, CMS (Sept. 10, 2024), https://tinyurl.com/y48mz7ep.
>
> III. Required coverage of updated Task Force recommendations for breast cancer screening; *Affordable Care Act Implementation FAQs – Set 18*, CMS (Sept. 10, 2024), https://tinyurl.com/34b6cn3f.

IV. Required coverage for tobacco use counseling and cessation interventions as recommended by the USPSTF; *Affordable Care Act Implementation FAQs – Set 19*, CMS (Sept. 10, 2024), https://tinyurl.com/yc6t5xba.

V. Required coverage of BRCA-related genetic testing and counseling for women; *Affordable Care Act Implementation FAQs – Set 34*, CMS (Sept. 10, 2024), https://tinyurl.com/u636bxwu.

VI. Required coverage of anesthesia, specialist counseling, pathology exams and bowel preparation in connection with colonoscopies; *Affordable Care Act Implementation FAQs – Set 26*, CMS (Sept. 10, 2024), https://tinyurl.com/3urzx3ux.

VII. Permissibility of excluding weight management services for adult obesity from coverage; *Affordable Care Act Implementation FAQs – Set 29*, CMS (Sept. 10, 2024), https://tinyurl.com/4yby9hbp.

VIII. Interaction between HRSA's Women's Preventive Services Guidelines and Task Force recommendations; *Affordable Care Act Implementation FAQs – Set 35*, CMS (Sept. 10, 2024), https://tinyurl.com/ju8vksj5.

IX. Coverage of ancillary services associated with PrEP and clarification of allowable medical management techniques for PrEP; *Affordable Care Act Implementation FAQs – Set 47*, CMS (Sept. 10, 2024), https://tinyurl.com/5yafja7a.

X. Rapid coverage of COVID-related Task Force recommendations; *Affordable Care Act Implementation FAQs – Set 50*, CMS (Sept. 10, 2024), https://tinyurl.com/52u7s678; *FAQs About Affordable Care Act and Coronavirus Aid, Relief, and Economic Security Act Implementation Part 59*, CMS (Apr. 13, 2023), https://tinyurl.com/32987zrk.

XI. Coverage requirements considering the lower court's decision in this case now pending before the Court; *Id.*; and

XII. Coverage requirements for PrEP following the Task Force's updated 2023 recommendation. *FAQs About Affordable Care Act and Women's Health and Cancer Rights Act Implementation Part 68*, CMS (Oct. 21, 2024), https://tinyurl.com/3kftp5vp.

It is the tri-agencies rather than the Task Force that possess the independent authority and responsibility for determining how to implement the

Task Force's recommendations for purposes of health insurance coverage requirements.

CONCLUSION

HIV and hepatitis continues to impact millions of Americans, requiring ongoing medical treatment and burdening the American economy. Even should this Court decline to sever the section of 42 U.S.C. 299b-4(a)(6) that the Petitioners take issue with, it should recognize a reasonable construction of the statute in favor of a constitutionally sound interpretation. Furthermore, the Court should recognize Congress's intention on the face of the statute to preserve political independence and avoidance of political influence with respect to its recommendation process, which is altogether distinct from the subsequent policy-making role retained by politically accountable principle.

Respectfully submitted,

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APPENDIX

TABLE OF CONTENTS

APPENDIX

LIST OF *AMICI CURIAE*

HIV AND HEPATITIS POLICY INSTITUTE

ADAP ADVOCACY ASSOCIATION

AIDS ALABAMA, INC.

AMERICAN ACADEMY OF HIV MEDICINE

CARING AMBASSADORS PROGRAM, INC.

COMMUNITY ACCESS NATIONAL NETWORK

COMMUNITY LIVER ALLIANCE

COMMUNITY RESEARCH INSTITUTE OF NEW ENGLAND, INC. d/b/a COMMUNITY RESOURCE INITIATIVE

FAST-TRACK CITIES INSTITUTE

FRANNIE PEABODY CENTER

GEORGIA AIDS COALITION

GLOBAL LIVER INSTITUTE

HEP B UNITED

HEPATITIS B FOUNDATION

HOUSING WORKS, INC.

INTERNATIONAL ASSOCIATION OF
PROVIDERS OF AIDS CARE

LATINO COMMISSION ON AIDS

NATIONAL MINORITY AIDS COUNCIL

SEXUALITY INFORMATION AND EDUCATION
COUNCIL OF THE UNITED STATES d/b/a
SIECUS

VIVENT HEALTH