No. 23-10326

# IN THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT

 $\begin{array}{c} \text{BRAIDWOOD MANAGEMENT, INC., } \textit{et al.,} \\ \textit{Plaintiffs-Appellees-Cross-Appellants,} \end{array}$ 

v.

XAVIER BECERRA, et al., Defendants-Appellants-Cross-Appellees.

On Appeal from the United States District Court for the Northern District of Texas, No. 4:20-CV-283-O, Hon. Reed C. O'Connor

# BRIEF FOR AMERICAN PUBLIC HEALTH ASSOCIATION, PUBLIC HEALTH DEANS AND SCHOLARS, THE ROBERT WOOD JOHNSON FOUNDATION, AND PUBLIC HEALTH ADVOCATES AS AMICI CURIAE IN SUPPORT OF DEFENDANTS-APPELLANTS

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# Case No. 23-10326, Braidwood Management, Inc., et al. v. Xavier Becerra, et al.

The undersigned counsel of record certifies that the following listed persons and entities as described in Rule 28.2.1, in addition to those disclosed in the parties' statements of interested persons, have an interest in this case's outcome. These representations are made in order that the judges of this Court may evaluate possible disqualification or recusal.

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The American Public Health Association is a professional association. It is not publicly traded and has no parent corporation. No publicly held corporation owns 10% or more of its stock.

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#### Robert Wood Johnson Foundation

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#### Trust for America's Health

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## TABLE OF CONTENTS

|          |   | Page |
|----------|---|------|
| SUF      | ATE DISCLOSURE STATEMENT AND PPLEMENTAL STATEMENT OF INTERESTED RTIES   | i    |
| TABLE O  | F AUTHORITIES   | xiv  |
| INTERES  | ST OF AMICI CURIAE  | 1    |
| INTRODU  | UCTION AND SUMMARY OF ARGUMENT  | 4    |
| ARGUME   | ENT   | 7    |
| AM]      | TRICT COURT'S DECISION WILL CAUSE<br>ERICANS TO SUFFER INCREASED ILLNESS AND<br>EN DEATH  | 7    |
| A.       | The district court's order eliminates guaranteed cost-<br>free coverage for life-saving services.                                       | 8    |
| В.       | The ACA's requirement of cost-free coverage has significantly increased Americans' use of these services.                               | 15   |
| C.       | Without the federal requirement, companies and insurers will re-impose cost-sharing, which will reduce the use of life-saving services. |      |
| D.       | The district court's universal remedy is the principal source of these draconian consequences   | 22   |
| CONCLU   | SION  | 26   |
| APPEND   | IX A  | 27   |
| APPEND   | IX B  | 40   |
| CERTIFIC | CATE OF SERVICE   | 48   |
| CERTIFIC | CATIONS UNDER ECF FILING STANDARDS  | 49   |
| CERTIFIC | CATE OF COMPLIANCE  | 50   |

## TABLE OF AUTHORITIES

|  | Page(s) |
|--|---------|
| Cases  |         |
| Arizona v. Biden,<br>40 F.4th 375 (6th Cir. 2022)                            | 23      |
| Cargill v. Garland,<br>57 F.4th 447 (5th Cir. 2023)                          | 23      |
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| Gonzales-Veliz v. Barr,<br>938 F.3d 219 (5th Cir. 2019)                      | 23      |
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|--|----|
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#### INTEREST OF AMICI CURIAE

The American Public Health Association ("APHA"), which was founded in 1872, is the leading professional organization for public health professionals in the United States. APHA shares the latest research and information, promotes best practices, and advocates for public health issues and policies grounded in scientific research. APHA represents more than 24,000 individual members and is the only organization that combines a 150-year perspective, a broad-based member community, and a focus on influencing federal policy to improve the public's health.<sup>1</sup>

The individual *amici* are a group of 108 distinguished deans and professors of public health with deep expertise in policies that promote population health and alleviate barriers to care. They are identified in Appendix A.

The Robert Wood Johnson Foundation ("RWJF") is the nation's largest philanthropic organization dedicated solely to health. It supports efforts to build a national Culture of Health rooted in equity that provides

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<sup>&</sup>lt;sup>1</sup> No counsel for a party authored this brief in whole or in part, and no person other than *amicus* or its counsel contributed money that was intended to fund the preparation or submission of this brief. *See* Fed. R. App. P. 29(a)(4)(E). All parties have consented to the filing of this brief.

every individual with a fair and just opportunity for health and wellbeing. As part of those efforts, RWJF has supported research demonstrating the benefits of comprehensive coverage for no-cost preventive health services.

Trust for America's Health ("TFAH") is a nonpartisan, nonprofit organization focused on public health research and policy. TFAH is committed to promoting optimal health for every person and community and making health equity foundational to policymaking at all levels. The organization's work is focused on the antecedents of poor health and on policies and programs to advance an evidence-based public health system that is ready to meet the challenges of the 21st century. TFAH develops reports and other resources and initiatives to educate the public and recommends policies to promote health and wellbeing and to make the prevention of illness and injury a national priority.

ChangeLab Solutions is an interdisciplinary team of lawyers, planners, policy analysts, public health practitioners, and other professionals who work across the nation to advance equitable laws and policies that ensure healthy lives for all. With more than two decades of experience in enacting policy, systems, and environmental changes at

local and state levels, ChangeLab Solutions focuses on eliminating health disparities by addressing the social determinants of health. It envisions healthy, equitable communities where every person is economically secure and can attain their full health potential.

APHA has a strong interest in ensuring the continued availability of cost-free coverage for preventive healthcare, given its mission to promote public health through evidence-based policies. The individual *amici*, RWJF, TFAH, and ChangeLab Solutions all share that interest. *Amici* file this brief to explain the importance of the cost-free preventive services requirement invalidated by the district court and the significant harm to public health that will result if that determination is permitted to stand.

#### INTRODUCTION AND SUMMARY OF ARGUMENT

The district court invalidated a critically important provision of the Affordable Care Act ("ACA") that ensures more than 150 million Americans' access to essential life-saving tests and treatments. *Amici* submit this brief to explain that, if the ruling is permitted to stand, deadly diseases will not be detected and important treatments will be unavailable—resulting in serious illnesses, chronic medical conditions, and deaths that otherwise would have been prevented.

Prior to enactment of the ACA, a significant number of health insurance plans failed to cover preventive tests and other medical services for the detection and prevention of major diseases. Plans that did provide coverage often required patients to pay a share of the cost, which deterred many patients from obtaining these life-saving services.

To protect Americans' health, the ACA requires virtually all private insurance plans to cover, cost-free, four essential categories of preventive services. One of those categories is "evidence-based items or services" with an A or B recommendation from the U.S Preventive Services Task Force ("USPSTF"). See 42 U.S.C. § 300gg-13(a)(1). The USPSTF is a

panel of experts that rigorously evaluates peer-reviewed scientific evidence to recommend especially valuable preventive services.<sup>2</sup>

These services save and dramatically improve Americans' lives by identifying and addressing health risks early, so they can be treated more effectively; by preventing diseases from occurring at all; and by protecting all Americans against the risk of transmission of communicable diseases. They are critical to reducing the incidence and severity of numerous diseases and life-threatening conditions, and are especially important to maternal and child health.<sup>3</sup> And the ACA's requirement of cost-free coverage has dramatically increased use of these vital services by all Americans.

The district court's decision eliminates this requirement nationwide for dozens of life-saving services recommended by the USPSTF—every preventive service specified after the enactment of the ACA in 2010. Without the ACA's requirement, some companies and

 $<sup>^2</sup>$  See U.S. Preventive Servs. Task Force, About the USPSTF (last visited Apr. 21, 2023), https://bit.ly/3UVQLSs.

<sup>&</sup>lt;sup>3</sup> See Caitlin Murphy et al., Braidwood Management v Becerra Could Eliminate Three Quarters of the Affordable Care Act's Preventive Benefits for Women, Infants, and Children (June 8, 2023), https://bit.ly/3PqRz13.

insurers will re-impose cost-sharing. Some may eliminate coverage completely.

It is certain that without cost-free coverage, many Americans will not use these services: studies consistently demonstrate that when people are required to pay part of the cost of preventive care, they often do not obtain it. That will lead to more serious illnesses and even deaths among the individuals deprived of coverage. It also will affect Americans more broadly, because many of the covered services prevent and treat illnesses that, if not detected and treated, can be spread among the population generally.

This brief discusses the particular preventive services affected, and the adverse public health consequences of the elimination of the cost-free coverage requirement for those services.

Importantly, those widespread adverse consequences flow in large measure from the district court's decision to grant a "universal remedy" that bars the government from implementing or enforcing the cost-free coverage requirement nationwide. That broad relief is impermissible in the circumstances of this case, where it is not necessary to protect the very small number of Plaintiffs here; where none of the entities regulated

by the provision (insurance companies) have challenged it; and where almost none of the tens of thousands of affected companies or many millions of affected individuals are before the Court.

This Court should reverse the district court's decision. At a minimum, it should limit any remedy to what is necessary to redress any harm to Plaintiffs, and leave unaffected the more than 150 million Americans that benefit from the cost-free coverage requirement.

#### **ARGUMENT**

## THE DISTRICT COURT'S DECISION WILL CAUSE AMERICANS TO SUFFER INCREASED ILLNESS AND EVEN DEATH.

Congress determined that to promote the public health—and prevent Americans from suffering from serious diseases, including diseases that can lead to death—it is necessary to remove barriers to Americans' use of preventive health services. Congress therefore included in the ACA provisions mandating that insurers cover many of those services cost-free. See 42 U.S.C. § 300gg-13(a).

The government's brief demonstrates why Congress acted well within its constitutional authority in relying on the expertise of the USPSTF to identify one of the categories of preventive services

warranting cost-free coverage.<sup>4</sup> Amici write separately to explain the serious harm to Americans' health that will be the inevitable consequence of eliminating the preventive services requirement for USPSTF-recommended services.

### A. The district court's order eliminates guaranteed costfree coverage for life-saving services.

The district court's order eliminates guaranteed cost-free coverage for at least two dozen services with USPSTF recommendations published or updated after 2010, which are listed in Appendix B. These life-saving services include:

• <u>Lung cancer screening for high-risk persons</u>: Lung cancer is the second most common cancer and the leading cause of cancer death in the United States. Studies demonstrate that this cancer is significantly more treatable when detected

<sup>&</sup>lt;sup>4</sup> We agree with the government that if the Court were to conclude otherwise, any constitutional violation can be remedied by severing and invalidating the statute's limitations on secretarial oversight. Opening Br. for the Federal Defs. 35-40.

<sup>&</sup>lt;sup>5</sup> U.S. Preventive Servs. Taskforce, Screening for Lung Cancer: US Preventive Services Task Force Recommendation Statement, 325 J. Am. Med. Ass'n 962 (2021), https://bit.ly/3n32Etg (Screening for Lung Cancer).

<sup>&</sup>lt;sup>6</sup> See Am. Cancer Soc'y, Key Statistics for Lung Cancer (Jan. 12, 2023), https://bit.ly/3oEF1Yo.

early,<sup>7</sup> which is why the USPSTF recommended screenings in 2013 and expanded that recommendation to apply to more persons in 2021.<sup>8</sup>

• Colorectal cancer screening for adults 45-49:9 Colorectal cancer is the Nation's third leading cause of death from cancer, and its incidence has increased for adults 40-49 years old. Old. Colorectal cancer screening is especially beneficial because it involves removing precancerous growths. So screening not only detects cancer early, but keeps it from developing in the first place. The USPSTF's 2021 recommendation provides this benefit to 15-17.5 million

<sup>&</sup>lt;sup>7</sup> See Screening for Lung Cancer at 962.

<sup>&</sup>lt;sup>8</sup> See id. at 965.

<sup>&</sup>lt;sup>9</sup> See U.S. Preventive Servs. Taskforce, Screening for Colorectal Cancer: US Preventive Services Task Force Recommendation Statement, 325 J. Am. Med. Ass'n 1965 (2021), https://bit.ly/3oy6oDA.

<sup>&</sup>lt;sup>10</sup> *Id.* at 1965.

<sup>&</sup>lt;sup>11</sup> See Assistant Sec'y for Planning & Evaluation, U.S. Dep't of Health and Human Servs., Access to Preventive Services Without Cost-Sharing: Evidence from the Affordable Care Act 8 (Jan. 11, 2022), https://bit.ly/41rGtfm (Access to Preventive Services).

additional people, by expanding to include a dults 45-49 years old.  $^{12}$ 

- Statins to Prevent Cardiovascular Disease: <sup>13</sup> Cardiovascular disease is the leading cause of death in the United States. <sup>14</sup> For those at increased risk, statins effectively reduce both cardiovascular-disease events and mortality. <sup>15</sup> The USPTSF therefore recommended statins for at-risk adults 40-75 years old in 2016 and 2022, enabling cost-free access to this potentially life-saving drug. <sup>16</sup>
- <u>Preexposure Prophylaxis ("PrEP") to Prevent HIV</u>:<sup>17</sup> An estimated 1.1 million Americans are living with HIV.<sup>18</sup> By

 $<sup>^{12}</sup>$  *Id*.

<sup>&</sup>lt;sup>13</sup> See U.S. Preventive Servs. Taskforce, Statin Use for the Primary Prevention of Cardiovascular Disease in Adults: US Preventive Services Task Force Recommendation Statement, 328 J. Am. Med. Ass'n 746 (2022), https://bit.ly/3N56mgW.

<sup>&</sup>lt;sup>14</sup> *Id.* at 746.

<sup>&</sup>lt;sup>15</sup> See *id*. at 748 tbl.

<sup>&</sup>lt;sup>16</sup> See id. at 747, 750.

<sup>&</sup>lt;sup>17</sup> See U.S. Preventive Servs. Taskforce, Preexposure Prophylaxis for the Prevention of HIV Infection: US Preventive Services Task Force Recommendation Statement, 321 J. Am. Med. Ass'n 2203 (2019), https://bit.ly/3UUF5Q7.

<sup>&</sup>lt;sup>18</sup> *Id.* at 2204-05.

preventing HIV acquisition among those who are HIVnegative, PrEP protects the health of those who use the
service and reduces further HIV transmission in the
community.<sup>19</sup> One study found that if the number of
individuals using PrEP increased by 25%, new HIV cases
would decrease by 54%.<sup>20</sup> Conversely, a recent study suggests
that there will be 1140 additional HIV transmissions among
men who have sex with men for every 10% reduction in PrEP
coverage caused by the district court's ruling.<sup>21</sup>

• <u>Screening for Hepatitis B Infection in Adolescents and Adults</u>: 22 862,000 Americans are estimated to be living with

<sup>&</sup>lt;sup>19</sup> *Id.* at 2204.

<sup>&</sup>lt;sup>20</sup> Ruchita Balasubramanian et al., *Projected Impact of Expanded Long-Acting Injectable PrEP Use Among Men Who Have Sex With Men on Local HIV Epidemics*, 91 J. of Acquired Immune Deficiency Syndrome 144 (2022), https://bit.ly/3H7bz3L.

<sup>&</sup>lt;sup>21</sup> A. David Paltiel et al., *Increased HIV Transmissions With Reduced Insurance Coverage for HIV Preexposure Prophylaxis: Potential Consequences of Braidwood Management v. Becerra, 10 Open Forum Infectious Diseases 1 (2023), https://bit.ly/3H4nM9t.* 

<sup>&</sup>lt;sup>22</sup> U.S. Preventive Servs. Taskforce, Screening for Hepatitis B Virus Infection in Adolescents and Adults: US Preventive Services Task Force Recommendation Statement, 324 J. Am. Med. Ass'n 2415 (2020), https://bit.ly/3H4Zj3W.

chronic infection of the hepatitis B virus.<sup>23</sup> For 15-40% of these individuals, chronic infection will develop into cirrhosis, liver cancer, or liver failure, which can be deadly.<sup>24</sup> Crucially, it is estimated that 68% of people with chronic hepatitis B are not aware of their infection, and may not have symptoms until the onset of serious illness—this not only results in delayed treatment, but also increases the likelihood of unknowing transmission to others.<sup>25</sup> Screening of at-risk individuals, as recommended by the USPSTF in 2014 and 2020, addresses these problems.<sup>26</sup>

Screening for Hepatitis C Infection in Adolescents and Adults: <sup>27</sup> As of March 2020, Hepatitis C virus was "associated with more deaths in the United States than the top 60 other

<sup>&</sup>lt;sup>23</sup> *Id.* at 2415.

 $<sup>^{24}</sup>$  *Id*.

 $<sup>^{25}</sup>$  *Id*.

<sup>&</sup>lt;sup>26</sup> See id. at 2416.

<sup>&</sup>lt;sup>27</sup> U.S. Preventive Servs. Taskforce, Screening for Hepatitis C Virus Infection in Adolescents and Adults: US Preventive Services Task Force Recommendation Statement, 323 J. Am. Med. Ass'n 970 (2020), https://bit.ly/3KVwmIN.

reportable infectious diseases *combined*."<sup>28</sup> An estimated 4.1 million Americans have past or current Hepatitis C infection.<sup>29</sup> The USPSTF recommended screening in 2013 and then greatly broadened the scope of the recommendation to adults 18-79 years old, concluding that early detection and treatment leads to significantly improved health outcomes.<sup>30</sup>

• Aspirin Use to Prevent Preeclampsia:<sup>31</sup> Preeclampsia is "one of the most serious health problems that affect pregnant persons."<sup>32</sup> It is a leading cause of maternal death in the United States,<sup>33</sup> and can also lead to preterm births.<sup>34</sup> Daily low-dose use of aspirin—recommended by the USPSTF in

<sup>&</sup>lt;sup>28</sup> *Id.* at 970 (emphasis added).

<sup>&</sup>lt;sup>29</sup> *Id*.

<sup>&</sup>lt;sup>30</sup> See id. at 972.

<sup>&</sup>lt;sup>31</sup> U.S. Preventive Servs. Taskforce, Aspirin Use to Prevent Preeclampsia and Related Morbidity and Mortality: US Preventive Services Task Force Recommendation Statement, 326 J. Am. Med. Ass'n 1186, 1186 (2021), https://bit.ly/3oD9oig (Aspirin Use to Prevent Preeclampsia).

<sup>&</sup>lt;sup>32</sup> *Id.* at 1186.

<sup>&</sup>lt;sup>33</sup> Sarosh Rana et al., *Preeclampsia: Pathophysiology, Challenges, and Perspectives*, 124 Circulation Res. 1094, 1094 (2019), https://bit.ly/3H4DVeV.

 $<sup>^{34}\,</sup>Aspirin\,\,Use$  to Prevent Preeclampsia at 1186.

2021—reduces the risk of preeclampsia, preterm birth, and maternal mortality, thus protecting both maternal and infant health.<sup>35</sup>

These are only a few of the services for which the district court's order eliminates guaranteed cost-free coverage. Others include expanded screening for genetic mutations that increase women's risk of breast cancer by 45-65% by age 70;<sup>36</sup> expanded screening for prediabetes and type 2 diabetes, enabling earlier detection and treatment;<sup>37</sup> and exercise interventions for at-risk adults 65 and older to prevent falls, which are the leading cause of injury-related morbidity and mortality among older American adults.<sup>38</sup>

<sup>&</sup>lt;sup>35</sup> *Id.* at 1187.

<sup>&</sup>lt;sup>36</sup> U.S. Preventive Servs. Taskforce, Risk Assessment, Genetic Counseling, and Genetic Testing for BRCA-Related Cancer: US Preventive Services Task Force Recommendation Statement, 322 J. Am. Med. Ass'n 652 (2019), https://bit.ly/3mUZ44C.

<sup>&</sup>lt;sup>37</sup> U.S. Preventive Servs. Taskforce, Screening for Prediabetes and Type 2 Diabetes: US Preventive Services Task Force Recommendation Statement, 326 J. Am. Med. Ass'n 736 (2021), https://bit.ly/3H0HpiQ.

<sup>&</sup>lt;sup>38</sup> U.S. Preventive Servs. Taskforce, Interventions to Prevent Falls in Community-Dwelling Older Adults: US Preventive Services Task Force Recommendation Statement, 319 J. Am. Med. Ass'n 1696, 1696 (2021), https://bit.ly/3UXsY4I.

Saving lives and preventing illness are the most important benefits of cost-free coverage for these services, which not only promote the health of the insured but in many cases also protect third parties and the broader population from further transmission of disease. In addition, the services also reduce healthcare costs.<sup>39</sup> Illnesses that are prevented need not be treated at all, saving significant health costs. As Congress reasoned, for example, preventing patients from developing colon cancer through a screening that costs "a couple hundred dollars" is much more cost-effective than spending "tens of thousands of dollars" having to treat it.<sup>40</sup>

B. The ACA's requirement of cost-free coverage has significantly increased Americans' use of these services.

The Department of Health and Human Services ("HHS") estimates that 151.6 million people, as of January 2022, were enrolled in private health insurance plans subject to the ACA's preventive services requirement.<sup>41</sup> By eliminating cost-sharing, the ACA has increased

<sup>&</sup>lt;sup>39</sup> See Kaiser Family Foundation, Preventive Services Covered by Private Health Plans Under the ACA 1 (Aug. 2015), https://bit.ly/3oBU98W.

<sup>&</sup>lt;sup>40</sup> 155 Cong. Rec. 32890 (2009) (statement of Sen. Cardin).

<sup>&</sup>lt;sup>41</sup> Access to Preventive Services at 3, 5.

access to and utilization of preventive services. Indeed, approximately 100 million Americans used the free preventive services guaranteed by the ACA in 2018.<sup>42</sup> The number is likely even higher today: because the number of Americans with private health insurance coverage has increased since then, the use of preventive services surely has increased as well.<sup>43</sup>

There can be no doubt that eliminating cost-sharing has increased Americans' use of preventive services. An extensive review of 35 academic studies found that eliminating cost-sharing "led to increases in utilization" of preventive services since the ACA was enacted, including "substantial increases" among the financially vulnerable.<sup>44</sup> One study, for

<sup>&</sup>lt;sup>42</sup> Krutika Amin et al., Preventive Services Use Among People With Private Insurance Coverage (Mar. 20, 2023), https://bit.ly/3oxjfWO.

Prevention, Interactive Summary Health Statistics for Adults – 2019-2021 (last visited Apr. 24, 2023), https://bit.ly/3LoZf1j (selecting topic "Private health insurance at time of interview: Adults aged 18-64") (showing 1.7% rise in percentage of adults with private health insurance from 2019 to 2021). Based on estimated population distribution by age, that increase corresponds to over 4 million additional individuals with private health insurance. See Kaiser Family Foundation, Population Distribution by Age (last visited Apr. 27, 2023), https://bit.ly/3HkyDfu.

<sup>&</sup>lt;sup>44</sup> Hope C. Norris et al., *Utilization Impact of Cost-Sharing Elimination* for Preventive Care Services: A Rapid Review, 79 Med. Care Res. & Rev. 175, 192, 194 (2022); see also Access to Preventive Services at 10; Xuesong

example, found increased use of a variety of preventive services at community health centers across 14 states.<sup>45</sup>

This increase is a direct result of the elimination of cost-sharing. Multiple studies demonstrate that "the presence of cost-sharing, even if the amount is relatively modest, deters patients from receiving care." One study, for example, found that patient cost-sharing produced a 9-10% decline in use of mammograms and 8-10% decline in use of pap smears. 47 Indeed, prior to the ACA, 9% of insured men and 13% of insured

Han et al., Has Recommended Preventive Service Use Increased After Elimination of Cost-Sharing As Part of the Affordable Care Act in the United States?, 78 Prev. Med. 85 (2015), https://bit.ly/41sg8ht.

<sup>&</sup>lt;sup>45</sup> Brigit Hatch et al., Impacts of the Affordable Care Act on Receipt of Women's Preventive Services in Community Health Centers in Medicaid Expansion and Nonexpansion States, 31 Women's Health Issues 9 (2021), https://bit.ly/43UD1vp.

<sup>46</sup> Norris, supra n.44, at 175; see also Has Recommended Preventive Service Use Increased?, at 85 (collecting studies); Amal N. Trivedi et al., Effect of Cost-Sharing on Screening Mammography in Medicare Health Plans, 358 N. England J. Med. 375, 375 (2008), https://bit.ly/3Amo6fU (noting that even "[r]elatively small copayments" have been found to be associated with decreased use of effective preventive care); Robert H. Brook et al., The Health Insurance Experiment: A Classic RAND Study Speaks theCurrent Healthcare Reform Debate(2006).tohttps://bit.ly/3H3byhn.

<sup>&</sup>lt;sup>47</sup> Geetesh Solanki & Helen Halpin Schauffler, Cost-sharing and the Utilization of Clinical Preventive Services, 17 Am. J. Preventive Med. 127 (1999), https://bit.ly/3NmKFcn.

women—and 31% of low-income men and 35% of low-income women—reported postponing preventive services because of cost.<sup>48</sup> And a survey of 2,199 Americans conducted after the district court's ruling found that 40% of respondents would not utilize most preventive services without cost-free coverage.<sup>49</sup>

These results are unsurprising, given that cost generally is a major barrier to healthcare access. In 2022, 28% of American adults, including 26% of insured adults, went without medical care because they could not afford it.<sup>50</sup> Moreover, since preventive services "do not address acute health problems," people may be more likely to "skip such care" in particular.<sup>51</sup> And in deciding whether to pay for preventive care, individuals likely will not consider the substantial benefits to third parties and population health generally that flow from broad use of preventive services.

<sup>&</sup>lt;sup>48</sup> Kaiser Family Foundation, *supra* n. 39, at 1.

<sup>&</sup>lt;sup>49</sup> Jay Asser, *Patients Likely to Skip Preventive Care if ACA Ruling Holds*, Healthleaders (Mar. 17, 2023), https://bit.ly/3AiiP94.

<sup>&</sup>lt;sup>50</sup> Board of Governors of the Federal Reserve System, *Economic Well-Being of U.S. Households in 2022*, at 34-35 (May 2023), https://bit.ly/3plW967.

<sup>&</sup>lt;sup>51</sup> Laura Skopec & Jessica Banthin, Free Preventive Services Improve Access to Care, at 2 (July 2022), https://bit.ly/3pcDQjE.

Plaintiffs have suggested, without support, that "rational people" will continue to use preventive services even with cost-sharing imposed, simply because the services are "valuable."<sup>52</sup> But this assumption is squarely contradicted by the abundant academic research discussed above, which demonstrates that "[c]onsumer cost-sharing . . . diminish[es] utilization of preventive services."<sup>53</sup>

C. Without the federal requirement, companies and insurers will re-impose cost-sharing, which will reduce the use of life-saving services.

The district court's decision allows companies and insurers to reimpose cost-sharing for preventive services. Some companies and insurers will do just that—and many may do so with just sixty days' notice to covered individuals.<sup>54</sup>

That was the case before the ACA, and it is the reason why Congress enacted the preventive services requirement. Thus, HHS estimated in 2015 that the preventive services requirement had brought

<sup>&</sup>lt;sup>52</sup> ROA.2204-05.

 $<sup>^{53}</sup>$  Norris, supra n. 44, at 175.

<sup>&</sup>lt;sup>54</sup> See ROA.2170-71; ROA.2178; see also 42 U.S.C. § 300gg-15(d)(4) (requiring group health plans and health insurance issuers to provide 60 days' notice of material modifications).

76 million Americans expanded cost-free access that they previously lacked.<sup>55</sup>

A recent survey of large employers confirms this reality. Eight percent of employers reported that, without the ACA's requirement, they would impose cost-sharing for preventive services while another 12% were uncertain whether they would. 56 Even if only 8-20% of employers impose cost-sharing, millions of Americans would be affected. And once some insurers and companies impose cost-sharing, it may become a competitive disadvantage not to, because much of the cost savings from preventive care will not accrue until after the end of the covered year—because that is when costlier treatments will be avoided. This may lead even more insurers and companies to drop cost-free coverage.

Indeed, that is what companies have done in other contexts where cost-free coverage is not required. For example, although IRS regulations

<sup>&</sup>lt;sup>55</sup> Assistant Sec'y for Planning & Evaluation, U.S. Dep't of Health and Human Servs., *The Affordable Care Act Is Improving Access to Preventive Services for Millions of Americans*, at 1 (May 14, 2015), https://bit.ly/43RpzIP.

<sup>&</sup>lt;sup>56</sup> Employee Benefit Res. Inst., Will Employers Introduce Cost Sharing for Preventive Services? Findings from EBRI's First Employer Pulse Survey (Oct. 27, 2022), https://bit.ly/41tbAY3.

allow companies' health savings account (HSA)-eligible plans to cover the cost of certain services related to chronic conditions even when the insured has not satisfied the deductible, a recent study shows only 8% of companies covered the costs of all of those services.<sup>57</sup>

Many patients will forgo life-saving preventive services if required to pay for them, because even "modest" cost-sharing "deters patients from receiving care."<sup>58</sup> In addition, by replacing the ACA's clear rules for preventive services coverage with the choices of particular insurers, the district court's ruling will leave providers and patients uncertain as to what services are or are not covered cost-free. Faced with that uncertainty, providers may stop recommending, and patients may stop using, crucial services—even if some plans retain cost-free coverage.<sup>59</sup> Providers who are uncertain what is covered may err on the side of not

<sup>&</sup>lt;sup>57</sup> Employee Benefit Res. Inst., Employer Uptake of Pre-Deductible Coverage for Preventive Services in HSA-Eligible Health Plans (Oct. 14, 2021), https://bit.ly/3N7RqhR.

<sup>&</sup>lt;sup>58</sup> Norris, *supra* n. 44, at 175.

<sup>&</sup>lt;sup>59</sup> See Michele Late, Court Ruling on Prevention Coverage 'Disastrous for Public Health', Pub. Health Newswire (Mar. 31, 2023), https://bit.ly/3UWSqXX ("The confusion and uncertainty will no doubt be a deterrent to early and effective life-saving interventions.").

providing or prescribing services, while patients may not even seek services they suspect might not be covered.

In sum, the district court's order will lead to fewer patients receiving life-saving preventive healthcare. Patients across the Nation may miss cancer screenings and other important services, including critical maternal healthcare. Others will contract diseases that could have been avoided. Without early detection and treatment, more Americans will suffer serious illness and even death.

# D. The district court's universal remedy is the principal source of these draconian consequences.

If the district court had granted relief only to Plaintiffs, the adverse consequences just discussed would be limited to the employees of the two company plaintiffs, the individual plaintiffs, and their families—a quite small group of individuals. It is the district court's decision to grant a universal remedy and issue a nationwide injunction that produces the very substantial adverse public health consequences.

This dispute over a small number of private plaintiffs' health insurance options provides no legitimate basis for eliminating important statutory protections safeguarding the health of more than 150 million Americans.

Grants of nationwide relief are controversial. See, e.g., Dep't of Homeland Sec. v. New York, 140 S. Ct. 599, 600 (2020) (Gorsuch, J., concurring) (nationwide injunctions "raise serious questions about the scope of courts' equitable powers under Article III"); Arizona v. Biden, 40 F.4th 375, 396 (6th Cir. 2022) (Sutton, C.J., concurring) (observing that nationwide injunctions "seem to take the judicial power beyond its traditionally understood uses"); Georgia v. President of the United States, 46 F.4th 1283, 1303 (11th Cir. 2022) (cautioning that "nationwide injunctions push against the boundaries of judicial power"); City of Chicago v. Barr, 961 F.3d 882, 912 (7th Cir. 2020) ("Courts and commentators . . . have recognized serious concerns with imposing injunctive relief that extends beyond the parties before the court.").

That is because the federal courts' "constitutionally prescribed role is to vindicate the individual rights of the people appearing before it." *Gill v. Whitford*, 138 S. Ct. 1916, 1933 (2018); *see also Gonzales-Veliz v. Barr*, 938 F.3d 219, 228 (5th Cir. 2019) (citing *Trump v. Hawaii*, 138 S. Ct. 2392, 2427–28 (2018) (Thomas, J., concurring) for the proposition that "the traditional function of equitable relief is to vindicate the rights of the parties in the suit").

Even in the context of an action under the Administrative Procedure Act, this Court has stated that "[i]t is well-established that '[a] plaintiff's remedy must be tailored to redress the plaintiff's particular injury"—and that a remedy "more limited" than universal vacatur may be appropriate. Cargill v. Garland, 57 F.4th 447, 472 (5th Cir. 2023) (en banc) (quoting Whitford, 138 S. Ct. at 1934); see also 5 U.S.C. § 702 (preserving courts' authority to "deny relief on any other appropriate legal or equitable ground"); Weinberger v. Romero-Barcelo, 456 U.S. 305, 320 (1982) (holding that "a major departure from the long tradition of equity practice should not be lightly implied").

Here, the district court believed it was *obligated* to order universal vacatur. *See* ROA.2122. It therefore failed to take into account the harms caused by nationwide relief and did not determine that a universal remedy was necessary to provide full relief to Plaintiffs.

As the government explains in detail (Br. 41-50), that broad relief is unjustified and impermissible here. That is particularly so because none of the parties subject to the requirement—insurance companies—and only a miniscule number of otherwise affected parties—companies and individuals—have challenged the statutory requirement. This is not

a case where organizations representing a significant portion of regulated entities, or of otherwise burdened parties, are before the Court.

Moreover, the adverse consequences of the district court's universal remedy fall on the more than 150 million Americans who are not parties to this action. They will suffer the significant public-health harms and risks—increased illness, more severe health complications, and in some cases death—all of which is unnecessary to provide full relief to the Plaintiffs before this Court.

This Court should reverse the decision below. But if it does not, the Court should at a minimum narrow the district court's nationwide injunction, tailoring any relief to extend no further than necessary to redress any harms to Plaintiffs.

## **CONCLUSION**

The Court should reverse the district court's judgment relating to the services specified by the USPSTF.

Dated: June 27, 2023 Respectfully submitted,

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#### APPENDIX A

#### LIST OF AMICI CURIAE

- 1. American Public Health Association
- 2. Robert Wood Johnson Foundation
- 3. Trust for America's Health
- 4. ChangeLab Solutions

#### **Public Health Deans**

- 5. Burroughs, Thomas E., PhD, MS, MA, Dean and Professor, SLU College for Public Health and Social Justice, Saint Louis University
- 6. Chandler, G. Thomas, MS, PhD, Dean and Professor of Environmental Health Sciences, Arnold School of Public Health, University of South Carolina
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#### APPENDIX B

#### LIST OF AFFECTED SERVICES<sup>60</sup>

### Services With A or B Recommendation After 2010

| Service                 | Recommendation   |  |
|-------------------------|--|--|
| Screening for Lung      | U.S. Preventive Servs. Taskforce, Screening for        |  |
| Cancer                  | Lung Cancer: US Preventive Services Task Force         |  |
|                         | Recommendation Statement, 325 J. Am. Med.              |  |
|                         | Ass'n 962 (2021), https://bit.ly/3n32Etg.              |  |
| Interventions to        | U.S. Preventive Servs. Taskforce, <i>Interventions</i> |  |
| Prevent Falls in        | to Prevent Falls in Community-Dwelling Older           |  |
| Community-Dwelling      | Adults: US Preventive Services Task Force              |  |
| Older Adults            | Recommendation Statement,                              |  |
|                         | 319 J. Am. Med. Ass'n 1696 (2021),                     |  |
|                         | https://bit.ly/3UXsY4I.                                |  |
| Screening for Hepatitis | U.S. Preventive Servs. Taskforce, Screening for        |  |
| B Virus Infection in    | Hepatitis B Virus Infection in Adolescents and         |  |
| Adolescents and Adults  | Adults: US Preventive Services Task Force              |  |
|                         | Recommendation Statement, 324 J. Am. Med.              |  |
|                         | Ass'n 2415 (2020), https://bit.ly/3H4Zj3W.             |  |
| Screening for Hepatitis | U.S. Preventive Servs. Taskforce, Screening for        |  |
| C Virus Infection in    | Hepatitis C Virus Infection in Adolescents and         |  |
| Adolescents and Adults  | Adults: US Preventive Services Task Force              |  |
|                         | Recommendation Statement, 323 J. Am. Med.              |  |
|                         | Ass'n 970 (2020), https://bit.ly/3KVwmIN.              |  |

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These lists were created by comparing current USPSTF recommendations to the list of recommendations as of September 2011 in the USPSTF's First Annual Report to Congress on High-Priority Evidence Gaps for Clinical Preventive Services. Compare U.S. Preventive Servs. Task Force, Published Recommendations (last visited Apr. 21, 2023), https://bit.ly/3H4AQeU (listing current recommendations) with U.S. Preventive Servs. Task Force, First Annual Report to Congress on High-Priority Evidence Gaps for Clinical Preventive Services – Appendix C (Dec. 2011), https://bit.ly/41XGbg9.

| Ducaynaguna                              | II C Droventive Conve Tealries Drawnsaura  |  |
|--|--|--|
| Preexposure  Drophylovia for the         | U.S. Preventive Servs. Taskforce, <i>Preexposure</i>                                   |  |
| Prophylaxis for the<br>Prevention of HIV | Prophylaxis for the Prevention of HIV Infection:                                       |  |
|  | US Preventive Services Task Force  |  |
| Infection                                | Recommendation Statement, 321 J. Am. Med.  |  |
|  | Ass'n 2203 (2019), https://bit.ly/3UUF5Q7.   |  |
| Aspirin Use to Prevent                   | U.S. Preventive Servs. Taskforce, Aspirin Use to                                       |  |
| Preeclampsia and                         | Prevent Preeclampsia and Related Morbidity and   |  |
| Related Morbidity and                    | Mortality: US Preventive Services Task Force   |  |
| Mortality                                | Recommendation Statement, 326 J. Am. Med.  |  |
|  | Ass'n 1186 (2021), https://bit.ly/3oD9oig.   |  |
| Behavioral Counseling                    | U.S. Preventive Servs. Taskforce, Behavioral   |  |
| to Prevent Skin Cancer                   | Counseling to Prevent Skin Cancer: US  |  |
|  | Preventive Services Task Force Recommendation  |  |
|  | Statement, 319 J. Am. Med. Ass'n 1134 (2018),  |  |
|  | https://bit.ly/3LBsPkd.  |  |
| Interventions to                         | U.S. Preventive Servs. Taskforce, <i>Interventions</i>                                 |  |
| Prevent Perinatal                        | to Prevent Perinatal Depression: US Preventive   |  |
| Depression                               | Services Task Force Recommendation Statement,  |  |
|  | 321 J. Am. Med. Ass'n 580 (2019),  |  |
|  | https://bit.ly/40LTFL3.  |  |
| Screening for                            | U.S. Preventive Servs. Taskforce, Screening for  |  |
| Unhealthy Drug Use                       | Unhealthy Drug Use: US Preventive Services   |  |
| emicaring Brag esc                       | Task Force Recommendation Statement, 323 J.  |  |
|  | Am. Med. Ass'n 2301 (2020),  |  |
|  | https://bit.ly/421YrFd.  |  |
| Behavioral Counseling                    | U.S. Preventive Servs. Taskforce, Behavioral   |  |
| Interventions for                        |  |  |
|  | Counseling Interventions for Healthy Weight and Weight Cain in Programmy US Proportion |  |
| Healthy Weight and                       | Weight Gain in Pregnancy: US Preventive  |  |
| Weight Gain in                           | Services Task Force Recommendation Statement,  |  |
| Pregnancy                                | 325 J. Am. Med. Ass'n 2087 (2020),   |  |
|  | https://bit.ly/3ndIDAk.  |  |

# Services With Change to A or B Recommendation After 2010

| Service           | Recommendation            | Change Since 2010              |
|-------------------|---------------------------|--------------------------------|
| Statin Use to     | U.S. Preventive Servs.    | The current recommendation     |
| Prevent           | Taskforce, Statin Use for | and the 2016 recommendation    |
| Cardiovascular    | the Primary Prevention    | are updated to include the use |
| Disease           | of Cardiovascular         | of statins rather than only    |
|                   | Disease in Adults: US     | screening for lipid disorders. |
|                   | Preventive Services Task  |                                |
|                   | Force Recommendation      |                                |
|                   | Statement,                |                                |
|                   | 328 J. Am. Med. Ass'n     |                                |
|                   | 746 (2022),               |                                |
|                   | https://bit.ly/3N56mgW.   |                                |
| Medication Use    | U.S. Preventive Servs.    | The current recommendation     |
| to Reduce Risk of | Taskforce, Medication     | and the 2013 recommendation    |
| Breast Cancer     | Use to Reduce Risk of     | are updated to include         |
|                   | Breast Cancer: US         | offering to prescribe risk-    |
|                   | Preventive Services Task  | reducing medications.          |
|                   | Force Recommendation      |                                |
|                   | Statement, 322 J. Am.     |                                |
|                   | Med. Ass'n 857 (2020),    |                                |
|                   | https://bit.ly/41JnAor.   |                                |
| Screening for     | U.S. Preventive Servs.    | The current recommendation     |
| Prediabetes and   | Taskforce, Screening for  | expands the covered            |
| Type 2 Diabetes   | Prediabetes and Type 2    | population.                    |
|                   | Diabetes: US Preventive   |                                |
|                   | Services Task Force       |                                |
|                   | Recommendation            |                                |
|                   | Statement, 326 J. Am.     |                                |
|                   | Med. Ass'n 736 (2021),    |                                |
|                   | https://bit.ly/3H0HpiQ.   |                                |

| Screening for     | U.S. Preventive Servs.   | The current recommendation   |
|-------------------|--------------------------|------------------------------|
| Colorectal Cancer | Taskforce, Screening for | expands the covered          |
| (Adults 45 to 49  | Colorectal Cancer: US    | population to include adults |
| years)            | Preventive Services Task | aged 45 to 49 years.         |
|                   | Force Recommendation     |                              |
|                   | Statement, 325 J. Am.    |                              |
|                   | Med. Ass'n 1965 (2021),  |                              |
|                   | https://bit.ly/3oy6oDA.  |                              |
| Screening for     | U.S. Preventive Servs.   | The current recommendation   |
| Colorectal Cancer | Taskforce, Screening for | expands the recommended      |
| (Adults 50 to 75  | Colorectal Cancer: US    | screening strategies.        |
| years)            | Preventive Services Task |                              |
|                   | Force Recommendation     |                              |
|                   | Statement, 325 J. Am.    |                              |
|                   | Med. Ass'n 1965 (2021),  |                              |
|                   | https://bit.ly/3oy6oDA.  |                              |
| Screening for     | U.S. Preventive Servs.   | The current recommendation   |
| Osteoporosis to   | Taskforce, Screening for | expands the covered          |
| Prevent           | Osteoporosis to Prevent  | population.                  |
| Fractures         | Fractures: US Preventive |                              |
|                   | Services Task Force      |                              |
|                   | Recommendation           |                              |
|                   | Statement, 319 J. Am.    |                              |
|                   | Med. Ass'n 2521 (2018),  |                              |
|                   | https://bit.ly/41MnYT3.  |                              |
| Screening for     | U.S. Preventive Servs.   | The current recommendation   |
| Hypertension in   | Taskforce, Screening for | and the 2015 recommendation  |
| Adults            | Hypertension in Adults:  | are updated to include       |
|                   | US Preventive Services   | optimal screening intervals. |
|                   | Task Force               | _                            |
|                   | Recommendation           |                              |
|                   | Statement, 325 J. Am.    |                              |
|                   | Med. Ass'n 1650 (2021),  |                              |
|                   | https://bit.ly/3Vcsvvs.  |                              |

| D 1 · 1           | H C D                          | mı , ı, |
|-------------------|--------------------------------|--|
| Behavioral        | U.S. Preventive Servs.         | The current recommendation               |
| Counseling        | Taskforce, Behavioral          | expands the covered                      |
| Interventions to  | Counseling Interventions       | population based on                      |
| Promote a         | to Promote a Healthy           | cardiovascular risk factors.             |
| Healthy Diet and  | Diet and Physical              |  |
| Physical Activity | Activity for                   |  |
| for               | Cardiovascular Disease         |  |
| Cardiovascular    | Prevention in Adults           |  |
| Disease           | With Cardiovascular            |  |
| Prevention in     | Risk Factors: US               |  |
| Adults With       | Preventive Services Task       |  |
| Cardiovascular    | Force Recommendation           |  |
| Risk Factors      | Statement, 324 J. Am.          |  |
|                   | Med. Ass'n 2069 (2020),        |  |
|                   | https://bit.ly/3oNXOAL.        |  |
| Risk Assessment,  | U.S. Preventive Servs.         | The current recommendation               |
| Genetic           | Taskforce, Risk                | expands the covered                      |
| Counseling, and   | Assessment, Genetic            | population.                              |
| Genetic Testing   | Counseling, and Genetic        |  |
| for BRCA-         | Testing for BRCA-              |  |
| Related Cancer    | Related Cancer: US             |  |
|                   | Preventive Services Task       |  |
|                   | Force Recommendation           |  |
|                   | Statement, 322 J. Am.          |  |
|                   | Med. Ass'n 652 (2019),         |  |
|                   | https://bit.ly/3mUZ44C.        |  |
| Screening for     | U.S. Preventive Servs.         | The current recommendation               |
| Depression in     | Taskforce, Screening for       | expands the circumstances in             |
| Adults            | Depression in Adults: US       | which screening is                       |
|                   | Preventive Services Task       | recommended and is updated               |
|                   | $Force\ Recommendation$        | to include specific                      |
|                   | Statement, 315 J. Am.          | recommendations for                      |
|                   | Med. Ass'n 380 (2016),         | pregnant and postpartum                  |
|                   | https://bit.ly/3oRBWEM.        | women.                                   |
|                   | 1100ps.//b10.1y/0010D W 12111. | W OIIICII.                               |

| Interventions for | U.S. Preventive Servs.   | The current recommendation   |
|-------------------|--------------------------|------------------------------|
| Tobacco Smoking   | Taskforce, Interventions | expands the recommended      |
| Cessation in      | for Tobacco Smoking      | interventions.               |
| Adults, Including | Cessation in Adults,     |                              |
| Pregnant Persons  | Including Pregnant       |                              |
| (Nonpregnant      | Persons: US Preventive   |                              |
| Adults)           | Services Task Force      |                              |
|                   | Recommendation           |                              |
|                   | Statement, 325 J. Am.    |                              |
|                   | Med. Ass'n 265 (2021),   |                              |
|                   | https://bit.ly/41Mm4lx.  |                              |
| Interventions for | U.S. Preventive Servs.   | The current recommendation   |
| Tobacco Smoking   | Taskforce, Interventions | and the 2015 recommendation  |
| Cessation in      | for Tobacco Smoking      | expand the recommended       |
| Adults, Including | Cessation in Adults,     | interventions.               |
| Pregnant Persons  | Including Pregnant       |                              |
| (Pregnant         | Persons: US Preventive   |                              |
| Persons)          | Services Task Force      |                              |
|                   | Recommendation           |                              |
|                   | Statement, 325 J. Am.    |                              |
|                   | Med. Ass'n 265 (2021),   |                              |
|                   | https://bit.ly/41Mm4lx.  |                              |
| Screening for     | U.S. Preventive Servs.   | The current recommendation   |
| Chlamydia and     | Taskforce, Screening for | and the 2014 recommendation  |
| Gonorrhea         | Chlamydia and            | expand the covered           |
|                   | Gonorrhea: US            | population for screening for |
|                   | Preventive Services Task | gonorrhea.                   |
|                   | Force Recommendation     |                              |
|                   | Statement, 326 J. Am.    |                              |
|                   | Med. Ass'n 949 (2021),   |                              |
|                   | https://bit.ly/3ncUMFQ.  |                              |

| D 1 · 1          | H G D                    | 701                         |
|------------------|--------------------------|-----------------------------|
| Behavioral       | U.S. Preventive Servs.   | The current recommendation  |
| Counseling       | Taskforce, Behavioral    | expands the recommended     |
| Interventions to | Counseling Interventions | interventions.              |
| Prevent Sexually | to Prevent Sexually      |                             |
| Transmitted      | Transmitted Infections:  |                             |
| Infections       | US Preventive Services   |                             |
|                  | Task Force               |                             |
|                  | Recommendation           |                             |
|                  | Statement, 324 J. Am.    |                             |
|                  | Med. Ass'n 674 (2020),   |                             |
|                  | https://bit.ly/3oOyGtL.  |                             |
| Screening for    | U.S. Preventive Servs.   | The current recommendation  |
| HIV Infection    | Taskforce, Screening for | and the 2013 recommendation |
|                  | HIV Infection: US        | expand the covered          |
|                  | Preventive Services Task | population.                 |
|                  | Force Recommendation     |                             |
|                  | Statement, 321 J. Am.    |                             |
|                  | Med. Ass'n 2326 (2019),  |                             |
|                  | https://bit.ly/3NiPy5U.  |                             |
| Screening and    | U.S. Preventive Servs.   | The current recommendation  |
| Behavioral       | Taskforce, Screening and | and the 2013 recommendation |
| Counseling       | Behavioral Counseling    | expand the forms of         |
| Interventions to | Interventions to Reduce  | unhealthy alcohol use       |
| Reduce           | Unhealthy Alcohol Use    | covered.                    |
| Unhealthy        | in Adolescents and       |                             |
| Alcohol Use in   | Adults: US Preventive    |                             |
| Adolescents and  | Services Task Force      |                             |
| Adults           | Recommendation           |                             |
|                  | Statement, 320 J. Am.    |                             |
|                  | Med. Ass'n 1899 (2018),  |                             |
|                  | https://bit.ly/3LxNs0N.  |                             |

|                    | T                        |                                |
|--------------------|--------------------------|--------------------------------|
| Screening for      | U.S. Preventive Servs.   | The current recommendation     |
| Syphilis Infection | Taskforce, Screening for | and the 2016 recommendation    |
| in Nonpregnant     | Syphilis Infection in    | update the covered population  |
| Adolescents and    | Nonpregnant              | to explicitly include          |
| Adults             | Adolescents and Adults:  | adolescents at increased risk. |
|                    | US Preventive Services   |                                |
|                    | Task Force               |                                |
|                    | Recommendation           |                                |
|                    | Statement, 328 J. Am.    |                                |
|                    | Med. Ass'n 1243 (2022),  |                                |
|                    | https://bit.ly/3ndN5Py.  |                                |
| Screening for      | U.S. Preventive Servs.   | The current recommendation     |
| Preeclampsia       | Taskforce, Screening for | is updated to recommend        |
| _                  | Preeclampsia: US         | screening during each          |
|                    | Preventive Services Task | prenatal care visit throughout |
|                    | Force Recommendation     | pregnancy.                     |
|                    | Statement, 317 J. Am.    |                                |
|                    | Med. Ass'n 1661 (2017),  |                                |
|                    | https://bit.ly/41IvEpB.  |                                |

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I certify that a true and correct copy of the above document was

filed and served on June 27, 2023, via ECF upon counsel of record for the

parties. I further certify that a copy of this brief was served on

Christopher M. Lynch, counsel for U.S. Department of Justice, via United

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/s/ Andrew J. Pincus

Andrew J. Pincus

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eral Rule of Appellate Procedure 29(a)(5) because this brief contains

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Andrew J. Pincus