IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
FORT WORTH DIVISION

BRAIDWOOD MANAGEMENT, INC., *et al.*, Plaintiffs, v. XAVIER BECERRA, *et al.*, Defendants.	Civil Action No. 4:20-cv-00283-O

DEFENDANTS' MOTION FOR PARTIAL STAY OF JUDGMENT PENDING APPEAL

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DEFENDANTS' MOTION FOR PARTIAL STAY OF JUDGMENT PENDING APPEAL

Defendants respectfully request that this Court stay, pending appeal, a portion of its March 30, 2023 Final Judgment (ECF No. 114). The Court should stay the judgment to the extent it provides relief beyond the Plaintiffs in this case. Specifically, Defendants request that the Court stay the first paragraph of item 3 of the Final Judgment, in which the Court ordered that

> any and all agency actions taken to implement or enforce the preventive care coverage requirements in response to an "A" or "B" recommendation by the PSTF on or after March 23, 2010 are **VACATED** and Defendants and their officers, agents, servants, and employees are **ENJOINED** from implementing or enforcing 42 U.S.C. § 300gg-13(a)(1)'s compulsory coverage requirements in response to an "A" or "B" rating from PSTF in the future.

Final Judgment at 1-2. Defendants' requested stay would not impact the second paragraph of item 3 in the Final Judgment, which declares the coverage requirements invalid as to the prevailing Plaintiffs and enjoins Defendants from enforcing the requirements as to them. These plaintiffs thus would continue, pending appeal, to benefit from complete relief to redress the injuries the Court found them to be experiencing.[1]

A stay of the order to the extent it extends beyond Plaintiffs is necessary to prevent irreparable harm to Americans across the country who would be needlessly deprived of life-saving coverage. The coverage requirements subject to the Court's judgment have been in effect for over a decade and ensure coverage for certain preventive services, without cost sharing, to over 150 million Americans. The affected coverage requirements include numerous critical services, like cholesterol medications to prevent heart disease, PrEP medications to prevent HIV infection, lung

[1] Defendants respectfully request that the Court resolve the instant motion by April 20, 2023, to afford them the opportunity to file an emergency motion in the Fifth Circuit requesting a stay. Defendants further request that, should the Court deny the instant motion, it issue a 14-day administrative stay to enable Defendants to seek a stay pending appeal from the Fifth Circuit.

cancer screenings, and colonoscopies for individuals 45 to 49 years old. The requirement for health plans to cover preventive services without cost sharing has been demonstrated to save lives. Its elimination would do the opposite. After over a decade in effect, the elimination of this requirement would also cause confusion, as healthcare providers and patients alike struggle to understand what preventive services are covered and at what cost (if any) to which individuals in light of the Court's judgment.

In contrast, the limited stay Defendants seek would not cause any harm to the six prevailing Plaintiffs, five of whom do not even currently purchase or provide health insurance. They would continue to benefit from the portion of the Final Judgment providing relief tailored to them. Because this balance of the equities overwhelmingly favors a limited stay, and because the government is likely to succeed on the appeal of the nationwide relief ordered by the Court, the Court should stay the requested portion of the judgment.

LEGAL STANDARD

Courts consider four factors in assessing the propriety of granting a motion to stay a judgment pending appeal: (1) the movant's likelihood of prevailing on the merits of the appeal, (2) whether the movant will suffer irreparable damage absent a stay, (3) the harm that other parties will suffer if a stay is granted, and (4) the public interest. *See Hilton v. Braunskill*, 481 U.S. 770, 776 (1987); *Planned Parenthood of Greater Tex. Surgical Health Servs. v. Abbott*, 734 F.3d 406, 410 (5th Cir. 2013). When the Government is a party, its interests and the public interest overlap in the balancing of harms. *See Nken v. Holder*, 556 U.S. 418, 426 (2009). Under those standards, Defendants are entitled to a stay of the Court's universal vacatur and injunctive relief. *See Dep't of Def.* v. *Meinhold*, 510 U.S. 939, 939 (1993) (staying district court order insofar as it "grants relief to persons other than [the plaintiff]").

ARGUMENT

Defendants have appealed the Court's judgment in its entirety and respectfully submit that they are likely to secure a complete reversal of this Court's holding that the Appointments Clause bars enforcement of 42 U.S.C. § 300gg-13(a)(1)'s requirement that health insurers and employer sponsored health plans cover certain preventive services. But Defendants do not address the merits of the Appointments Clause issue or related severability issues in this motion because Defendants are not seeking to stay the Court's judgment to the extent it applies to Plaintiffs.[2] Instead, Defendants seek a stay pending appeal only the portion of the Court's judgment that extends beyond what is necessary to provide full relief to Plaintiffs and effectively eliminates protections for essential healthcare coverage for millions of people across the Nation—every person in the United States who has or might seek health coverage subject to Section 300gg-13(a)(1). Defendants' likelihood of success on appeal, together with the lopsided balance of hardships, weigh heavily in favor of granting the partial stay being sought pending appellate review.

Defendants Are Likely To Succeed On Appeal Of the Universal Relief Ordered By the Court: Although Defendants recognize that the Court has ruled against them as to the scope of relief, the government is likely to succeed on appeal of that issue, and has, at the very least, raised serious legal questions and presented a substantial case. *See Arnold v. Garlock, Inc.*, 278 F.3d 426, 438-39 (5th Cir. 2001).[3] Among the substantial questions raised by Defendants is whether the Court erred in awarding Plaintiffs universal relief. And Defendants respectfully submit that they

[2] Defendants likewise do not seek a stay of the RFRA portion of the Court's judgment, which is limited to the prevailing Plaintiffs and a single preventive service.

[3] Defendants incorporate by reference their prior remedy arguments, s*ee* ECF Nos. 99 & 112; *see also* ECF Nos. 64 & 83. Defendants reserve the right to make any and all arguments on appeal, but limit their discussion here to the arguments addressing the scope of remedy because of the limited scope of the government's stay request in the instant motion.

are likely to succeed on appeal in arguing that, even assuming that universal relief may be available in some circumstances, such relief was not properly ordered in the particular circumstances of this case. Indeed, Plaintiffs themselves have conceded that "[t]he issue of universal remedies is one of the most contentious and unresolved issues in modern litigation." Pls.' Suppl. Br. Supp. Mot. Summ. J. at 2, ECF No. 98. And the Fifth Circuit has made clear that universal remedies like nationwide injunctions are not "required or even the norm." *Louisiana v. Becerra*, 20 F.4th 260, 263 (5th Cir. 2021). Instead, they "must be justified based on the circumstances." *Id.* (quotation marks omitted). That is because "[i]njunctive relief should be limited in scope to the extent necessary to protect the interests of the parties[,]" and "[i]t is well-settled that a district court abuses its discretion when it drafts an injunction that is unnecessarily broad in scope." *Alley v. U.S. Dep't of Health & Hum. Servs.*, 590 F.3d 1195, 1205 (11th Cir. 2009) (quoting *Keener v. Convergys Corp.*, 342 F.3d 1264, 1269 (11th Cir. 2003)). By contrast, "universal remedies . . . seem to take the judicial power beyond its traditionally understood uses, permitting district courts to order the government to . . . refrain from acting toward nonparties in the case," even though "[t]he law already has a mechanism for applying a judgment to third parties"—the class action. *Arizona v. Biden*, 40 F.4th 375, 396 (6th Cir. 2022) (Sutton, C.J., concurring). These principles apply not only to nationwide injunctions, but also to universal vacaturs that likewise prevent the application of agency action to anyone throughout the United States. And there is no basis for such relief here, where declaratory and injunctive relief barring application of Section 300gg-13(a)(1) to the plaintiffs would afford them complete relief.

When a district court orders "the government to take (or not take) some action with respect to those who are strangers to the suit, it is hard to see how the court could still be acting in the judicial role of resolving cases and controversies." *Dep't of Homeland Sec. v. New York*, 140 S. Ct.

599, 600 (2020) (mem.) (Gorsuch, J., concurring). These constitutional limitations are reinforced by traditional principles of equity, which dictate that relief should, at a minimum, be "no more burdensome to the defendant than necessary to provide complete relief to the plaintiffs." *Madsen v. Women's Health Ctr., Inc.*, 512 U.S. 753, 765 (1994) (quoting *Califano v. Yamasaki*, 442 U.S. 682, 702 (1979)); *see also Arizona*, 40 F.4th at 397 (Sutton, C.J., concurring).

Nationwide relief also takes a "toll on the federal court system." *Trump v. Hawaii*, 138 S. Ct. 2392, 2425 (2018) (Thomas, J., concurring). It "undermines the judicial system's goals of allowing the 'airing of competing views' and permitting multiple judges and circuits to weigh in on significant issues." *Florida v. U.S. Dep't of Health & Hum. Servs.*, 19 F.4th 1271,1283 (11th Cir. 2021) (quoting *Dep't of Homeland Sec.*, 140 S. Ct. at 600 (Gorsuch, J., concurring)). Such relief thus is seriously at odds with the Supreme Court's decision in *United States v. Mendoza*, 464 U.S. 154 (1984), where, in holding that the government is not subject to nonmutual offensive collateral estoppel, the Court reasoned that "[a]llowing only one final adjudication would deprive" it "of the benefit it receives from permitting several courts of appeals to explore a difficult question before th[e] Court grants certiorari." *Id*. at 160.

Nationwide relief also has the effect of "encouraging forum shopping, and making every case a national emergency for the courts and for the Executive Branch." *Hawaii*, 138 S. Ct. at 2425 (Thomas, J., concurring). It impedes the government's ability to implement its policies because the government must "prevail in all 94 district courts and all 12 regional courts of appeals" while one plaintiff can derail a nationwide policy with a single victory. *Arizona v. Biden*, 31 F.4th 469, 484 (6th Cir. 2022) (Sutton, C.J., concurring). And it may erode confidence in the Judiciary by creating an impression that it is setting national policy. "All in all, nationwide injunctions have not been good for the rule of law." *Id*. at 485.

Moreover, Plaintiffs brought this suit as a challenge to a federal *statute*, not as an Administrative Procedure Act (APA) suit challenging *agency action*. Nonetheless, Plaintiffs argued, and the Court concluded, that universal relief was appropriate here under Section 706 of the APA. But even if the APA applied in this case, there is no sound reason to conclude that Congress "meant to upset the bedrock practice of case-by-case judgments with respect to the parties in each case" by adopting the "unremarkable" "set aside" language in Section 706. *Arizona*, 40 F.4th at 396 (Sutton, C.J., concurring). That language simply means that the Court, in deciding the case on the merits, must set aside—must decide the case without reliance on—the agency action found to be unlawful. The relief available in an action under the APA is governed not by Section 706, but by Section 703, which provides for traditional forms of equitable actions and relief, such as "declaratory judgments or writs of prohibitory or mandatory injunction[.]" 5 U.S.C. § 703. And the APA confirms traditional limitations on available relief by, among other things, providing that the statute's authorization of judicial review does not affect "the power or duty of the court to … deny relief on any … equitable ground[.]" *Id.* § 702(1). Congress enacted the APA against a background rule that statutory remedies should be construed in accordance with "traditions of equity practice," *Hecht Co. v. Bowles*, 321 U.S. 321, 329 (1944), and English and early American "courts of equity" typically "did not provide relief beyond the parties to the case[,]" *Hawaii*, 138 S. Ct. at 2427 (Thomas, J., concurring).

Thus, even if vacatur is an available form of equitable relief under the APA—and even if a *universal* vacatur or injunction could be available in some circumstances—such remedies were inequitable here. In this case, the Court's judgment stretched far beyond what was necessary to afford the plaintiffs complete redress, while simultaneously causing substantial disruption and harming millions of other Americans through the nullification of longstanding healthcare

protections. *See Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008) (traditional remedial principles account for "the public interest" and "the balance of equities"); *EME Homer City Generation, LP v. EPA*, 795 F.3d 118, 132 (D.C. Cir. 2015) (Kavanaugh, J.) (declining to vacate unlawful agency action under the APA because "vacatur could cause substantial disruption"). In this context, the universal vacatur entered by the Court is inequitable.

The serious legal questions raised in this case regarding the scope of remedy go beyond the questions of whether a nationwide injunction is appropriate and whether Section 706 authorizes vacatur—and indeed, those questions should not have even entered into this case. Here, Plaintiffs' challenge was not to an agency action, and Plaintiffs did not pursue an APA claim.[4] Instead, Plaintiffs challenged the constitutionality of a federal statute, and they have contended that the Court cannot vacate a statute—i.e., cannot "delete a previously enacted statute from the books." Pls.' Reply in Supp. of Suppl. Mot. Summ. J. & Resp. to Pls.' [sic.]Suppl. Cross-Mot. for Summ. J. at 21, ECF No. 111; *see also* Jonathan F. Mitchell, *The Writ-of-Erasure Fallacy*, 104 Va. L. Rev. 933, 936 (2018) ("The federal courts have no authority to erase a duly enacted law from the statute books, and they have no power to veto or suspend a statute. The power of judicial review is more limited: It permits a court to decline to enforce a statute in a particular case or controversy, and it permits a court to enjoin executive officials from taking steps to enforce a statute—though only while the court's injunction remains in effect.") (footnotes omitted). Declaratory or injunctive relief that would prevent the government from enforcing the *statute* against Plaintiffs was the only appropriate relief in this case, under Plaintiffs' theory. But even if Plaintiffs could also be

[4] Indeed, Plaintiffs have never identified which specific agency actions they intended to be vacated and enjoined, nor did the Court identify any such specific actions in its opinion or Final Judgment. *See* ECF Nos. 98, 111, 113 & 114. Nor did Plaintiffs identify any concrete injury flowing from such unspecified actions, or why it was necessary to vacate or enjoin them to provide plaintiffs with necessary relief.

understood as challenging regulations and other agency actions implementing Section 300gg-13(a)(1), that ancillary relief should also have been limited to an injunction barring enforcement of those measures against Plaintiffs, not vacatur of all agency actions and an injunction barring enforcement of them nationwide.

Moreover, by obtaining an APA remedy without raising an APA claim, Plaintiffs were able to effectively circumvent the six-year statute of limitations for civil actions against the federal government. 28 U.S.C. § 2401(a). Plaintiffs obtained vacatur of agency actions taken on or after March 23, 2010, even though they normally would have had no right to challenge actions taken before March 29, 2014 (six years before they filed their complaint). And the Court granted Plaintiffs vacatur of an unspecified set of past agency actions without considering the remedial questions that arise when a plaintiff invokes the Appointments Clause to challenge the validity of past administrative actions rather than seeking a purely prospective injunction against enforcement. *Cf. Buckley* v. *Valeo*, 424 U.S. 1, 142 (1976) (declining to grant relief that would "affect the validity" of "past acts" of improperly appointed officers). That anomalous result further highlights the problems with allowing Plaintiffs to pursue a universal APA vacatur remedy in this case.

With respect, although the Court has entered a judgment otherwise, Defendants have demonstrated a likelihood of success on appeal of the remedy provided in the first paragraph of item 3 of the Final Judgment sufficient to justify a stay of that portion of the judgment.

The Balance of the Equities Overwhelmingly Favors the Requested Stay: The balance of the equities overwhelmingly favors a stay: The six prevailing Plaintiffs will continue pending appeal to benefit from complete relief if a stay is granted, while approximately 150 million

Americans will lose numerous protections for their healthcare that have been in place for over a decade if no stay is granted.

Plaintiffs will face no harm from Defendants' requested partial stay. The portion of the judgment that is specifically directed to and protects the prevailing Plaintiffs—the declaration that the coverage requirements are invalid as applied to the prevailing Plaintiffs and the injunction precluding Defendants from enforcing the requirements against them—will remain in effect pending appeal. Thus, these plaintiffs will continue to have complete relief to redress their alleged injuries during the appeal. *See* Final Judgment at 2. Braidwood will be able to set the terms of its self-insured plan without the coverage requirements the Court declared invalid. And, although none could "guarantee" they would purchase health insurance in the future, the coverage requirements cannot be enforced against the remaining prevailing Plaintiffs, either, although they do not currently purchase health insurance for reasons independent of the coverage requirements at issue. *See generally* FAC ¶ 61, ECF No. 14 ("Braidwood Management Inc. is self-insured and provides health insurance to its employees."); Declaration of Joel Starnes ¶ 5, ECF No. 111-1 ("I stopped purchasing health insurance for myself and my family and switched to Christian bill-sharing in 2016."); id. ¶ 7; Second Declaration of John Kelley ¶¶ 5-6, ECF No. 111-2 ("I stopped purchasing health insurance for myself and my family and switched to Christian bill-sharing in 2016. . . . I stopped purchasing health insurance for my employees at Kelley Orthodontics in 2016 . . . ."); *id.* ¶ 8; Second Declaration of Zach Maxwell ¶ 5, ECF No. 111-3 ("My wife and I have not carried health insurance since January of 2021, when I left my previous job to start my own business."); *id.* ¶ 7. The requested stay will thus impose no hardship on the prevailing Plaintiffs at all.

By contrast, the public and Defendants face significant harm if the broad and universal relief ordered in the judgment is not stayed. As an initial matter, "any time a [government] is enjoined by a court from effectuating statutes enacted by representatives of its people, it suffers a form of irreparable injury." *Maryland* v. *King*, 567 U.S. 1301, 1303 (2012) (Roberts, C.J., in chambers) (citation omitted). But the harm here is much greater and more far-reaching. The coverage requirements eliminated by the Court's judgment encompass a wide range of preventive measures that are of utmost importance for patient health. Declaration of Lisa M. Gomez ("Gomez Decl.") ¶ 3; *see, e.g., id.* ¶ 7; Decl. of Jeff Wu ("Wu Decl.") ¶ 7. The instant motion highlights but a few examples of the numerous coverage requirements eliminated by the Court's judgment and the effects it could have for disease detection and treatment.

Some coverage requirements have been wholly invalidated by the Court's decision, because the PSTF had no corresponding A or B rating in place prior to March 23, 2010. For example:

- *HIV Prophylaxis (PrEP):* PSTF has issued an "A" recommendation that clinicians offer PrEP medications with effective antiretroviral therapy to persons who are at high risk of HIV acquisition.[5]
- *Lung Cancer screenings:* PSTF has issued a "B" recommendation for annual screening for lung cancer in adults aged 50-80 years who have a 20 pack-year smoking history and currently smoke or have quit within the past 15 years.[6]
- *Statins for cardiovascular disease*: PSTF has issued a "B" recommendation for the use of statins to prevent cardiovascular disease for adults aged 40 to 75 years with one or more risk factor.[7]

These requirements have significant importance for public health. For example, HIV is unquestionably an incurable, and potentially fatal, infectious disease. Since the first cases were

[5] *See* U.S. Preventive Services Task Force, A&B Recommendations, *available at* https://perma.cc/FC9Y-Y3DN.

[6] *Id.*

[7] *Id.*

reported in 1981, more than 700,000 persons in the United States have died of AIDS—which is the most severe stage of HIV—and nearly 16,000 HIV positive people in the United States and its territories died in 2019 alone. APP 380, ¶ 4, ECF No. 65. PrEP medications are remarkably effective at reducing the transmission of the virus that causes that disease, potentially reducing transmission by as much as 99%. APP 381, ¶ 7. Expanding the use of PrEP could have prevented an additional 17,000 HIV cases between 2015 and 2020. APP 382, ¶ 8; *see also* Wu Decl. ¶ 12. Yet the expense of these medications for individuals can be prohibitive, costing in some cases $20,000. APP 383, ¶ 13. Thus, the requirement to cover PrEP without cost sharing expanded the use of PrEP medications by reducing the cost barriers to use. This expanded use, in turn, results in reduced transmission of the HIV virus, and ultimately fewer deaths from conditions related to that virus.

Similarly, lung cancer screenings have an enormous life-saving impact. The five-year rate of survival when lung cancer is caught at an early stage is 61%. Wu Decl. ¶14. But the survival rate is only 7% for cases that are not caught until a late stage. *Id.* The requirement for coverage of early lung cancer screening without cost sharing can thus directly increase patients' life expectancy. Indeed, it has been estimated that the coverage requirement at issue in this case could save approximately 10,000 to 20,000 lives each year. *Id.*

Likewise, the requirement that statins—medication that reduces cholesterol—be covered without cost sharing also saves lives. Cardiovascular disease is the leading cause of death in the United States, and statin use reduces the probability of cardiovascular events like heart attacks and strokes. *Id.* ¶ 15. But poor adherence to statin use is associated with increased risk of cardiovascular disease and death, and studies have shown that even a modest increase of $10 for copayments significantly reduced statin adherence. *Id.*

Other coverage requirements were not wholly eliminated by the Court's judgment, but their scope has been reduced. For these preventive services, an A or B rating from the PSTF was in effect on or before March 23, 2010, but more recent recommendations have expanded the populations for whom cost-free coverage is required or expanded the specific interventions that are covered because of advances in medical science and supporting data. For example:

- *Colorectal cancer screenings*: Prior to March 23, 2010, these screenings were not recommended for adults 45-49. *Id.* ¶ 13.

These expanded requirements make significant contributions to public health. Colon cancer remains one of the leading causes of cancer deaths. *Id.* Increased preventive screening has resulted in a decrease in colorectal cancer incidence. *Id.* But although colorectal cancer has decreased in older adults—who have had the benefit of a coverage requirement for colonoscopies prior to the expanded recommendation in 2021 for adults ages 45-49—colorectal cancer incidence has increased in these younger adults. *Id.* If the the requirement that these younger adults also be provided colon cancer screenings without a copay is eliminated, fewer individuals will be able to detect colon cancer early, and more will die from the disease.

Collectively, the coverage requirements that the Court's judgment prevents Defendants from enforcing nationwide has ensured that more than 150 million Americans can benefit from the above-listed and other preventive services without cost sharing. *Id.* ¶ 3. Absent the requested stay, millions of people will lose the protection of the requirements to include that coverage—or the ability to access them without cost-sharing—during the pendency of the appeals in this case. Available data suggests that more than a third of group health plans (data which, in 2020, covered approximately 14 million participants) may begin new policy years before January 1, 2024. That includes more than 20% of group health plans (available data for which, in 2020, covered approximately 6.3. million participants) that may start a new plan/policy year prior to July 1, 2023.

Gomez Decl. ¶ 5. Many additional plans will begin new policy years in January 2024. If the nationwide vacatur and injunction ordered by the Court remain in effect pending appeal, many of these plans could either eliminate coverage of the relevant preventive services or impose cost sharing for those services. *See id.* ¶¶ 4-6; Wu Decl. ¶¶ 5, 6, 8.

The loss of coverage—or the imposition of cost sharing—for this care would result in significant harm to the public. Increased barriers to obtaining preventive care would result in worse health outcomes. Numerous studies have found that the elimination of cost-sharing requirements for preventive medicine increases the utilization of those services and improves patient outcomes. *See* Wu Decl. ¶¶ 9-15; Gomez Decl. ¶ 7.

In sum, the coverage requirements eliminated by the Court's judgment have saved lives and have broadly benefited the healthcare system. Without a stay, these vital protections will be at risk.

Even if many employers or issuers do not change their plans or policies in the immediate future in response to the Court's judgment, some employers and insurers may do so during the course of the appeal in this case. The covered individuals, the healthcare system, and the public would still be adversely affected by the Court's universal relief. Since the ACA's passage thirteen years ago, preventive services with an A or B rating from the PSTF have been uniformly covered without cost sharing. Thus, providers and patients alike have known what preventive services are available without a cost barrier. Removing the coverage requirements previously in effect would lead to confusion and uncertainty about what services are available without cost sharing, causing some patients to forgo available services and some healthcare providers not to recommend services to eligible patients because of cost concerns. *See* Gomez Decl. ¶ 8; Wu Decl. ¶¶ 4, 16. Patients may also end up being billed for services that they thought were free when they obtained them.

Id. ¶ 16. Insurers too would face uncertainty for themselves and their insureds, especially as they prepare for new policy years. *See generally id.* This confusion would be exacerbated due to the immediacy of the Court's judgment, which provides no time for providers and consumers to determine and understand the effects of the judgment.

CONCLUSION

For the foregoing reasons, Defendants have demonstrated a likelihood of success on appeal of the scope of the universal relief ordered, and have demonstrated that the balance of the equities favors a stay. Defendants respectfully request that the Court stay the first paragraph of item 3 in its March 30, 2023 Final Judgment (ECF No. 114) for the duration of appellate proceedings.

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Certificate of Service

On April 12, 2023, I electronically submitted the foregoing document with the clerk of court for the U.S. District Court, Northern District of Texas, using the electronic case filing system of the court. I hereby certify that I have served all parties who have appeared in the case electronically or by another manner authorized by Federal Rule of Civil Procedure 5(b)(2).

/s/ Christopher M. Lynch
Christopher M. Lynch

Certificate of Conference

Pursuant to Northern District of Texas Local Rule 7.1, on April 12, 2023, I conferred with Jonathan Mitchell, counsel for Plaintiffs, about whether Plaintiffs would consent to the relief requested herein, and Mr. Mitchell advised me that Plaintiffs opposed this requested relief.

/s/ Christopher M. Lynch
Christopher M. Lynch

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
FORT WORTH DIVISION

BRAIDWOOD MANAGEMENT, INC., *et al.*, Plaintiffs, v. XAVIER BECERRA, *et al.*, Defendants.	Civil Action No. 4:20-cv-00283-O

DECLARATION OF JEFF WU

I, Jeff Wu, pursuant to 28 U.S.C.§ 1746, and based upon my personal knowledge and information made known to me in the course of my employment, hereby make the following declaration with respect to the above-captioned matter:

1. I currently serve as the Deputy Director for Policy in the Center for Consumer Information & Insurance Oversight (CCIIO) at the Centers for Medicare & Medicaid Services (CMS). In my role as the Deputy Director, I oversee policy for the commercial health insurance market, including the Health Insurance Exchanges (exchanges).

2. On March 30, 2023, the United States District Court for the Northern District of Texas issued a decision in the case of *Braidwood Management Inc. v. Becerra*, 4:20-cv-00283-O, vacating any and all actions taken by the Departments of Labor, Health and Human Services (HHS), and the Treasury (collectively, the Departments) to implement or enforce the Affordable Care Act's preventive service coverage requirements in response to an "A" or "B" rating by the United States Preventive Services Task Force (USPSTF) on or after March 23, 2010, and

enjoining the Departments from implementing or enforcing the preventive service coverage requirements in response to an "A" or "B" rating from USPSTF in the future (the "*Braidwood* decision"). On March 31, 2023, the U.S. Department of Justice filed a notice of appeal.

3. More than 150 million people with private insurance currently can receive preventive services without cost-sharing under the ACA. *See* Access to Preventive Services without Cost-sharing: Evidence from the Affordable Care Act, Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health and Human Services, Issue Brief No. HP-2022-01 (January 2022), https://perma.cc/UH32-KX6D.

4. The *Braidwood* decision will likely lead to individuals losing access to services, either because their plans or issuers drop coverage of certain preventive services or because the plans or issuers impose cost sharing on such services, leading to individuals forgoing preventive care out of concern about paying for these services. Indeed, the *Braidwood* decision could generate enough confusion that consumers may be concerned they will face cost sharing even when they will not, which could further lead to a decrease in utilization of preventive services. These losses or changes in coverage may result in adverse health outcomes.

5. Most group health plans and group and individual market health insurance policies operate on a calendar year basis, but a significant minority operate on different cycles. For example, universities may offer health insurance policies tied to their academic years and local and state governments may offer group health plans using state fiscal years. Group health plans start in a variety of months throughout the year based on what makes sense for their coverage needs (for example, if a business launched in September, they likely would have started coverage in September and will continue starting their plan years in September moving forward).

6. Plans and issuers do not typically make changes to coverage or cost sharing mid-

year because they price their insurance premiums or premium contributions and design their health plans based on coverage for a full year, and issuers have signed contracts with enrollees and with employers stating that they will cover certain services at certain costs through the end of the plan year. However, certain mid-year changes might be permissible under these contracts, and at least some plans or issuers are expected either to drop coverage or impose cost sharing for certain preventive services because of the *Braidwood* decision. Because not all plans and policies operate on the calendar year cycle, and because certain mid-year changes might be permissible, some of this expected coverage loss could occur in the near future.

7. The *Braidwood* decision affects dozens of preventive services that were added or modified after March 23, 2010, including PrEP for people at high-risk of HIV, colorectal cancer screening for people ages 45-49, lung cancer screenings, and statins for adults at increased risk for cardiovascular disease, just to name a few.

8. Indeed, in light of the *Braidwood* decision, CMS expects that some employers will drop some of the more costly preventive services or impose cost sharing on such services. CMS also expects that some enrollees will choose to forgo preventive services due to plans or issuers imposing cost sharing on such services. For example, employers may decide to drop PrEP coverage (and related ancillary services) because it is a relatively expensive service to cover, it is a newer recommendation, and individuals eligible for PrEP may not be a risk profile that plans and issuers want to attract. It is also possible that some employers may decide to drop coverage of colonoscopies for adults age 45 to 49 due to the cost of such procedures.

9. A number of studies on the effects of cost sharing on health care services have shown a reduction in the use of services after cost sharing increased, regardless of income. *See* Kaiser Commission on Medicaid and the Uninsured, *Premiums and Cost-Sharing in Medicaid: A*

Review of Research Findings (2013), https://perma.cc/U5S6-74KP. More recent research on the effects of cost sharing on low-income individuals also found reductions in the use of health care services, and even small increases in cost sharing can create insurmountable financial barriers for people with low incomes. *See id.* at 6.

10. Research has also shown significant declines specifically in the utilization of preventive services after the introduction of or increase in cost sharing. *See id.* at 6-7. For example, one study analyzed the effect of cost sharing on mammogram utilization among Medicare beneficiaries, comparing the use of mammography services for individuals in plans that had increased or instituted new copays to individuals in plans that had not. *See id.* at 9. The results showed that biennial screening rates were 8.3 percentage points lower in cost sharing plans than in those with full coverage, and that the effect was magnified for women residing in lower income areas. *See id.* (citing Amal N. Trivedi et al., *Effect of Cost Sharing on Screening Mammography in Medicare Health Plans*, 358(4) NEW ENG. J. MED. 375, 375 (2008)); *see also id.* at 8-10 (compiling other studies showing a decrease in utilization of preventive services after the introduction of or increase in cost sharing).

11. In addition to studies demonstrating that cost sharing leads to a decrease in utilization of services, a recent poll indicates that a similar result can be expected here. The Morning Consult (a business intelligence company) polled a sample of 2,199 U.S. adults in January 2023 to better understand if preventive service utilization would be affected by the potential *Braidwood* decision. *See* Jay Asser, HealthLeaders, *Patients Likely to Skip Preventive Care if ACA Rulings Holds* (Mar. 17, 2023), https://perma.cc/RKS3-EXXM. At least two in five respondents said that cost sharing barriers would prevent them from obtaining most of the preventive services currently covered by the Affordable Care Act. *See id.*

12. A decrease in the utilization of preventive services is likely to lead to adverse health outcomes. For example, according to one recent study of men who have sex with men (MSM), for every 10% decrease in PrEP coverage resulting from the anticipated *Braidwood* decision (i.e. for every 10% decrease in PrEP-indicated MSM receiving PrEP), the authors estimate an additional 1,140 HIV infections in the following year in that population. *See* A. David Paltiel et al., *Increased HIV Transmissions With Reduced Insurance Coverage for HIV Preexposure Prophylaxis* (2023), https://perma.cc/ED2W-X7KL. The authors call this a "conservative" estimate, as they only considered primary HIV transmission effects in the year after the ruling, ignoring both infections occurring beyond one year and all secondary transmissions. *Id.* Additionally, PrEP is used by other populations and can help prevent maternal HIV infection and therefore the risk of transmitting HIV to a child through childbirth or breast feeding.

13. Younger people could also lose coverage for colorectal cancer screening, as the 2021 recommendation from USPSTF lowered the minimum age of screening from 50 to 45. Colorectal cancer is the third leading cause of cancer death in the nation with cases increasing in younger ages. *See* American Cancer Society, *Key Statistics for Colorectal Cancer* (2023), https://perma.cc/Y7G6-NPST. During a colonoscopy, physicians remove pre-cancerous polyps as they find them to avoid such polyps becoming cancerous in subsequent years. The American Cancer Society notes that "observational studies suggest that colonoscopy can help reduce [colorectal cancer] incidence by about 40% and mortality by about 60%." *See* American Cancer Society, *Colorectal Cancer: Facts and Figures 2020-2022* at 19, https://perma.cc/PFS2-6L64. The rate of people being diagnosed with colon or rectal cancer each year has dropped overall since the mid-1980s, mainly because more people are getting screened and changing their

lifestyle-related risk factors. *See supra*, *Key Statistics for Colorectal Cancer*, https://perma.cc/Y7G6-NPST.. From 2011 to 2019, colorectal cancer incidence rates dropped by about 1% each year, but this downward trend is mostly in older adults. *Id.* In people younger than 50, rates have been increasing by 1% to 2% a year since the mid-1990s. *Id.* These percentages are significant given the number of new cases each year—the American Cancer Society estimates that there will be 106,970 new cases of colon cancer and 46,050 new cases of rectal cancer in the United States in 2023. *See id.*

14. People could also lose coverage for lung cancer screening, as the USPSTF issued its initial recommendation for lung cancer screening in 2014, and then later expanded it. Lung cancer is the leading cause of cancer deaths among both women and men. *See* American Lung Association, *Lung Cancer Key Findings* (2022), https://perma.cc/6BJZ-AN87. Screening with annual low-dose CT scans can reduce the lung cancer death rate by up to 20% by detecting tumors at early stages when the cancer is more likely to be curable. *Id.* Lung cancer five-year survival rates are significantly higher when cases are diagnosed at an early stage (61%), compared to when they are not caught until a late stage (7%). *Id.* Early diagnosis rates for lung cancer increased by 33% between 2015 and 2020. *See* American Lung Association, *State of Lung Cancer 2020 Report* at 4, https://perma.cc/T8QU-WFRH. Some estimates indicate that the USPSTF recommendations will reduce lung cancer mortality by an estimated 20% to 33% for high-risk individuals, saving approximately 10,000 to 20,000 additional lives each year. *See* American Society of Clinical Oncology Daily News, *Lung Cancer Screening Remains Poor. Here's How to Increase Rates and Save Lives* (Mar. 20, 2022), https://dailynews.ascopubs.org/do/lung-cancer-screening-remains-poor-here-s-increase-rates-and-save-lives.

15. Statins are yet another example of coverage people could lose with potentially devastating health outcomes. Cardiovascular disease is the leading cause of morbidity and death in the United States. While the USPSTF had earlier recommended screening for people at increased risk for cardiovascular disease, in 2016 USPSTF recommended (and later updated) that clinicians prescribe a statin for the prevention of cardiovascular disease in certain adults with risk factors, as statin use reduces the probability of cardiovascular events, such as heart attacks and strokes. *See* U.S. Preventative Services Task Force, *Statin Use for the Primary Prevention of Cardiovascular Disease in Adults: Preventative Medication* (Aug. 23, 2022), https://perma.cc/82AC-NHYU. Lower copayments for statin medications have been associated with higher levels of adherence, with a $10 increase in copayments resulting in a 1.8 percentage point reduction in the likelihood of adherence for new users and a 3 percentage point reduction in the likelihood of adherence for continuing users. *See* Teresa B. Gibson & Tami L. Mark, *Impact of Statin Copayments on Adherence and Medical Care Utilization and Expenditures*, AMERICAN JOURNAL OF MANAGED CARE (2006), https://perma.cc/MYC8-G4R5. Studies find that poor adherence to statins is associated with increased risks of cardiovascular disease and death. *See* Mary A. De Vera et al., *Impact of Statin Adherence on Cardiovascular Disease and Mortality Outcomes: A Systematic Review*, BRITISH JOURNAL OF CLINICAL PHARMACOLOGY (2014), https://perma.cc/9LMV-M4XT.

16. In addition to the expected losses of coverage, the *Braidwood* decision will also lead to uncertainty in the health insurance market during the pendency of the appeal and will create confusion for a variety of entities, particularly enrollees and providers. For example, enrollees in plans that make mid-year coverage changes may suddenly be billed for services that they thought would be free, creating confusion and significant frustration. Also, providers may

be conflicted if current best practices and standards of care suggest they prescribe preventive services that are now no longer covered.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed on April 12, 2022

Jeff Wu
Deputy Director for Policy
Center for Consumer Information & Insurance Oversight (CCIIO)
Centers for Medicare & Medicaid Services (CMS)

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
FORT WORTH DIVISION

BRAIDWOOD MANAGEMENT, INC., *et al.*, Plaintiffs, v. XAVIER BECERRA, *et al.*, Defendants.	Civil Action No. 4:20-cv-00283-O

DECLARATION OF ASSISTANT SECRETARY LISA M. GOMEZ

I, LISA M. GOMEZ, make this declaration, under the penalty of perjury, in support of a stay while this matter is under appeal.

1. I am the Assistant Secretary for Employee Benefits Security with the United States Department of Labor ("Department"). In the course of my official duties, I have knowledge of the facts set forth in this declaration and I am competent to testify to the facts set forth herein.

2. An estimated 133 million Americans have health coverage through 2.5 million Employee Retirement Income Security Act (ERISA)-covered health plans, including both participants (i.e., employees covered under the group health plan) and their beneficiaries.[1] The

[1] There were an estimated 133 million participants and beneficiaries covered by ERISA health plans in CY2020 that could be subject to the Affordable Care Act (ACA) preventive care requirements. An additional 75 million individuals were covered by public-sector employer sponsored health insurance or other private health insurance—which includes individuals who have coverage that is subject to these requirements. Source: Employee Benefits Security Administration (EBSA) estimates based on the Health Insurance Coverage Bulletin: Abstract of Auxiliary Data for the March 2021 Annual Social and Economic Supplement to the Current

Department estimates that there are approximately 200,000 large group health plans covered by ERISA, and 2.3 million ERISA-covered small group health plans, with an estimated 49 million participants in large group plans and 13 million participants in small group plans.[2]

3. In the absence of a stay, a significant number of Americans who are covered by an ERISA health plan face the threat of losing access to the cost-free preventive care coverage required pursuant to an "A" or "B" recommendation by the USPSTF on or after March 23, 2010. The recommendations made by the USPSTF on or after March 23, 2010—which ERISA plans would no longer be required to cover unless a stay is imposed—touch on virtually every aspect of patient health, including HIV Prophylaxis (PrEP), Hepatitis C screenings, and lung cancer screenings.

4. As a result of the court's judgment, plans are now generally free, subject to any state laws that may apply to the underlying insurance coverage or contractual provisions, to add cost-sharing requirements for or drop coverage altogether for preventive care recommended by the USPSTF on or after March 23, 2010. Plans could make such coverage changes in the middle of a plan or policy year and, as a result, plan participants could lose broad coverage for certain preventive care services immediately. Plans are also generally free to make these preventive care coverage changes at the start of the next plan/policy year, and thus plan participants could lose such coverage at any point over the next 12 months.

Population Survey (August 2022), https://perma.cc/VAR7-TGUA. Note that these estimates for individuals in ERISA health plans, public-sector employer sponsored health insurance, and other private health insurance include individuals in grandfathered plans that are exempt from the ACA preventive care requirements.

[2] EBSA estimates based on the 2021 MEPS-IC and Census of Business Data https://meps.ahrq.gov/data_stats/summ_tables/insr/national/series_1/2021/ic21_ia_g.pdf

5. While some plans may continue providing all of the cost-free preventive care coverage, it is likely that a material number of plans will elect to drop coverage for the preventive services at issue, either in the middle of a plan year or (more likely) at the start of the next plan year, or at a minimum elect to begin imposing cost sharing for such services. Based on available data, EBSA anticipates that a number of plans will start new plan/policy years before January 1, 2024. For example, of the roughly 73,000 plans that submitted annual reporting forms to EBSA for plan year 2020, more than one-third (35.7 percent) covering 14.2 million participants had plan years that ended between April 30 and December 30. That includes 22.3 percent of plans (representing 6.3 million participants) that had plan years that ended between April 30 and June 30..[3]

6. As the Departments' 2015 Final Rules on preventive services explained, historically, health insurance issuers have had little incentive to cover preventive services, the benefits of which may only be realized in the future when an individual may no longer be enrolled with that issuer..[4] We expect that such is also often the case with group health plans. This has been borne out by the implementation of preventive care mandates based on USPSTF recommendations. For example, according to a report by the American College of Radiology, a large number of plans adopted cost-free coverage for lung-cancer screenings only after the USPSTF gave such

[3] Source: 2020 Form 5500 filings. Of the estimated 2.5 million ERISA health plans, only 73,125 filed Form 5500s for plan year 2020. This is largely due to a filing exemption for health plans (other than plans required to file the Form M-1) with fewer than 100 participants as of the beginning of the plan year (small plans) that are unfunded, fully insured, or a combination of insured and unfunded. As such, the distribution of plan ending periods reported here is not necessarily representative of the larger ERISA universe.

[4] 80 Fed. Reg. 41318, 41330-31 (July 14, 2015).

screenings a B rating in March of 2021.[5] The Department therefore expects that many plans would not provide cost-free coverage in the absence of a requirement.

7. A loss of coverage for cost-free preventive care would have a substantial negative impact on the health and well-being of plan participants and beneficiaries. Data has shown that without cost-free services, Americans are less inclined to access lifesaving and cost-saving preventive services. For example, as the Department explained in the preamble to the 2015 Final Rules on preventive services, a number of factors prevent widespread use of preventive services, including costs, ethnic/gender disparities,[6] and a general lack of knowledge as to the benefits of preventive services..[7] In addition, many preventive services generate benefits that do not accrue immediately to the individual that receives the services, making the individual less likely to avail themselves of the services, especially in the face of direct, immediate costs. Furthermore, some of the benefits of preventive services accrue to society as a whole and thus are not factored into an individual's decision-making over whether to obtain such services. In sum, the elimination of coverage for these services, or the imposition of cost-sharing for their use, will cause fewer Americans to avail themselves of these services, leading to higher overall health care costs, a sicker population, and loss of life from conditions that could have been prevented. Ensuring that preventive care services are available on a cost-free basis is important to overcoming the barriers to accessing vital health care services.

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[5] American College of Radiology, *Status of Lung Cancer Screening Coverage* (2022), https://perma.cc/D688-TKUE.

[6] 80 Fed. Reg. at 41330 (citing Call, K. T., McAlpine, D. D., Garcia, C. M., Shippee, N., Beebe, T., Adeniyi, T. C., & Shippee, T. (2014). Barriers to Care in an Ethnically Diverse Publicly Insured Population. Medical Care).

[7] 80 Fed. Reg. at 41330 (citing Reed, M. E., Graetz, I., Fung, V., Newhouse, J. P., & Hsu, J. (2012). In consumer-driven health plans, a majority of patients were unaware of free or low-cost preventive care. Health Affairs, 31(12), 2641–2648).

8. These problems would be exacerbated if the loss of these coverage requirements takes effect immediately. Absent a stay of the district court's judgment, if an appeal in this case is ultimately successful, providers and patients will be unnecessarily subjected to abrupt changes in the terms of coverage. Abrupt changes in preventive care coverage—particularly for services that have been covered for a decade or longer—is likely to lead to confusion among providers (with respect to what they recommend for their patients) and patients (with respect to the cost impact of such services).

I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge.

Executed on the 12th of April, 2023 in Washington, D.C.

/s/ Lisa M. Gomez Digitally signed by Lisa M. Gomez Date: 2023.04.12 13:12:31 -04'00'

Assistant Secretary for
Employee Benefits Security
US Department of Labor

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
FORT WORTH DIVISION

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

Plaintiffs,

v.

XAVIER BECERRA, *et al.*,

Defendants.

Civil Action No. 4:20-cv-00283-O

ORDER

Upon consideration of Defendants' Motion for Partial Stay of Judgment Pending Appeal, it is hereby:

ORDERED that the motion is **GRANTED**, and it is further

ORDERED that the first paragraph of item 3 of the Court's Final Judgment, ECF No. 114, which provides that

> any and all agency actions taken to implement or enforce the preventive care coverage requirements in response to an "A" or "B" recommendation by the PSTF on or after March 23, 2010 are **VACATED** and Defendants and their officers, agents, servants, and employees are **ENJOINED** from implementing or enforcing 42 U.S.C. § 300gg-13(a)(1)'s compulsory coverage requirements in response to an "A" or "B" rating from PSTF in the future,

is **STAYED** pending appeal and shall not take effect during the duration of appellate proceedings in this case. The remainder of the Final Judgment shall remain in effect.

SO ORDERED.

REED O'CONNOR
United States District Judge