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

JOHN KELLEY, et al., Plaintiffs, v. XAVIER BECERRA, in his official capacity as Secretary of Health and Human Services, et al., Defendants.	Case No. 4:20-cv-00283-O Judge Reed O'Connor

BRIEF OF AMICI STATES ILLINOIS, CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, THE DISTRICT OF COLUMBIA, HAWAII, MAINE, MARYLAND, MASSACHUSETTS, MICHIGAN, NEVADA, NEW JERSEY, NEW MEXICO, NEW YORK, NORTH CAROLINA, OREGON, PENNSYLVANIA, RHODE ISLAND, VERMONT, AND WASHINGTON IN SUPPORT OF THE DEFENDANTS' MOTION FOR SUMMARY JUDGMENT PURSUANT TO LOCAL RULE 7.2(b)

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INTRODUCTION AND INTEREST OF AMICI STATES

The Amici States of Illinois, California, Colorado, Connecticut, Delaware, The District of Columbia, Hawaii, Maine, Maryland, Massachusetts, Michigan, Nevada, New Jersey, New Mexico, New York, North Carolina, Oregon, Pennsylvania, Rhode Island, Vermont, and Washington ("Amici States") submit this brief in support of Defendants Xavier Becerra, in his official capacity as Secretary of Health and Human Services; Janet Yellen, in her official capacity as Secretary of the Treasury; Martin Walsh, in his official capacity as Secretary of Labor; and the United States of America.

The Amici States have a vital interest in protecting the health and welfare of their citizens, an interest substantially advanced by the challenged provisions of the Affordable Care Act (the "Act"). The Amici States have directly benefitted from and continue to depend on the Act's preventive services provisions, 42 U.S.C. § 300gg-13(a)(1)-(4), which have improved public health outcomes for their residents. The Amici States also operate public health agencies and offer guidance to health insurers within their jurisdictions. They are therefore interested in the outcome of this litigation for the additional reason that they have expended considerable time and resources to implement the Act's requirements, and should the plaintiffs prevail, Amici States will be required to expend additional resources to provide guidance and healthcare if the challenged provisions are enjoined. If the Court were to invalidate the preventive services provisions, that result could destabilize the Amici States' public health systems—including interfering with their abilities to meaningfully respond to the COVID-19 pandemic—which would have a significant effect on their residents. The Amici States thus urge the Court to reject the plaintiffs' sweeping challenges to the Affordable Care Act's preventive services provisions.

ARGUMENT

I. The preventive services provisions have improved public health outcomes within the Amici States, engendered substantial reliance interests, and created a strong public interest weighing against an injunction.

The plaintiffs challenge the Affordable Care Act's preventive services provisions, which collectively require private insurers to "provide coverage for" and "not impose any cost sharing requirements for" certain preventive health services. 42 U.S.C. § 300gg-13(a)(1)-(4). As the plaintiffs seek to enjoin the federal government from enforcing those provisions, the Court must consider the equities, including the public's interest in the government's continued ability to enforce the provisions. *See Winter v. Natural Res. Def. Council*, 555 U.S. 7, 32 (2008) (explaining that "[a]n injunction is a matter of equitable discretion" and that courts must "pay particular regard for the public consequences in employing" that remedy). As this brief explains, the equities weigh strongly in favor of denying the plaintiffs' requested relief—particularly now, as the provisions strengthen the ability of the federal, state, and local governments to respond to the COVID-19 pandemic.

Since their enactment in 2010, these provisions have had a significant and positive impact on Amici States and their residents. Over the last decade, millions of Americans have relied on the preventive services provisions to obtain no-cost preventive care, improving not only their own health and welfare, but public health outcomes more broadly. The Amici States have likewise come to rely on these provisions in building their public health systems over the last decade. The plaintiffs' desired relief would turn back the clock on these reforms.

A. The preventive services provisions have improved public health outcomes for the Amici States' residents.

The preventive services provisions have achieved Congress's primary goal: They have expanded access to low-cost preventive services among people who need those services most and,

in doing so, shifted the national legal framework around public health. Prior to the enactment of the Affordable Care Act, that framework was largely individualized and reactive, focused on treating and curing disease rather than improving population health and preventing the contraction of illness. John Aloysius Cogan, *The Affordable Care Act's Preventive Services Mandate: Breaking Down the Barriers to Nationwide Access to Preventive Services*, 39 J. OF L. MED. ETHICS 355 (2011). This individualized, cure-focused model of healthcare was partially the result of a nationally fragmented legal landscape: Private insurers were regulated by a range of vertical and horizontal laws and rules from states and the federal government, none of which incentivized insurers to support public health considerations. *Id.* at 359-362.

Since the passage of the Act—and, in particular, the preventive services provisions challenged here—preventive services have become significantly more available and accessible to those individuals who need them most. Most basically, 71 million people now have access to free vaccines, cancer screenings, and primary care, among other services. Nadia Chait & Sherry Glied, *Promoting Prevention Under the Affordable Care Act*, 39 ANN. REV. PUB. HEALTH 507 (2018), at 514. A range of academic studies suggests that individuals who have access to no-cost preventive services use them: One study of over 60,000 insured adults, for instance, found a significant increase in the uptake of blood pressure checks, cholesterol checks, and flu vaccinations in the wake of the Affordable Care Act's implementation. Xuesong 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 PREVENTIVE MED. 85 (2015). The preventive services provisions, in other words, have had their intended effect: They have improved access to health services for the Amici States' residents and millions of others like them. Enjoining those provisions would significantly limit access to those important preventive services.

But the improvement in public-health outcomes the Amici States have witnessed is not limited to those Americans who directly use the preventive services covered by the Act. Rather, the preventive services provisions have also alleviated financial and other burdens placed on state public health systems, allowing those systems to better address and prevent other serious public health issues.

Most notably, the Amici States, like a majority of states, run and fund local public health clinics that serve their residents (primarily medically underserved or low-income residents). *See, e.g.*, D.J. Landry et al., *Public Health Departments Providing Sexually Transmitted Disease Services*, 28 FAMILY PLANNING PERSPECTIVES 161 (1995). Before the enactment of the preventive services provisions, states were required to devote substantial budgetary resources to supplying preventive services at such clinics. The preventive services provisions, however, have allowed state public health departments to bill insurance providers when insured people visit state-run health clinics providing vaccinations and other services. *See* Chait & Glied, *supra*, at 517 (citing a study showing that 42% of patients at one public health clinic were insured at the time of their visit but chose the health clinic for confidentiality and convenience purposes). Public health agencies that are able to bill insurance carriers for substantial portions of their caseloads "increase their capacity by allowing for the redirection of funds that would have previously been used on these services." *Id.* States have used this additional departmental capacity to focus on "more traditional public health functions, . . . including disease surveillance." *Id.* This, in turn, has allowed states' public health departments to develop and deploy additional health interventions, expanding and improving health outcomes for all residents.

Similarly, the inclusion of pre-exposure prophylaxis ("PrEP") medication, which helps prevent HIV and AIDS, in the list of preventive services covered by the Act—a medication the

plaintiffs specifically target, Pls.' MSJ, ECF 45, at 30—likewise has had substantial public health benefits for the Amici States and their residents. By the end of 2019, an estimated 1,189,700 people in the United States were HIV-positive, and over 10% of those HIV-positive individuals were unaware of their infection. U.S. Department of Health and Human Services, HIV.gov, *U.S. Statistics*.[1] That same year, over 15,000 HIV-positive individuals died. *Id.* As HIV is generally spread via close contact between individuals, the most effective measures of decreasing infection rates and managing care are at the local level, including through state public health departments. *See* Panagiotoglou et al., *Building the Case For Localized Approaches To HIV: Structural Conditions And Health System Capacity To Address The HIV/AIDS Epidemic In Six US Cities*, 22 AIDS BEHAV. 3071 (2018) (describing city-level "HIV microepidemics" and advocating for targeted, local HIV interventions). Many Amici States have established programs of this nature; for example, the Illinois Department of Public Health's HIV and AIDS Section maintains and funds a PrEP medication assistance program for individuals who need last-resort access to the medication. The preventive services provisions enable these programs by making insurers the first line of defense against HIV and AIDS; without these provisions, the demand placed on state and local governments for preventive services might disrupt their ability to provide safety-net services of this kind.

The result of the preventive services provisions has thus been, in part, to reduce the overall burden placed on state and local public health systems, freeing those systems to pursue other public health interventions. As an example, states with available resources were able to undergo rigorous contact-tracing programs at the start of the COVID-19 pandemic, while states and regions without public health resources or states experiencing other public health crises were not able to respond

[1] https://www.hiv.gov/hiv-basics/overview/data-and-trends/statistics (last updated June 2, 2021).

as quickly or thoroughly. *See, e.g.*, Melvin et al., *The Role of Public Health in COVID-19 Emergency Response Efforts from a Rural Health Perspective*, 17 PREVENTING CHRONIC DISEASE 1 (2020), at 3 (describing challenges of under-resourced and understaffed community health centers, including challenges with contact tracing and providing staff with personal protective equipment); *see also* Jennifer Seelig, *The Need for Contact Tracing Continues*, ABC NEWS10 (June 3, 2021) (describing New York's robust contract-tracing program, reaching 83% of people who tested positive and 88% of their contacts, with 7,430 contact-tracing staff statewide).[2] As states enter the third year of the pandemic, it is imperative that they do not lose the progress in improving public health outcomes that was made possible in part through the preventative services provisions.

B. States have expended time and resources implementing the preventive services provisions.

The preventive services provisions are important to the Amici States for a second reason: many have expended considerable resources creating legal and regulatory infrastructures to support the provisions. If the court were to invalidate the preventive services provisions, this infrastructure would be disrupted, frustrating the Amici States' efforts to help implement Congress' vision and requiring them to operate in limbo during a critical period for public health.

To take one example, many states have passed statutes and promulgated regulations expressly incorporating the recommendations of the advisory boards that the plaintiffs challenge. Illinois, for instance, has promulgated a regulation paralleling the challenged provision that requires insurers governed by state law to cover at no cost the same preventive services recommended by the United States Preventive Services Task Force (PSTF), Advisory Committee

[2] https://www.news10.com/news/local-news/the-need-for-contact-tracing-continues/. All websites last visited January 28, 2022.

on Immunization Practices (ACIP), and Health Resources and Services Administration (HRSA). *See* Ill. Admin. Code 2001.8(a)(1)(A)-(C). Other states have taken similar steps. *See, e.g.*, N.Y. Ins. Law § 3216(g)(17)(E); Cal. Health & Saf. Code, § 1367.002(a); 18 Del. Code § 3558(b); Va. Code Ann. § 38.2-3438-3442; D.C. Code § 31-3834.02(a)(2); N.J. Stat. § 17B:26-2.1mm; Md. Code Ann., Ins. § 15-1A-10.

If the plaintiffs' challenge to the preventive services provisions succeeds, these regulating bodies and advisory panels will be enjoined from performing the duties Congress gave them in the Affordable Care Act, necessitating costly and burdensome changes to the states' own regulatory frameworks for determining which services must be covered by those private insurers governed by state law.[3] Further, even states that have not implemented laws mirroring the Affordable Care Act's preventive services provisions have enjoyed the benefits afforded by those provisions. Invalidating the challenged provisions will require those states to reassess their regulatory frameworks for private insurers operating in their jurisdictions. This type of overhaul would impose significant burdens on states at a time when public health agencies and infrastructure can ill afford such disruption.

II. The plaintiffs' challenges to the preventive services provisions fail.

The plaintiffs seek to enjoin the preventive services provisions on two primary bases: that they violate the Appointments Clause and that, at least as applied to certain preventive services,

[3] The fact that some states have enacted provisions that, like those challenged here, require private insurers to cover certain preventive services does not mean that these states would not be affected by a judgment setting aside the Affordable Care Act's preventive services provisions. For example, these state-law insurance requirements do not apply to self-insured employer health plans, which cover more than half of all Americans. *See* 29 U.S.C. §§ 1144(a), (b)(2)(A); Sonfeld et al., *U.S. Insurance Coverage of Contraceptives and the Impact of Contraceptive Coverage Mandates, 2002*, 36 PERSP. SEXUAL & REPRO. HEALTH 72, 76 (2004). So many of the Amici States' residents are covered only by the Affordable Care Act's requirements, not by the state-law requirements those states have independently imposed.

they violate the plaintiffs' rights under the Religious Freedom Restoration Act ("RFRA"), 20 U.S.C. § 2000bb *et seq.*; Pls.' MSJ at 12–24, 30–37.[4] Each of these arguments fails on the merits and should be rejected. The plaintiffs' Appointments Clause claims fail because the members of the advisory committees Congress tasked with identifying preventive services are not "officers of the United States." And the plaintiffs' RFRA claims fail because the specific preventive services challenged by the plaintiffs do not substantially burden their religious rights and are, in any event, the least restrictive means to meeting a compelling government interest.

A. The plaintiffs' Appointment Clause claims fail because members of the PSTF, ACIP, and HRSA are not "officers of the United States."

The plaintiffs' primary argument is that the preventive services provisions are unconstitutional because they draw on "recommendations" issued by the members of the PSTF and ACIP—two advisory entities—and on "guidelines" issued by HRSA, a subdivision of the U.S. Department of Health and Human Services. Pls.' MSJ at 12–24. According to the plaintiffs, the members of PSTF and ACIP and the HRSA Administrator are "officers of the United States," but they have not been appointed in the manner required by the Appointments Clause. The plaintiffs' premise is incorrect. The members of PSTF and ACIP and the HRSA Administrator lack both the formal, continuous relationship with the federal government and the degree of authority necessary to be "officers" within the meaning of the Appointments Clause.

An individual "must occupy a 'continuing' position established by law" to qualify as an "officer" within the meaning of the Appointments Clause. *Lucia v. SEC*, 138 S. Ct. 2044, 2051 (2018). The Fifth Circuit has interpreted "officer" to require "a continuing and formalized

[4] The plaintiffs also argue briefly that the challenged provisions violated the nondelegation doctrine and the Vesting Clause. Pls.' MSJ 24-30. The Court should reject those arguments on the grounds identified by the defendants.

relationship of employment with the United States Government," *Riley v. St. Luke's Episcopal Hosp.*, 252 F.3d 749, 757 (5th Cir. 2001) (en banc). An "officer" must also "exercise significant authority pursuant to the laws of the United States." *Buckley v. Valeo*, 424 U.S. 1, 126 (1976) (per curiam); *accord Lucia*, 138 S. Ct. at 2051. Members of the PSTF and ACIP fail both requirements. They are neither federal employees, nor do they exercise "continuing" authority. In addition, none of the individuals identified by the plaintiffs exercise "significant authority pursuant to" federal law. The plaintiffs' Appointment Clause claims therefore fail.

1. Members of the PSTF, ACIP, and HRSA lack a formal, continuous relationship with the federal government.

The plaintiffs' challenges to the role entrusted to members of the PSTF and ACIP fail at the outset because the members of these advisory entities lack "a continuing and formalized relationship of employment with the United States Government." *Riley*, 252 F.3d at 757.

In *Riley*, the Fifth Circuit, sitting en banc, held that *qui tam* relators are not "officers of the United States" requiring appointment consistent with the Clause because relators "do not draw a government salary and are not required to establish their fitness for public employment." *Id.* at 758. In reaching that conclusion, the en banc panel relied in part on the Supreme Court's decisions in *Auffmordt v. Hedden*, 137 U.S. 310 (1890), and *United States v. Germaine*, 99 U.S. 508 (1878), each of which concluded that private individuals whose services were used by the federal government only intermittently were not "officers of the United States."

The same is true here. The volunteer members of the PSTF do not have a formalized relationship of employment with the United States. They are not afforded emoluments and do not draw a government salary; instead, they generally maintain full-time practices of medicine (or other professional activities) while lending their expertise to the federal government and the states. *See* 85 Fed. Reg. 711, 712 (Jan. 7, 2020) (PSTF members are all "volunteers and do not receive

any compensation beyond support for travel to in-person meetings."). Similarly, ACIP is comprised primarily of non-federal employees, who likewise do not receive salaries for their participation. *See* U.S. Ctrs. for Disease Control & Prevention, *Advisory Committee on Immunization Practices (ACIP): Charter*.[5] Both advisory entities likewise provide only intermittent services to the federal government, much like the individuals in *Auffmordt* and *Germaine*. *See Riley*, 252 F.3d at 757-58. The volunteer members of each entity by necessity do not have a "continuing and formalized relationship of employment with the United States," as *Riley* requires, *id.* at 757. The plaintiffs' challenge with respect to the PSTF and ACIP fails on that basis alone.

Recognizing that *Riley* requires dismissal of the bulk of their Appointments Clause claims, the plaintiffs ask the Court to ignore or rewrite it, insisting that it "finds no support in" the Supreme Court's recent opinion in *Lucia*. Pls.' MSJ at 16. As the plaintiffs acknowledge, however, *id.*, this Court lacks the power to decline to apply binding Fifth Circuit precedent, and the plaintiffs' suggestion that the Court merely "interpret[]" *Riley* in their preferred manner, *id.* at 16-17, fares little better.[6] *Riley*'s reliance on the fact that the *qui tam* relators there lacked a "formalized . . . employment" relationship with the federal government—in the Fifth Circuit's words, that they did not "draw a government salary" and were "not required to establish their fitness for public employment," 252 F.3d at 757-58—was an essential premise of its holding, not merely dictum that the Court may "interpret" away. Pls.' MSJ at 16. This Court is bound to apply *Riley*.

[5] https://www.cdc.gov/vaccines/acip/committee/charter.html (last updated July 14, 2020).

[6] The plaintiffs also ask the Court to ignore or rewrite *Riley* because it "contradicts" a 2007 opinion of the Office of Legal Counsel. Pls.' MSJ 16 (citing *Officers of the United States Within the Meaning of the Appointments Clause*, 31 Op. O.L.C. 73, 78 (Apr. 16, 2007)). But the Office of Legal Counsel's opinions are, of course, not binding on the Court, so there is no need to read *Riley* in light of the 2007 opinion.

In any event, there is no tension between *Riley* and *Lucia*. *Riley* rests in large part on the Supreme Court's decision in *Germaine*, which, as the Court explained in *Lucia*, "held that 'civil surgeons' (doctors hired to perform various physical exams) were" not officers "because their duties were 'occasional and temporary' rather than 'continuing and permanent.'" 138 S. Ct. at 2051 (quoting *Germaine*, 99 U.S. at 511–12). The plaintiffs suggest that the Supreme Court's description of *Germaine* in *Lucia* establishes that there is no requirement that a federal officer "receive[] payment or emoluments for his work." Pls.' MSJ at 16. But this aspect of the analysis was not at issue in *Lucia*, which focused on whether the administrative law judges (ALJs) at issue in that case "exercised significant authority" under federal law. 138 S. Ct. at 2051; *accord id.* at 2053 (noting that "everyone . . . agree[d]" in *Lucia* that the ALJs held a "continuing office established by law"). Regardless, *Germaine*'s ultimate conclusion—that a private citizen empaneled for "occasional and intermittent" service to the federal government is not an officer of the United States, 99 U.S. at 512—is consistent with both *Lucia* and *Riley*. Under *Germaine*, *Lucia*, and *Riley*, the non-employee members of the PSTF and ACIP are not federal officers.

The plaintiffs' contrary argument would deem every advisory committee convened by statute to satisfy at least the first part of *Lucia*'s test. The federal government maintains an average of 1,000 advisory boards with varying duties, time commitments, and levels of required expertise. *See* Fed. Advisory Committee Act (FACA) Database, U.S. GSA (2021).[7] Some, like the National Advisory Council on Innovation and Entrepreneurship advising the Department of Commerce, are meant to function partially as community engagement boards and are tasked with facilitating federal dialogue with the innovation, entrepreneurship, and workforce development communities. *See* U.S. Economic Development Administration, National Advisory Council on Innovation and

[7] https://www.facadatabase.gov/FACA/FACAPublicPage.

Entrepreneurship (NACIE) (2021).[8] Others, like the Advisory Committee for Biological Sciences within the National Science Foundation, are bodies tasked with reviewing highly technical information and making recommendations to government agencies and branches. *See* National Science Foundation, Directorate for Biological Sciences Advisory Committee (BIO AC) (2021).[9] These committees reflect the federal government's recognition that elected officials often do not possess the level of specific, technical, or scientific expertise necessary to cover all topics that the federal government must regulate. But under the plaintiffs' view, the members of each of these committees—or, at the very least, any committee convened by statute—occupy "continuing positions" that are "established by law" and so are one step toward being deemed "officers of the United States." Pls.' MSJ 13. That cannot be right.

2. Members of the PSTF and ACIP, and the HRSA Administrator, lack the level of authority required to be "officers" within the meaning of the Appointments Clause.

Even if the plaintiffs were correct that "officers" need not have an employment relationship with the federal government, their Appointments Clause challenges would still fail because PSTF, ACIP, and HRSA do not exercise "significant authority" under federal law, *Lucia*, 138 S. Ct. at 2051. They merely issue recommendations or guidelines regarding the preventive services that private insurers must cover.

Lucia, which the plaintiffs heavily rely on, confirms that the "significant authority" requirement is not met here. At issue in *Lucia* was the constitutionality of the appointment of SEC ALJs—adjudicative officers that wielded "nearly all the tools of federal trial judges." 138 S. Ct. at 2053. The Court answered the question whether the ALJs exercised "significant authority" under

[8] https://www.eda.gov/oie/nacie/.

[9] https://www.nsf.gov/bio/advisory.jsp.

federal law by reference to its prior opinion in *Freytag v. Commissioner*, 501 U.S. 868 (1991), holding that the ALJs enjoyed substantially the same power as the "special trial judges" (STJs) at issue in *Freytag* and so were "officers of the United States." As evidence of the "significant" authority wielded by both kinds of adjudicative officers, the Court cited core responsibilities held by STJs and ALJs, such as receiving evidence and examining witnesses at hearings, taking pre-hearing depositions, administering oaths, ruling on motions, regulating the course of hearings and the conduct of counsel, ruling on the admissibility of evidence, and issuing subpoenas. 138 S. Ct. at 2053. The Court also relied on ALJs' and STJs' power to enforce compliance with certain orders and to punish contumacious conduct "by means as severe as excluding the offender from the hearing." *Id.*

Neither the PSTF and ACIP members nor the HRSA Administrator are given any authority comparable to that discussed in *Lucia*. They cannot compel individuals or businesses to appear anywhere or to answer any questions. They cannot issue definitive rulings with respect to rights and responsibilities. They cannot themselves regulate any conduct whatsoever. They have no enforcement authority at all—not even to enforce their own recommendations. As the Act reflects these entities merely issue "recommendations" and "guidelines." 42 U.S.C. § 300gg-13(a)(1)-(4). They and their members are not officers of the United States.

The plaintiffs' primary counterargument is that Congress has required private insurers to cover preventive services and has tasked the advisory entities and HRSA with identifying what those services are. Pls.' MSJ 14-15, 18-19. But Congress has not entrusted these entities with "significant discretion" on matters of policy or practice, as in *Lucia*, 138 S. Ct. at 2052. Instead, *Congress* has made the judgment that private insurers should have to cover certain preventive services at no charge. It has merely tasked the PSTF, ACIP, and HRSA with exercising their expert

judgment to make "recommendations" and issue "guidance" regarding the exact services that should be covered. 42 U.S.C. § 300gg-13(a)(1)-(4). In that sense, these entities' roles are no different than those of the private organizations whose standards Congress frequently incorporates into federal law. *See, e.g.*, 4 U.S.C. § 119(a)(2) (requiring certain databases to be "provided in a format approved by the American National Standards Institute's Accredited Standards Committee"); 42 U.S.C. § 6293(b)(8) (requiring certain test procedures to "be the test procedures specified in ASME A112.19.6–1990"). The plaintiffs' only response is that these standard-setting organizations are not chartered by federal statute. Pls'. MSJ, at 14 n.40. But the question whether an individual has a sufficiently formalized relationship with the federal government to constitute being an "officer" is distinct from whether he or she is entrusted with the authority that accompanies such a position. *See Lucia*, 138 S. Ct. at 2051. The plaintiffs' position appears to be that any private entity whose recommendations are incorporated into federal law has been delegated "significant authority" under federal law. *Id.* That would amount to an unprecedented incursion into Congress' ability to rely on expert entities in setting policy.

B. The plaintiffs' RFRA claims fail.

The plaintiffs' RFRA claims, which are levied only at the requirement that private insurers cover PrEP medication, *see* Compl. ¶¶ 108-111, also fail.[10] RFRA generally prohibits the federal government from "substantially burden[ing] a person's exercise of religion" unless it establishes that the practice in question "is in furtherance of a compelling governmental interest" and "is the least restrictive means of furthering" that interest. 42 U.S.C. § 2000bb-1(a), (b); *see Little Sisters*

[10] The plaintiffs' motion for summary judgment appears to cast a wider net, arguing that they have also asserted meritorious RFRA claims against a range of other preventive services, including "screenings and behavioral counseling for STDs and drug use." Pls.' MSJ, ECF 45, at 30. But the plaintiffs' complaint pleads an RFRA claim only against the requirement to cover PrEP, Compl. ¶¶ 108-111, and they cannot amend the complaint in their motion for summary judgment.

of the Poor Saints Peter & Paul Home v. Pennsylvania, 140 S. Ct. 2367, 2383 (2020). Here, the plaintiffs' RFRA claims fail on multiple grounds.

First, the plaintiffs have failed to establish that the requirement that private insurers cover PrEP medication "substantially burdens" their religious beliefs. The plaintiffs do not articulate any specific religious objection to PrEP medication itself. *See* Pls.' MSJ at 31; *see also, e.g.*, App. 36 (plaintiff Kelley's attestation regarding his religious beliefs). Rather, the plaintiffs explain that they object to "subsidizing lifestyles that violate their religious beliefs," Pls.' MSJ at 31—namely, "homosexual behavior, intravenous drug use, and sexual activity outside of marriage between one man and one woman," *id.* at 32—which they assert that providing PrEP medication does. But the plaintiffs provide no evidentiary support for their assertion that requiring insurers to cover PrEP medication without cost sharing in fact facilitates or encourages any of the identified conduct. Absent any such evidence, the plaintiffs cannot establish that any burden on their religious beliefs is "substantial," as required by RFRA. The plaintiffs' mere assertion that they believe such a connection to exist is not sufficient.

The plaintiffs analogize this case to *Burwell v. Hobby Lobby Stores, Inc.*, 573 U.S. 682 (2014), which upheld a RFRA claim brought against a requirement that private health insurers cover contraceptives. Pls.' MSJ at 31–32. But the plaintiffs in *Hobby Lobby* specifically objected to the medication that insurers were required to cover. *See* 573 U.S. at 691 (explaining that the plaintiffs had "religious objections to abortion," and held religious beliefs that the four contraceptive methods at issue terminated pregnancies). Here, by contrast, the plaintiffs at bottom object not to the actual covered medication, but to voluntary conduct that they assert—without

evidentiary support—is facilitated by the provision of that medication. *Hobby Lobby* provides no support for such an attenuated claim.[11]

The plaintiffs assert that, under *Hobby Lobby* and subsequent cases, the Court "*must* accept [their] complicity-based objections to unwanted health-insurance coverage," "no matter how attenuated" those objections may seem. Pls.' MSJ at 32. That is incorrect. Although Amici States do not question the sincerity of the plaintiffs' religious objections (at least understood as objections to certain "lifestyles" that they associate with HIV-positive status, Pls.' MSJ at 31), the sincerity of a RFRA plaintiff's belief is an analytically distinct question from whether challenged government conduct imposes a "substantial burden" on that belief. That much is evident from RFRA's text, which expressly requires that there be a "substantial[] burden" on a person's "exercise of religion." 42 U.S.C. § 2000bb-1(a), (b). *Cf. United States v. Lee*, 455 U.S. 252, 257 (1982) ("Not all burdens on religion are unconstitutional.").[12] The plaintiffs' suggestion appears to be that a substantial burden exists any time a litigant sincerely believes that it does. As multiple courts of appeals have explained, however, that argument "collapse[s] the distinction between beliefs and substantial burden, such that the latter could be established simply through the sincerity of the former." *Catholic Health Care Sys. v. Burwell*, 796 F.3d 207, 217 (2d Cir. 2015), *vacated*,

[11] The plaintiffs' speculation is also incorrect, as PrEP is used by many people for many reasons, including by married heterosexual people who are or may be HIV-positive and want to ensure that their children are not born with HIV. The plaintiffs make no argument as to how this situation—a recognized diagnostic purpose of PrEP, *see* U.S. Preventive Services Task Force, *Preexposure Prophylaxis for the Prevention of HIV Infection*, 321 J. AM. MED. ASS'N 2203, 2206 (2019) [hereinafter PSTF, *PrEP Recommendation*]—could be understood to encourage behavior to which they object.

[12] Nor does the legislative history of RFRA support the plaintiffs' assertions. *See Little Sisters of the Poor Home for the Aged v. Burwell*, 794 F.3d 1151, 1176 (10th Cir. 2015) (explaining that Congress "added the word 'substantially'" to RFRA's text during the drafting process "to clarify that only some burdens would violate the act"), *vacated sub nom. Zubik v. Burwell*, 136 S. Ct. 1557 (2016).

136 S. Ct. 2450 (2016); *see also, e.g.*, *Geneva Coll. v. Sec'y U.S. Dep't of Health & Human Servs.*, 778 F.3d 422, 442 (3d Cir. 2015) ("RFRA's reference to substantial burdens expressly calls for a qualitative assessment of the burden that the accommodation imposes on . . . the exercise of religion."), *vacated sub nom. Zubik v. Burwell*, 136 S. Ct. 1557 (2016); *Little Sisters of the Poor*, 794 F.3d at 1176; *Priests for Life v. HHS*, 772 F.3d 229, 247 (D.C. Cir. 2014), *vacated sub nom. Zubik v. Burwell*, 136 S. Ct. 1557 (2016). If "RFRA plaintiffs need only to assert that their religious beliefs were substantially burdened" in order to force the government to defend its actions through the strict-scrutiny lens, "federal courts would be reduced to rubber stamps." *Catholic Health Care Sys.*, 796 F.3d at 218. No court has required that result.

Second, the requirement that private insurers cover PrEP medication without cost sharing is justified by a "compelling governmental interest." 42 U.S.C. § 2000bb-1(b). As the PSTF has explained, over 30,000 individuals are diagnosed with HIV each year, and over 15,000 HIV-positive individuals died in 2019. PSTF, *PrEP Recommendation*, *supra*, at 2204, 2208; *see also U.S. Statistics*, *supra* note 1. PrEP medication is highly effective, yet it "is currently not used [by] many persons at high risk of HIV infection." PSTF, *PrEP Recommendation*, *supra*, at 2208-209. The government has a compelling interest in ensuring that individuals have access to life-saving medication. *See Medtronic, Inc. v. Lohr*, 518 U.S. 470, 475 (1996). The plaintiffs do not genuinely dispute that the federal government *could* have a compelling interest in requiring private insurers to cover the cost of preventive services of all kinds, including PrEP medication; their main objection is that Congress failed to specify that PrEP medication *in particular* must be covered by insurers. As explained, however, Congress reasonably and constitutionally asked a range of expert advisory entities to issue "recommendations" and "guidance" regarding the exact services that insurers should cover. That determination does not undercut the "compelling" nature of the federal

government's interest in ensuring that services like PrEP are made available without cost sharing to individuals who need them.

Finally, the preventive services provisions are the least restrictive means Congress could have chosen to ensure meaningful access to PrEP (and similar preventive services). The plaintiffs' only suggestion to the contrary is that Congress could establish an elaborate new program that would allow non-objecting providers to "seek reimbursement from the government for the services that they provide to uninsured or underinsured patients," Pls.' MSJ 36—that is, an entirely new system of public health insurance targeted only at preventive care. But plaintiffs identify no case to have imposed injunctive relief on the federal government on the thought that Congress could simply have established an entirely new administrative apparatus instead. *Cf. Sherbert v. Verner*, 374 U.S. 398, 408 (1963) (describing proposed exemption that, "while theoretically possible, appeared to present an administrative problem of such magnitude . . . that [it] would have rendered the entire statutory scheme unworkable"). The plaintiffs point to *Hobby Lobby* for the proposition that such an analysis is permissible, *see* Pls.' MSJ 36-37, but the language on which they rely is dicta on which the Court ultimately did "not rely . . . in order to conclude that" the regulations there violated RFRA, *Hobby Lobby*, 573 U.S. at 730. In any event, the reality is much starker: Granting the plaintiffs the relief they seek and allowing them to not provide (or pay for) insurance that would cover PrEP would deepen residents' financial reliance on state and local public health systems and upend progress made toward putting an end to the HIV epidemic. *Supra* pp. 2-7. RFRA does not require that result.

CONCLUSION

The plaintiffs' motion for summary judgment should be denied, and the defendants' cross-motion for summary judgment should be granted.

Date: January 28, 2022

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on January 28, 2022, the foregoing proposed *amicus* brief was filed on the Court's electronic filing system with a motion for leave of Court to file. Notice of this filing therefore will be sent to all parties for whom counsel has entered an appearance through the Court's electronic filing system, and Parties may access this filing through the Court's system.

Date: January 28, 2022

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