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

JOHN KELLEY, *et al.*, Plaintiffs, v. ALEX M. AZAR II, *et al.*, Defendants.	Civil Action No. 4:20-cv-00283-O

DEFENDANTS' MOTION TO DISMISS
FIRST AMENDED COMPLAINT PURSUANT TO RULES 12(B)(1) AND 12(B)(6)

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INTRODUCTION

In this case, Plaintiffs seek a second bite at the apple. They attack the insurance coverage requirements for preventive care services established pursuant to the Affordable Care Act, including the requirement that covered health insurance plans cover all FDA-approved methods of birth control for women without cost sharing (the "Contraceptive Mandate"). Yet nearly two years ago, several of the same Plaintiffs brought a challenge before this Court under the Religious Freedom Restoration Act ("RFRA") to the Contraceptive Mandate. *See DeOtte v. Azar*, 393 F. Supp. 3d 490 (N.D. Tex. 2019). They prevailed: the Court concluded that the requirement did not apply to them and they were free to secure health insurance that excluded contraceptive coverage.

In an attempt to avoid this obvious defect, the original Plaintiffs have been joined in their First Amended Complaint ("FAC") by six new Plaintiffs. But this does not help: Two of these new Plaintiffs are no differently situated than the original Plaintiffs, and the other four fail to establish a cognizable injury redressable by the Court.

Plaintiffs' claims must in any event fail. First, they have no standing to bring the vast majority of their claims. Despite their stated intent to challenge all preventive coverage requirements, they have not identified any specific requirement that purportedly injures them aside from the Contraceptive Mandate and the requirement that HIV prevention medications be covered. Nor do they have standing to bring their Contraceptive Mandate claims, most of which are also barred by *res judicata*. Second, their Complaint fails to state a claim with respect to each of their new claims, which not only fail on the merits, but are also variously forfeited, untimely, and/or sketched out in only conclusory allegations. Fundamentally, most of the FAC rests on the basic misunderstanding that the ACA's preventive care requirements are established through the discretion of rogue executive branch officials, when in fact the requirements reflect *Congress's* judgment that insurance must cover standard contemporary preventive medical services, subject

to well-recognized sorts of exceptions. The Complaint should be dismissed.

BACKGROUND

The Affordable Care Act requires health insurers to provide coverage for certain evidence-based preventive services without requiring the insured to share the cost of those services. 42 U.S.C. § 300gg-13. As the practice of medicine is continually advancing, Congress made the judgment to incorporate the evolving recommendations of medical experts as to what constitutes the most critical preventive services, rather than identifying a fixed list of services that insurers must cover. *See id.* As relevant to this case, the statute incorporates four sets of preventive care recommendations and guidelines: items and services with an "A" or "B" grade from the United States Preventive Services Task Force ("PSTF"), *id.* § 300gg-13(a)(1); immunizations with a recommendation from the Centers for Disease Control and Prevention's ("CDC") Advisory Committee on Immunization Practices ("ACIP"), *id.* § 300gg-13(a)(2); the Health Resources and Services Administration's ("HRSA") "comprehensive guidelines" for preventive care and screenings "with respect to infants, children, and adolescents," *id.* § 300gg-13(a)(3); and HRSA's "comprehensive guidelines" for women's preventive care and screenings, *id.* § 300gg-13(a)(4).

Defendants' agencies together issued an interim final rule on July 19, 2010 that identified the relevant recommendations and guidelines referenced by the first three provisions. 75 Fed. Reg. 41,726, 41,740 (July 19, 2010). The rule also requested public comments and set forth the means of determining when future recommendations and guidelines from those entities would be considered final for purposes of those statutory provisions. *Id.* at 41,729. The notice also stated that the HRSA guidelines on women's preventive care were expected by August 1, 2011. *Id.* at 41728. The agencies ultimately issued a final rule that responded to comments on that interim final rule. 78 Fed. Reg. 39,870 (July 2, 2013).

In 2011, HRSA issued its guidelines for women's preventive care, which included all FDA-approved contraceptive methods. *See* First Amended Complaint ("FAC") ¶ 21 (ECF No. 14). This requirement, sometimes referred to as the "Contraceptive Mandate," has been implemented through "notice-and-comment regulations" promulgated jointly by the Secretary of Health and Human Services, Secretary of the Treasury, and Secretary of Labor. *Id.* ¶ 22. The Secretaries have "solicited public comments on a number of occasions" regarding implementation of the Contraceptive Mandate, including in the course of "issuing and finalizing three interim final regulations prior to 2017." 83 Fed. Reg. 57,536, 57,539 (Nov. 15, 2018) (incorporated into ¶ 24 of the FAC). These implementing regulations "defined the scope of permissible exemptions and accommodations for certain religious objectors" to the Contraceptive Mandate. *Id.*

In 2018, the Departments issued a final rule that "exempts any non-profit or for-profit employer from the Contraceptive Mandate if it opposes the coverage of contraception for sincere religious reasons" and "ensur[es] that individual religious objectors would have the option to purchase health insurance that excludes contraception from any willing health insurance issuer." FAC ¶¶ 24, 25. Although enforcement of the 2018 final rule was enjoined on the day it was to take effect, *see* FAC ¶ 26, litigation was filed before this Court contending that the 2018 final rule's accommodation to religious objectors was required by RFRA. FAC ¶ 27; *see DeOtte v. Azar*, 393 F. Supp. 3d 490 (N.D. Tex. 2019). This Court certified classes of individuals who "(1) object to coverage or payments for some or all contraceptive services based on sincerely held religious beliefs; and (2) would be willing to purchase or obtain health insurance that excludes coverage or payments for some or all contraceptive services," and employers who "object[], based on [their] sincerely held religious beliefs, to . . . providing . . . coverage or payments for some or all contraceptive services." FAC Ex. 5 at 1. The Court "permanently enjoined federal officials from

enforcing the Contraceptive Mandate against any religious objector protected by the [2018] final rule." FAC ¶ 27.

On June 11, 2019, the PSTF issued a recommendation for preexposure prophylaxis (PrEP) drugs, which are antiviral medications that "decreas[e] the risk of HIV infection." FAC Ex. 6 at 1. The PSTF gave a grade of "A" to PrEP drugs for "[p]ersons at high risk of HIV acquisition." *Id.* The PSTF had posted a draft of that recommendation on its website for public comment for over a month, and the final recommendation included responses to the public comments the PSTF received. *Id.* Ex. 6 at 5. One such drug is Truvada. FAC at 2.

Four plaintiffs initially brought this action as a class action challenging the PSTF recommendations, ACIP recommendations, and HRSA guidelines—including the Contraceptive Mandate—on multiple grounds. *See generally* Complaint—Class Action ("Compl.") (ECF No. 1). In response to Defendants' motion to dismiss, Plaintiffs filed the FAC, withdrawing several causes of action and their class action claims, and adding six additional Plaintiffs. *Compare* Compl. *with* FAC. Plaintiffs John Kelley, Joel Starnes, Zach Maxwell, and Ashley Maxwell sue because they "do not want or need contraceptive coverage in their health insurance," "do not want or need free STD testing covered by their health insurance," and "do not want or need health insurance that covers Truvada or PrEP drugs." FAC ¶ 35. Each is "a Christian, and . . . unwilling to purchase health insurance that subsidizes abortifacient contraception or PrEP drugs that encourage and facilitate homosexual behavior." FAC ¶ 36. Each contends that, despite the *DeOtte* injunction permitting issuance of coverage that excludes contraceptive coverage, "few if any insurance companies are offering health insurance of this sort." FAC ¶ 37.

Plaintiffs Donovan Riddle, Karla Riddle, and Joel Miller object only to the Contraceptive Mandate and not any other preventive care requirement. They "do[] not hold religious or moral

objections to any of the FDA-approved contraceptive methods." FAC ¶¶ 40, 45. The Riddles' objection "is based solely on the fact that they [do] not need or want contraceptive coverage on account of Mrs. Riddle's hysterectomy," while Plaintiff Miller's objection "is based solely on the fact that he does not need or want contraceptive coverage because his wife is past her childbearing years." FAC ¶¶ 42, 47.

Plaintiff Gregory Scheideman does not object to any preventive care mandate on religious grounds, but only on the ground that they require him to "pay for preventive-care coverage that he does not want or need" and "force [his] company to pay higher premiums for health insurance that must cover preventive care free of charge." FAC ¶¶ 50-51.

Plaintiff Kelley Orthodontics "wishes to provide health insurance for its employees that excludes coverage of contraception, PrEP drugs, and other preventive care required by defendants' current interpretation and enforcement of 42 U.S.C. § 300gg-13," but alleges it has been "impossible for Kelley Orthodontics to purchase health insurance that excludes this unwanted coverage." FAC ¶¶ 55-56.

Plaintiff Braidwood Management Inc. ("Braidwood") employs the people who work at three business entities, each of which is owned by Steven Hotze. FAC ¶¶ 58–60. Hotze is also the sole trustee and beneficiary of the trust that owns Braidwood. FAC ¶ 59. Braidwood is self-insured and must offer ACA-compliant health insurance. FAC ¶ 61. Hotze "is a Christian," and alleges he is unwilling to allow Braidwood's self-insured plan to cover PrEP drugs "because those drugs facilitate or encourage homosexual behavior." FAC ¶¶ 62–63. Hotze also "objects to other preventive-care mandates" because they "deprive [him] of choice and make[] the provision of health care . . . more costly and expensive." FAC ¶ 64; *cf.* Compl. ¶ 53 (objecting to "preventive-care mandates that require Braidwood's plan to cover STD screenings and counseling for those

engaged in non-marital sexual behavior"). Braidwood is not currently required to provide contraceptive coverage because of the injunction in *DeOtte*. Compl. ¶ 117.

LEGAL STANDARD

To survive a motion to dismiss under Federal Rule of Civil Procedure 12(b)(1), the plaintiff bears the burden to establish a court's jurisdiction. *See Lujan v. Defs. of Wildlife*, 504 U.S. 555, 561 (1992). It is "presume[d] that federal courts lack jurisdiction unless the contrary appears affirmatively from the record." *DaimlerChrysler Corp. v. Cuno*, 547 U.S. 332, 342 n.3 (2006) (citation omitted).

Under both Rule 12(b)(1) and Rule 12(b)(6), to survive a motion to dismiss, a complaint must contain "enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). This "plausibility" standard "asks for more than a sheer possibility that a defendant has acted unlawfully." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (citation omitted). "Where a complaint pleads facts that are 'merely consistent with' a defendant's liability, it 'stops short of the line between possibility and plausibility of 'entitlement to relief.'" *Id*. (quoting *Twombly*, 550 U.S. at 557). While the Court accepts well-pleaded factual allegations as true, "mere conclusory statements" and "legal conclusion[s] couched as . . . factual allegation[s]" are "disentitle[d] . . . to th[is] presumption of truth." *Id*. at 678, 681 (citation omitted).

While courts apply the plausibility standard under both rules, "in examining a Rule 12(b)(1) motion, a district court is empowered to find facts as necessary to determine whether it has jurisdiction." *Machete Prods., LLC v. Page*, 809 F.3d 281, 287 (5th Cir. 2015). Accordingly, "the district court may consider evidence outside the pleadings and resolve factual disputes." *In re The Compl. of RLB Contracting, Inc., as Owner of the Dredge Jonathan King Boyd its Engine,*

Tackle, & Gear for Exoneration or Limitation of Liab. v. Butler, 773 F.3d 596, 601 (5th Cir. 2014). By contrast, "when ruling on Rule 12(b)(6) motions to dismiss, . . . [courts may examine] documents incorporated into the complaint by reference, and matters of which a court may take judicial notice." *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 322 (2007).

ARGUMENT

I. PLAINTIFFS LACK STANDING

A. Plaintiffs Kelley, Starnes, Zach and Ashley Maxwell, Kelley Orthodontics, and Braidwood Lack Standing to Challenge the Contraceptive Mandate

"As held by the Supreme Court, standing is an essential and unchanging part of the case-or-controversy requirement of Article III of the United States Constitution. Indeed, standing determines a court's fundamental power to even hear a suit." *Dall. S. Mill, Inc. v. Kaolin Mushroom Farms, Inc.*, No. 3:05-CV-1890-B, 2006 WL 8437487, at *3 (N.D. Tex. Aug. 10, 2006) (citing *Lujan*, 504 U.S. at 560; *Grant ex rel. Family Eldercare v. Gilbert*, 324 F.3d 383, 386 (5th Cir. 2003)). To meet their burden to establish standing, Plaintiffs must establish three elements: "(1) an 'injury in fact' that is (a) concrete and particularized and (b) actual or imminent; (2) a causal connection between the injury and the conduct complained of; and (3) the likelihood that a favorable decision will redress the injury." *Croft v. Governor of Tex.*, 562 F.3d 735, 745 (5th Cir. 2009). Because Plaintiffs[1] cannot show *any* of these three elements are present with respect to their claims regarding the Contraceptive Mandate, those claims must be dismissed.

[1] In this Part I.A and in Part II, *infra*, "Plaintiffs" refers only to Plaintiffs Kelley, Starnes, Zach Maxwell, Ashley Maxwell, Kelley Orthodontics, and, to the extent it seeks to challenge the Contraceptive Mandate, Braidwood. Braidwood does not allege the Contraceptive Mandate is causing it any injury, and for that reason alone fails to establish standing with respect to that mandate. To the extent the Complaint can be read to assert a claim against the Contraceptive Mandate by Braidwood Management, however, that Plaintiff does not have standing for the same reasons as the other Plaintiffs; in fact, as Braidwood Management, Inc. conceded in its original

First, Plaintiffs have no legally cognizable injury arising from the Contraceptive Mandate. The injury they allege, based on "defendants' enforcement of the federal Contraceptive Mandate," FAC ¶¶ 38, 57, cannot satisfy the requirements of Article III, because as Plaintiffs admit, this Court has already "permanently enjoined federal officials from enforcing the Contraceptive Mandate against any religious objector," including Plaintiffs. *Id.* ¶ 27, *see id.* Ex. 5. One would be hard-pressed to find a more textbook illustration of an action failing to satisfy the case or controversy requirement of Article III than this one: Here, Plaintiffs challenge a law that undisputedly does not apply to them because this Court has already so held. *See* FAC ¶¶ 24, 25, 27 & Ex. 5; *see generally DeOtte*, 393 F. Supp. 3d 490. Plaintiffs nowhere contend that the Contraceptive Mandate is being enforced upon them notwithstanding *DeOtte*'s explicitly forbidding any such enforcement. In the absence of any allegation that the challenged regulation applies to or is being enforced against them *at all*, Plaintiffs have no cognizable injury in fact. *See, e.g., KERM, Inc. v. FCC*, 353 F.3d 57, 59 (D.C. Cir. 2004) ("Where a petitioner is not subject to the administrative decision it challenges, courts are particularly disinclined to find that the requirements of standing are satisfied.").

Indeed, Plaintiffs do not allege that they are unable to purchase health insurance that excludes contraceptive coverage or that no such health insurance is available to them. They merely allege that the existence of the Contraceptive Mandate "*drastically restricts the available options* on the market," because "*few* if any insurance companies are offering health insurance of that sort." FAC ¶ 37 (emphasis added); *see also id.* ¶ 28. But Plaintiffs' allegations that their options to choose health insurance coverage are narrower than they would prefer are insufficient to establish a

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complaint, it was one of the named plaintiffs in *DeOtte* that secured itself an exemption from the Contraceptive Mandate. *See* Compl. ¶ 117.

cognizable injury, as there is no legally protected right to an unfettered choice in health insurance coverage. In short, Plaintiffs' mere wish that third parties were willing to offer them more (and more preferable) options for contraception-free health insurance fails to establish the requisite injury-in fact.

Article III standing also requires a plaintiff to show "a causal connection between the injury and the conduct complained of." *Lujan*, 504 U.S. at 560. Federal courts have jurisdiction only if the plaintiff's injury "fairly can be traced to the challenged [conduct] of the defendant, and [does] not . . . result[] from the independent action of some third party not before the court." *Simon v. E. Ky. Welfare Rights Org.*, 426 U.S. 26, 41–42 (1976). Courts are "reluctan[t] to endorse standing theories that rest on speculation about the decisions of independent actors." *Clapper v. Amnesty Int'l, USA*, 568 U.S. 398, 414 (2013). Thus, when the plaintiff's asserted injury "depends on the unfettered choices made by independent actors not before the courts," standing ordinarily becomes "substantially more difficult to establish." *Lujan*, 504 U.S. at 562 (citations omitted); *see also Inclusive Cmtys. Project, Inc. v. Dep't of Treasury*, 946 F.3d 649, 655–56 (5th Cir. 2019) ("Those standards make it difficult for a plaintiff to establish standing to challenge a government action if he isn't its direct object."). In these circumstances, the plaintiffs must show that the government's action will have a "determinative or coercive effect upon the action of" those third parties. *Bennett v. Spear*, 520 U.S. 154, 169 (1997).

Here, Plaintiffs concede that the Contraceptive Mandate does not apply to them, because this Court in *DeOtte* "permanently enjoined federal officials from enforcing [it] against any religious objector." FAC ¶ 27. They further concede that, as a result of the *DeOtte* injunction, "the protections conferred by the Trump Administration's final rule" which gives individual religious objectors "the option of purchas[ing] health insurance that excludes contraception from any willing

health insurance issuer" and "exempts any . . . employer from the Contraceptive Mandate if it opposes the coverage of contraception for sincere religious reasons" "are in full force and effect." *Id.* ¶¶ 24, 25, 27. This concession is fatal to Plaintiffs' contention that their putative injury is sufficiently traceable to Defendants to satisfy Article III.

Instead of challenging the actions of Defendants, Plaintiffs allege that "few if any insurance companies are currently offering health insurance" "that excludes contraception" even though "the *DeOtte* injunction permits issuers of health insurance to issue group or individual health insurance that excludes contraception to religious objectors." *Id.* ¶ 37; *see id.* ¶ 28. But this is simply admitting that their putative injuries "depend[] on the unfettered choices made by independent actors not before the [Court]"—the insurance companies—and that those companies are freely "permit[ted] . . . to issue" the type of insurance Plaintiffs want. *Lujan*, 504 U.S. at 562; FAC ¶¶ 31, 38. Although "few . . . are currently" choosing to do so, *id.* ¶ 37; *see id.* ¶ 28, Defendants' actions can necessarily have no "determinative or coercive effect" upon the actions of these third parties, given these parties are expressly permitted by law to do what Plaintiffs wish. *Bennett*, 520 U.S. at 169.

For the same reasons, Plaintiffs also cannot satisfy the third required element of standing. To do so, a plaintiff must show that "it is *likely*, as opposed to merely *speculative*, that the injury will be redressed by a favorable decision." *Inclusive Cmtys. Project*, 946 F.3d at 655 (quoting *Friends of the Earth, Inc. v. Laidlaw Envtl. Servs. (TOC), Inc.*, 528 U.S. 167, 181 (2000)) (emphasis added). Here, the Contraceptive Mandate already does not apply to Plaintiffs by virtue of the *DeOtte* injunction, and insurers remain free to offer them health insurance without contraceptive coverage. *See* FAC ¶¶ 27, 28, 37. Invalidating the Contraceptive Mandate would leave Plaintiffs in the same position: They would be, just as they are now, subject to the market-

based choices of issuers of health insurance, and those insurers would be free to offer health insurance with or without contraceptive coverage as they see fit. Whether those insurers would choose to offer a different menu of health insurance products in that scenario can only be the subject of speculation, which is insufficient to establish standing.[2]

B. Plaintiffs Donovan and Karla Riddle, Miller, and Scheideman Lack Standing to Bring Any of Their Claims

Plaintiffs Donovan Riddle, Karla Riddle, Miller, and Scheideman also lack standing. Although both Plaintiffs Riddle and Plaintiff Miller object only to the Contraceptive Mandate and not any of the other preventive care requirements, while Plaintiff Scheideman apparently objects to all such requirements, the defect in their standing is the same: they have not shown that any challenged mandate harms them. "Standing to sue must be proven, not merely asserted." *Doe v. Tangipahoa Par. Sch. Bd.*, 494 F.3d 494, 496–97 (5th Cir. 2007) (en banc). Here, Plaintiffs Donovan Riddle, Karla Riddle, Miller, and Scheideman do not allege that the mere presence of contraceptive coverage or other preventive care coverage in their insurance plan injures them or that their purchase of a plan that includes preventive care coverage enables conduct they find religiously objectionable; they assert only that it is "impossible" for them "to purchase health insurance unless [they] agree[] to pay for preventive care coverage that [they] do[] not want or need." FAC ¶¶ 41, 46. Neither the two Plaintiffs Riddle nor Plaintiff Miller explain how this injures them at all, and thus their putative injury is insufficiently "concrete" to establish standing. *Croft,*

[2] Plaintiffs' claims regarding the requirement that insurance cover PrEP medications fail for the same reason. The Complaint alleges that it is "impossible" for Plaintiffs Kelley, Starnes, Zach Maxwell, and Ashley Maxwell "to purchase health insurance that excludes" these services, even though the Complaint concedes that the requirement that these services be covered "will not take effect until 2021." FAC ¶¶ 31, 35. In other words, the Complaint concedes that private insurers have made the decision to cover these treatments regardless of Defendants' actions, so Plaintiffs cannot demonstrate the required elements of traceability and redressability.

562 F.3d at 745.

But even if their allegations are construed to assert the same injury as Plaintiff Scheideman, who contends that the inclusion of preventive care mandates "force[s] [him] to pay higher premiums for health insurance that must cover preventive care free of charge," it would still be insufficient to establish standing. FAC ¶ 51. That allegation is no more than mere *speculation* that, in the absence of the preventive services provision, Scheideman would have access to insurance plans that omit certain preventive care coverage and would cost less as a result. Scheideman does not allege any facts showing that, but for the preventive services provision, he would have access to a plan with lower premiums. Nor does Scheideman (unlike Miller and the Riddles, who focus only on contraceptive coverage) even identify any specific preventive care service that he objects to or would not choose on his own.

It is no surprise that Scheideman offers no allegations that the preventive services provision increases his premiums. His speculation runs against the agencies' determination over the course of years of rulemaking that insurers likely would not charge lower premiums even if they decided to offer a plan that omits any particular preventive services. Indeed, cost-savings, or at the very least cost-neutrality, are among the purposes of requiring coverage for preventive services: by preventing conditions that require expensive medical care, use of preventive services reduces the costs of insurance and can result in lower premiums. *See* 75 Fed. Reg. at 41,731, 41,733 (noting that "some of the benefits of preventive services accrue to society as a whole" and that "some of the recommended preventive services will result in savings due to lower healthcare costs").

This is particularly true of contraceptive coverage. The agencies that administer § 300gg-13(a)(4) have concluded throughout their rulemakings that "compliance with the contraceptive Mandate is cost-neutral to issuers, which indicates that no significant financial incentive exists to

omit contraceptive coverage." 82 Fed. Reg. 47,792, 47,819 (Oct. 13, 2017); *see also* 76 Fed. Reg. 46,621 (Aug 3, 2011) (initial regulation implementing Contraceptive Mandate noting "[t]he Departments expect that this amendment will not result in any additional significant burden or costs to the affected entities"). True, when the agencies issued their rules regarding the current conscience exemptions, upheld recently by the Supreme Court in *Little Sisters of the Poor v. Pennsylvania*, 140 S. Ct. 2367 (2020), the agencies acknowledged that it was possible "premiums may be expected to adjust to reflect changes in coverage" for plans that dropped contraceptive coverage under the exemption. 82 Fed. Reg. at 47,819. But the mere *possibility* that premiums might be different absent the Contraceptive Mandate is not sufficient to show that the Contraceptive Mandate has made Plaintiffs' premiums higher.

That deficiency also means that these Plaintiffs cannot show this lawsuit will redress their putative injury. They must show that, if they prevail in this case, insurers would likely offer them plans that are lower in price because they exclude the coverage of particular preventive services. *See, e.g.*, *Inclusive Cmtys. Project*, 946 F.3d at 655 (plaintiff must show that "it is *likely*, as opposed to merely *speculative*, that the injury will be redressed by a favorable decision." (emphasis added) (quoting *Friends of the Earth*, 528 U.S. at 181)). But they have provided no basis for that conclusion except for one sentence in the FAC speculating that the preventive services provision causes higher premiums. *See* FAC ¶ 51 ("The preventive care coverage mandates also force Dr. Scheideman's company to pay higher premiums for health insurance that must cover preventive care free of charge . . . ."). They have therefore failed to establish standing in this case.

C. All Plaintiffs Lack Standing to Challenge Preventive Care Requirements Other than the Contraceptive Mandate and the PrEP Coverage Requirement

Even if Plaintiffs could surmount the standing hurdles addressed above, no Plaintiff alleges that he, she, or it is harmed by the requirement that any specific care or service be covered except

contraception (required per HRSA's guidelines promulgated under 42 U.S.C. § 300gg-13(a)(4)) and PrEP medications (required as a result of PSTF's recommendation pursuant to 42 U.S.C. § 300gg-13(a)(1)). And no Plaintiff articulates how any putative injury from either the Contraceptive Mandate or the PrEP coverage requirement could be redressed by invalidating any preventive care provision other than those requirements. Accordingly, Plaintiffs have failed to establish standing to challenge the preventive care requirements established by ACIP pursuant to 42 U.S.C. § 300gg-13(a)(2), the preventive care requirements established by HRSA for infants, children, and adolescents pursuant to 42 U.S.C. § 300gg-13(a)(3), or any preventive care requirement other than contraception or PrEP medications promulgated pursuant to 42 U.S.C. § 300gg-13(a)(1) or (4).

II. *RES JUDICATA* BARS THE CHALLENGES OF PLAINTIFFS KELLEY, STARNES, ZACH AND ASHLEY MAXWELL, KELLEY ORTHODONTICS, AND BRAIDWOOD TO THE CONTRACEPTIVE MANDATE

As Plaintiffs concede in their Complaint, this Court previously "permanently enjoined federal officials from enforcing the Contraceptive Mandate against any religious objector" by giving "individual religious objectors . . . the option to purchase health insurance that excludes contraception from any willing health insurer" and "exempt[ing] any . . . employer from the Contraceptive Mandate if it opposes coverage of contraception for sincere religious reasons." FAC ¶¶ 24, 25, 27. The final judgment in that action, *DeOtte v. Azar*, 4:18-cv-825-O (N.D. Tex.), bars all of Plaintiffs' claims related to the Contraceptive Mandate by *res judicata*, because their claims here and those in *DeOtte* all arise from a "common nucleus of operative facts, and could have been brought in the first lawsuit." *Murry v. Tangherlini*, No. 4:12-CV-744-A, 2013 WL 1408763, at *4 (N.D. Tex. Apr. 8, 2013) (citing *Procter & Gamble Co. v. Amway Corp.*, 376 F.3d 496, 499 (5th Cir. 2004), *Nilsen v. City of Moss Point*, 701 F.2d 556, 561 (5th Cir. 1983)). Indeed, Plaintiffs attack the identical decade-old Contraceptive Mandate as in the prior suit based on the same

putative injury. Pursuant to the judgment in *DeOtte*, this mandate can no longer be applied to them; they cannot raise new legal theories to attack it now.

In the Fifth Circuit,

> [r]es judicata is appropriate if: 1) the parties to both actions are identical (or at least in privity); 2) the judgment in the first action is rendered by a court of competent jurisdiction; 3) the first action concluded with a final judgment on the merits; and 4) the same claim or cause of action is involved in both suits.

Ellis v. Amex Life Ins. Co., 211 F.3d 935, 937 (5th Cir. 2000). Each of these elements is satisfied here.[3]

First, the parties here are—at a minimum—in privity with those in *DeOtte*. Indeed, Plaintiff Kelley (who also "own[s]" Plaintiff Kelley Orthodontics, FAC ¶ 53) and Braidwood were named plaintiffs in that case.[4] Plaintiffs allege, in substance, that they are "religious objectors who wish to purchase health insurance" and who are "injur[ed]" by the Contraceptive Mandate." FAC ¶ 37. As such, the individual Plaintiffs are members of the plaintiff class certified in *DeOtte* that includes

> [a]ll current and future individuals in the United States who: (1) object to coverage or payments for some or all contraceptive services based on sincerely held religious beliefs; and (2) would be willing to purchase or obtain health insurance that excludes coverage or payments for some or all contraceptive services . . . .

Id. Ex. 5 at 1. And Plaintiff Kelley Orthodontics is a member of the class consisting of

[3] "[D]ismissal under Rule 12(b)(6) is appropriate if the *res judicata* bar is apparent from the complaint and judicially noticed facts . . . ." *Anderson v. Wells Fargo Bank, N.A.*, 953 F.3d 311, 314 (5th Cir. 2020). Here, Plaintiffs plead the facts related to the *DeOtte* case in their FAC and attach the judgment as an exhibit to their FAC. Moreover, "[i]t is well-settled that courts may judicially notice court records as evidence of judicial actions," and Defendants request that the Court take judicial notice of the cited records in the *DeOtte* case. *United States v. Huntsberry*, 956 F.3d 270, 285 (5th Cir. 2020); *see also Norris v. Hearst Tr.*, 500 F.3d 454, 461 n.9 (5th Cir. 2007).

[4] Plaintiffs here are also represented by the same counsel that represented the plaintiffs in *DeOtte*.

"[e]very . . . employer in the United States that objects, based on its sincerely held religious beliefs, to . . . providing . . . (i) coverage . . . for . . . contraceptive services; or (ii) a plan . . . that provides or arranges for such coverage or payments." *Id.*

The second and third criteria for *res judicata* are also satisfied: In *DeOtte,* which involved a challenge to the Contraceptive Mandate on the ground that it violated a federal statute, the Court entered final judgment in favor of the plaintiff classes on July 29, 2019.[5] *See id.* at 1-2.

Finally, this case arises from the same "transaction or occurrence" as *DeOtte*. The Fifth Circuit "appl[ies] a 'transactional' test in determining whether two suits involve the same claim, where the 'critical issue' is 'whether the plaintiff bases the two actions on the same nucleus of operative facts.'" *Ellis*, 211 F.3d at 938. *DeOtte* was premised on the facts that "Federal regulations require health insurance to cover all FDA-approved contraceptive methods," which the plaintiffs claimed "substantially burdens the religious exercise of employers and individuals who object to contraception and abortifacients," leading the plaintiffs to "seek an injunction against [their] enforcement." Am. Compl., *DeOtte*, at 1-2. As Plaintiffs' Complaint makes clear, the identical facts underlie this action. Here, Plaintiffs allege,

> In 2011, . . . [HRSA] issued a highly controversial pronouncement that compels private insurance to cover all forms of FDA approved contraceptive methods, including contraceptive methods that operate as abortifacients. . . . All of these agency-issued preventive-care mandates are unlawful, ... The Court should enjoin the defendants from enforcing any of these agency-issued preventive-care mandates.

[5] Although the final judgment in *DeOtte* has been appealed by a would-be intervenor, the District Court judgment continues to have preclusive effect pending the appeal. *See, e.g.*, *Prager v. El Paso Nat'l Bank*, 417 F.2d 1111, 1112 (5th Cir. 1969) ("The fact that the judgment is now on appeal to the New Mexico Supreme Court (where it remains undecided) has no effect on its absolute effect as a bar.").

FAC at 1-2. In short, Plaintiffs already prevailed in litigation challenging the Contraceptive Mandate, which no longer applies to them; they cannot raise new theories attacking it now based on the same alleged injury.

III. PLAINTIFFS' CONSTITUTIONAL AND ACA CLAIMS ARE TIME BARRED

Plaintiffs' claims under the U.S. Constitution and the ACA (Claims 1-4 of the FAC) are barred by the applicable statutes of limitations. In these claims, Plaintiffs contend that the ACA's preventive services provision, 42 U.S.C. § 300gg-13, which was "enacted into law" on March 23, 2010, violates the Appointments Clause, the Nondelegation Doctrine, and the Vesting Clause (Claims 1-3), and that the preventive services provision must be construed to encompass only those recommendations or guidelines in effect on the ACA's enactment date. FAC ¶ 97, *see generally id*. ¶¶ 66-107. Regardless of when these claims accrued, they are stale. This failure to bring timely claims deprives the Court of jurisdiction. *See Texas v. Rettig*, --- F.3d ---, 2020 WL 4376829 at *5 (5th Cir. Aug. 31, 2020) (noting "unlike the ordinary world of statutes of limitations, . . . the failure to sue the United States within the limitations period deprives [courts] of jurisdiction" because "[t]he United States enjoys sovereign immunity unless it consents to suit, and the terms of its consent circumscribe [a court's] jurisdiction" and "[t]he applicable statute of limitations is one such term of consent").

The preventive services provision of the ACA has now been in effect for more than 10 years, and the initial rules implementing that provision have now been in effect nearly that long. *See* FAC¶ 97; 75 Fed. Reg. 41,726 (July 19, 2010 regulations implementing the preventive services provision). The HRSA guidelines incorporating the Contraceptive Mandate, which did not exist at the time of the ACA's passage, were promulgated in August 2011 and have been law for 9 years and in effect for 8 years. *See* FAC ¶¶ 16 & 17 (recognizing August 2011 promulgation of the Contraceptive Mandate); 76 Fed. Reg. 46621, 46624 (Aug. 3, 2011) (noting that "[u]nder the July

19, 2010 interim final rules, group health plans and insurance issuers do not have to begin covering preventive services supported in HRSA guidelines until the first plan or policy year that begins one year after the guidelines are issued" and explaining that interim final rules were issued because providing the opportunity for comment before issuing the final rule "would mean that many students could not benefit from the new prevention coverage without cost-sharing following from the issuance of the guidelines until the 2013-14 school year, as opposed to the 2012-13 school year.").

Plaintiffs' constitutional claims are barred under the six-year statute of limitations governing civil actions against the United States. 28 U.S.C. § 2401(a) ("Except as provided by chapter 71 of title 41 [relating to contracting disputes], every civil action commenced against the United States shall be barred unless the complaint is filed within six years after the right of action first accrues."). The statute is unequivocal: Plaintiffs were required to file their claims within six years of the claims' accrual, which as to them could have been no later than when the Contraceptive Mandate and HRSA guidelines took effect eight years ago.[6] Plaintiffs cannot bring them at this late date.

Plaintiffs' statutory interpretation claim under the ACA fares no better. It is subject to the four year statute of limitations set forth in 28 U.S.C. § 1658(a), which provides that "[e]xcept as

[6] To the extent that Plaintiffs are challenging coverage of preventive services other than contraception, their claims expired even earlier, no later than September 23, 2010, when the July 19, 2010 implementing regulations first required coverage of services recommended pursuant to the other subsections of the statute. *See* 75 Fed. Reg. at 41,729 ("These interim final regulations provide that [preventive services] coverage must be provided for plan years . . . beginning on or after the later of September 23, 2010, or one year after the date the recommendation or guideline is issued."). For example, Plaintiffs' Vesting Clause claim, which is addressed only to subsection (a)(1) of the preventive services provision pertaining to PSTF recommendations, expired no later than September 23, 2010, when the implementing regulations first required coverage of a PSTF recommendation.

otherwise provided by law, a civil action arising under an Act of Congress enacted after the date of the enactment of this section may not be commenced later than 4 years after the cause of action accrues." *See, e.g., Palacios v. MedStar Health, Inc.*, 298 F. Supp. 3d 87, 91 (D.D.C. 2018) ("Palacios's . . . claim arises under 42 U.S.C. § 18116(a), which was enacted in 2010 as part of the Affordable Care Act. Thus, her civil action "arises under an Act of Congress enacted after" the December 1990 enactment date of the catch-all statute of limitations in section 1658(a)."). Here, too, Plaintiffs' cause of action can have accrued no later than the date that the HRSA guidelines including the Contraceptive Mandate first took effect, eight years ago, because those guidelines that were themselves not in existence at the time the ACA was passed (and it accrued even earlier insofar as Plaintiffs challenge coverage requirements other than contraception).

IV. PLAINTIFFS FAIL TO STATE A CLAIM FOR VIOLATION OF THE APPOINTMENTS CLAUSE OR THE VESTING CLAUSE

Plaintiffs fail to state a claim for a violation of the Appointments Clause for three reasons: (1) they have forfeited any such claim by failing to raise it before the agencies; (2) any putative defect in the appointments of the HRSA Administrator and the members of the ACIP has been resolved through ratification by an Officer of the United States; and (3) neither PSTF nor ACIP members must be appointed pursuant to the Appointments Clause. The Complaint also fails to state a claim that the ACA's incorporation of PSTF guidelines violates Article II's Vesting Clause.

First, although Plaintiffs contend that "[a]ll of" the "agency-issued preventive care mandates [established pursuant to the ACA] are unlawful,"[7] FAC at 2, they do not allege that they raised their contention that these provisions violate the Appointments Clause before the agencies

[7] Despite the breadth of their claims, Plaintiffs offer specific objections only to the Contraceptive Mandate, promulgated as part of the HRSA-supported guidelines pursuant to §300gg(a)(4), and the requirement that PrEP drugs be covered as a result of the PSTF's recommendation, pursuant to §300gg(a)(1).

in any of the many rulemakings implementing the ACA's preventive care provision from 2010 to the present, including the many rulemakings related to the implementation of the Contraceptive Mandate. They have therefore forfeited the claim. "It is well established that issues not raised in comments before the agency are waived and this Court will not consider them." *Nat'l Wildlife Fed'n v. EPA*, 286 F.3d 554, 562 (D.C. Cir. 2002). This applies with full force to Appointments Clause claims: Plaintiffs must make a "timely challenge" to the "validity of the appointment" to be "entitled to relief." *Lucia v. SEC*, 138 S. Ct. 2044, 2055 (2018). If a party does not object before the agency to the validity of a decisionmaker's appointment, that objection is waived. *See, e.g.*, *Carr v. Comm'r, SSA*, 961 F.3d 1267, 1268 (10th Cir. 2020) (Appointments Clause challenge forfeited because plaintiffs "failed to raise [it] in their administrative proceedings"); *Intercollegiate Broad. Sys., Inc. v. Copyright Royalty Bd.*, 574 F.3d 748, 755-56 (D.C. Cir. 2009) (per curiam) (Appointments Clause claim forfeited when never raised before the agency or in the opening appellate brief); *In re DBC*, 545 F.3d 1373, 1377 (Fed. Cir. 2008) (claim forfeited when never raised before agency); *Island Creek Coal Co. v. Bryan*, 937 F.3d 738, 754 (6th Cir. 2019) (claim forfeited when not timely raised before the agency); *accord D.R. Horton, Inc. v. NLRB*, 737 F.3d 344, 351 (5th Cir. 2013) (noting "challenges under the Appointments Clause are 'nonjurisdictional structural constitutional objections' that are within a court's discretion to consider" and declining to hear challenge to appointment of decisionmaker "not . . . presented to us in the initial briefing").

Plaintiffs had numerous opportunities to raise their Appointments Clause challenge before the agencies. Defendants first issued an initial Interim Final Rule implementing the ACA's preventive care provision and requesting comments on July 19, 2010. 75 Fed. Reg. at 41,726. Subsequently, Defendants "solicited public comments on a number of occasions" with respect to the three Interim Final Rules related to the Contraceptive Mandate promulgated prior to 2017. 83

Fed. Reg. 57,536, 57,539 (Nov. 15, 2018); *see also* 76 Fed. Reg. 46,621, 46,623 (Aug. 3, 2011) (noting "the Departments received considerable feedback regarding which preventive services for women should be considered for coverage"). And a draft version of the PSTF's PrEP recommendation "was posted for public comment" on the PSTF's website in November 2018. FAC Ex. 6 at 5. Plaintiffs could have raised their Appointments Clause concerns with the preventive care provision at any of these times. It is too late for them to raise this issue for the first time now before a court, after ten years and numerous opportunities to do so before the agencies.

Even if not forfeited, any possible Appointments Clause problem with the Contraceptive Mandate and related HRSA guidelines has been cured by the Secretary of Health and Human Services' ratification through agency rulemaking. "[R]egardless of whether" an initial decisionmaker "was or was not validly appointed under . . . the Appointments Clause," "a properly appointed official's ratification of an allegedly improper official's prior action, rather than mooting a claim, resolves the claim on the merits by remedy[ing] [the] defect (if any) from the initial appointment." *Guedes v. Bureau of Alcohol, Tobacco, Firearms & Explosives*, 920 F.3d 1, 13 (D.C. Cir. 2019) (quotation marks omitted); *accord Consumer Fin. Prot. Bureau v. Gordon*, 819 F.3d 1179, 1190-92 (9th Cir. 2016). Here, repeated actions by multiple Secretaries of Health and Human Services—who were unquestionably constitutionally appointed—to promulgate regulations for purposes of implementing the preventive services provision constitute their ratification, curing any conceivable defect in the appointment of the HRSA Administrator. *See, e.g.*, 78 Fed. Reg. at 39,872, 39,899 (notice of final regulations "[a]pproved" by Kathleen Sebelius, "Secretary, Department of Health and Human Services" noting "[t]hese final regulations promote . . . [the] important policy goal[]" of "provid[ing] women with access to contraceptive coverage without cost sharing, thereby advancing the compelling government interests in safeguarding

public health and ensuring that women have equal access to health care"); 83 Fed. Reg. 57,536, 57,537, 57,586 (final rules approved by Alex M. Azar II, "Secretary, Department of Health and Human Services" that "do not remove the contraceptive coverage requirement" but "expand the protections for the sincerely held religious objections of certain entities and individuals); *see also id.* at 57,539 (noting that "[s]ince 2011 . . . the Departments . . . have promulgated regulations to guide HRSA in exercising the discretion to allow exemption to [the Contraceptive Mandate], including issuing and finalizing three interim final regulations prior to 2017"); 77 Fed. Reg. 16,501, 16,503, 16,508 (Mar. 21, 2012) (Advance Notice of Proposed Rulemaking approved by HHS Secretary noting "the Departments committed to working with stakeholders to develop alternative ways of providing contraceptive coverage without cost sharing in order to accommodate . . . religious organizations with religious objections to such coverage").

Similarly, all recommendations made by ACIP are ratified by the Director of the Centers for Disease Control and Prevention, an Officer of the United States. *See* Charter of the Advisory Committee on Immunization Practices ("ACIP Charter") at 1 (Apr. 1, 2018)[8] ("Recommendations made by the ACIP are reviewed by the [Director of the Centers for Disease Control and Prevention ("CDC")], and if adopted, are published as official CDC/HHS recommendations in the Morbidity and Mortality Weekly Report (MMWR) and incorporated into CDC's immunization schedules. The CDC Director informs the Secretary of immunization recommendations."). The CDC Director is appointed by the Secretary of Health and Human Services, a "Head of Department" authorized to appoint officers pursuant to the Appointments Clause. *See* U.S. Const. art. II § 2, cl. 2; 5 U.S.C. § 3101.

[8] https://www.cdc.gov/vaccines/acip/committee/acip-charter.pdf.

Finally, members of the PSTF and members of ACIP are not "Officers of the United States" requiring appointment pursuant to the Appointments Clause. "Supreme Court precedent has established that the constitutional definition of an 'officer' encompasses, at a minimum, a continuing and formalized relationship of employment with the United States Government," such that officials who do not have such a relationship need not be appointed pursuant to the Appointments Clause. *Riley v. St. Luke's Episcopal Hosp.*, 252 F.3d 749, 757 (5th Cir. 2001).

Neither members of the PSTF nor ACIP meet the "minimum" criteria set forth in *Riley*. The PSTF "is made up of 16 volunteer members who are nationally recognized experts in prevention, evidence-based medicine, and primary care."[9] *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."). Any role staffed by part-time volunteers is, by definition, not a "continuing and formalized relationship of employment with the United States Government," requiring appointment pursuant to the Appointments Clause. *Riley*, 252 F.3d at 757.

Similarly, the ACIP is an advisory committee governed by the Federal Advisory Committee Act, which requires its members to include individuals who are not full-time or permanent part-time government employees. 5 U.S.C. app. § 3(2); *see also* ACIP Charter at 1. A group *required by law* to be composed of non-federal employees likewise necessarily cannot consist of those with a "continuing and formalized relationship of employment with the United States Government," requiring appointment pursuant to the Appointments Clause.[10] *Riley*, 252 F.3d at 757.

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[9] https://www.uspreventiveservicestaskforce.org/uspstf/about-uspstf/current-members.

[10] Moreover, even if members of ACIP were federal officers, they are appointed by the Secretary of HHS, who as a department head has the authority to appoint inferior officers. *See* 42 U.S.C. § 217a(a).

Plaintiffs' claim is based on a fundamental misapprehension of the role of PSTF and ACIP under the ACA's preventive health services provision, 42 U.S.C. § 300gg-13. Plaintiffs contend that in establishing the guidelines and recommendations for preventive care to be covered by health insurance pursuant to the preventive health services provision, these bodies act as "officers of the United States" requiring presidential appointment pursuant to the Appointments Clause because they exercise "significant authority pursuant to the laws of the United States." FAC ¶ 71 (quoting *Buckley v. Valeo*, 424 U.S. 1, 126 (1976)). This is not so.

The ACA's preventive services coverage provision does not establish any executive body or provide PSTF and ACIP with law enforcement or similar policymaking discretion. *See, e.g.*, *Lucia*, 138 S. Ct. 2052 ("exercis[ing] significant discretion" in the course of "tak[ing] testimony, conduct[ing] trials, rul[ing] on the admissibility of evidence, and . . . enforc[ing] compliance with discovery orders" makes SEC ALJ's officers of the United States for purposes of the Appointments Clause (quoting *Freytag v. Comm'r*, 501 U.S. 868, 881-82 (1991))); *Buckley*, 424 U.S. at 138 ("discretionary power to seek judicial relief" is "ultimate remedy for a breach of the law" delegated by the Constitution to the executive to be held by officers appointed pursuant to the Appointments Clause). Nor does it authorize PSTF and ACIP to make decisions about insurance coverage. The preventive services provision simply incorporates evolving standards of these bodies with medical expertise chosen by Congress to effectuate *Congress's* judgment that standard contemporary preventive services be covered by health insurance, subject to certain limited and well-recognized exceptions.

In other words, the expert bodies referenced in the statute simply make decisions about what standard preventive medical care should look like, and Congress itself made the decision that whatever this standard care is should generally be covered by insurance. This is consistent with

numerous statutes that incorporate by reference independent recommendations without creating any requirement that the heads of the recommending bodies be appointed as officers of the United States. *See, e.g.*, 4 U.S.C. § 119(a)(2) (electronic databases established by states "shall be provided in a format approved by the American National Standards Institute's Accredited Standards Committee X12"); 16 U.S.C. § 3372(a)(2)(A) (rendering it unlawful to import "any fish or wildlife taken, possessed, transported, or sold in violation of any law or regulation of any State or in violation of any foreign law"); 18 U.S.C. § 13(a) (establishing that those who commit acts on federal land "not made punishable by any enactment of Congress, [that] would be punishable [under State law if the state had jurisdiction] . . . by the laws thereof in force at the time of such act or omission, shall be guilty of a like offense and subject to a like punishment" as under State law); 42 U.S.C. § 6293(b)(8) ("Test procedures for water closets . . . shall be the test procedures specified in ASME A112.19.6–1990 . . . . If the test procedure requirements of ASME A112.19.6–1990 are revised at any time and approved by ANSI, the Secretary shall amend the test procedures . . . . to conform to such revised ASME/ANSI requirements . . . ."). Of course, no one understands the heads of independent bodies like ANSI, or heads of state governments or foreign states, to be "officers of the United States" simply because their rules or standards are incorporated into federal statutes. So too, here. Congress made the choice to incorporate the contemporary standards for preventive care as services covered by insurance, with those standards determined by certain independent medical expert bodies according to evidence-based expertise. Exercise of this scientific expertise is not an exercise of policy discretion or the Executive Power, and it does not require appointment pursuant to the Appointments Clause.

Plaintiffs' Vesting Clause claim, which is addressed only to the recommendations of the PSTF, also fails for this reason. The PSTF's recommendations, as incorporated into the ACA, are

not exercises of the Executive or Legislative Power. They are "evidence-based" scientific recommendations about the contemporary standard of care in preventive medicine. 42 U.S.C. § 300gg-13(a)(1). Congress made the judgment to incorporate evolving contemporary standards into the ACA so that whatever preventive care services were part of the "current" standard would be covered. *Id.* Just as independent bodies like ANSI, foreign governments, or state legislatures are not exercising the Legislative Power or the Executive Power, neither is the PSTF.

V. THE ACA'S PREVENTIVE SERVICES PROVISIONS DO NOT VIOLATE NONDELEGATION PRECEDENTS

Plaintiffs also fail to state a nondelegation claim. First, the recommendations and guidelines of PSTF, ACIP, and HRSA are not rules within the meaning of the Administrative Procedure Act. Instead, Congress chose in the ACA to adopt preexisting expert clinical guidelines and recommendations, as well as guidelines and recommendations that were later updated or developed. Especially with respect to the clinical recommendations and guidelines that, prior to the ACA, were already developed and would continue to be updated independent of the ACA, Congress itself was choosing what to incorporate into required coverage.

Furthermore, the statutory scheme provides a sufficient intelligible principle to guide any decision making and limit discretion. "[W]hen Congress confers decisionmaking authority," Congress must "'lay down by legislative act an intelligible principle to which the person or body authorized to [act] is directed to conform.'" *Whitman v. Am. Trucking Ass'ns*, 531 U.S. 457, 472 (2001) (emphasis omitted). The Supreme Court has "almost never felt qualified to second-guess Congress regarding the permissible degree of policy judgment that can be left to those executing or applying the law." *Big Time Vapes, Inc. v. FDA*, 963 F.3d 436, 442-43 (5th Cir. 2020) (quoting *Whitman* 531 U.S. at 474–75). Under nondelegation principles, "[t]he Court has found only two delegations to be unconstitutional. Ever." *Id.* at 446. Notably, the Court has even "blessed

delegations that authorize regulation in the 'public interest' or to 'protect the public health.'" *Id.* at 442 n.18 (citing *Whitman*, 531 U.S. at 472).

The statutory provisions at issue here satisfy the intelligible-principle test announced by the Supreme Court. Each provision sets the criteria that govern what recommendations and guidelines are incorporated into the statute. For § 300gg-13(a)(1), the statute specifies that it will incorporate only "evidence-based items or services" that have been recommended by the PSTF with a grade of "A" or "B." An "A" grade reflects "high certainty that the net benefit [of the service] is substantial," while a "B" grade reflects either "high certainty that the net benefit is moderate" or "moderate certainty that the net benefit is moderate to substantial."[11] And the PSTF's statute further states that the PSTF makes recommendations regarding "clinical preventive services" on the basis of "the scientific evidence related to the effectiveness, appropriateness, and cost-effectiveness of clinical preventive services." 42 U.S.C. § 299b-4(a)(1). Those statutory provisions supply sufficient guidance and limitations on the PSTF's decision making.

The same is true for § 300gg-13(a)(2), which dictates incorporation only of "immunizations" that have a "recommendation from the" ACIP "with respect to the individual involved." That clearly delineates ACIP recommendations that are incorporated into the statute's mandate. And likewise for § 300gg-13(a)(3), which identifies HRSA's guidelines of "evidence-informed preventive care and screenings" "with respect to infants, children, and adolescents."

The statutory mandate to develop guidelines for women's preventive care, § 300gg-13(a)(4), likewise satisfies the intelligible-principle test. That provision incorporates only those "preventive care and screenings" that HRSA supported "with respect to women." By setting those several criteria—that the agency identify care and screenings, that they be of a preventive nature,

[11] https://www.uspreventiveservicestaskforce.org/uspstf/grade-definitions.

and that they be focused on women's preventive needs specifically—Congress gave sufficient guidance. That statutory guidance is sufficient to serve as an intelligible principle even if it does not lay out the precise criteria that govern every part of the agencies' analyses. *See Whitman*, 531 U.S. at 474–75; *Am. Power & Light Co. v. SEC*, 329 U.S. 90, 104 (1946) (in applying intelligible-principle test, statutory terms can "derive much meaningful content from the purpose of the Act, its factual background and the statutory context in which they appear"). That guidance is certainly more exact than an instruction to issue guidelines "in the 'public interest.'" *Whitman*, 531 U.S. at 474.

The Supreme Court's recent decision in *Little Sisters of the Poor* is not to the contrary. The Court noted expressly that it was not presented with a nondelegation challenge in that case. 140 S. Ct. at 2382. And although the Court stated that § 300gg-13(a)(4) is "silent as to *what* those 'comprehensive guidelines' must contain, or how HRSA must go about creating them," *id.*at 2381, the Court did not dispute that the statute instructed HRSA to create comprehensive guidelines for "preventive care and screenings," and not for some other kind of care (or something totally unrelated to care). That is still a sufficient intelligible principle to satisfy nondelegation precedents, even if it leaves HRSA with a great deal of discretion in executing its task.

VI. THE CHALLENGED PROVISIONS INCORPORATE RECOMMENDATIONS AND GUIDELINES ISSUED AFTER THE STATUTE'S ENACTMENT

Plaintiffs assert that the word "current" and the phrase "in effect" must refer only and permanently to the recommendations that existed at the time of the ACA's passing, rather than the recommendations that are current and in effect at any given time. That argument finds no support in the text of the statute and plainly countermands its structure and purpose, as does the suggestion that the statutory references to "comprehensive guidelines" are so limited. This Court should reject Plaintiffs' invitation to rewrite the statute.

The terms "current" and "have in effect" are most naturally read to allow consideration of recommendations that are current and in effect at the time of the application of the statute. The challenged provisions all require interpretation at a particular point in time in the insurance context: the time that a plan or an insurer is "offering group or individual health insurance coverage." 42 U.S.C. § 300gg-13(a). At the point in which the adequacy of the coverage is at issue—namely, the time during which the coverage is offered—insurers and plans must provide coverage for recommendations that are "current" or "in effect." If Congress had wanted the terms to be given purely retrospective effect, it would have stated as much, especially because statutory terms "used in the present tense include the future as well as the present." 1 U.S.C. § 1.

Plaintiffs' reading would be in tension with the remainder of § 300gg-13 itself. Section 300gg-13(a)(5) provides that "the current recommendations of the [PSTF] regarding breast cancer screening, mammography, and prevention shall be considered the most current other than those issued in or around November 2009." Had Congress wished to make permanent the pre-November 2009 recommendation, it would have referred to that specific recommendation, or referred to the most recent recommendation "prior to" the November 2009 one. Instead, it allowed whatever recommendation was current at the time coverage was offered, but skipping the November 2009 recommendation until the November 2009 recommendation was superseded, *i.e.* during the period while the November 2009 recommendation was the "current" recommendation.

The Supreme Court did not endorse a contrary rule in *Carcieri v. Salazar*, 555 U.S. 379 (2009), cited by Plaintiffs. There, the Court held that a statutory reference to "any recognized Indian tribe now under Federal jurisdiction" was limited to those recognized Indian tribes under federal jurisdiction at the time of enactment. *Id.* at 395. But the Court did not hold that "now" always means the time of a statute's enactment. Instead, the Court interpreted the word by looking

at the particular statutory language at issue, other statutory language from the same Act, and other evidence. That textual analysis in the present case leads to the opposite conclusion.

The structure of the ACA further shows that the challenged provisions all incorporate post-enactment recommendations and guidelines. To begin with, the statute sets out timing rules on when future recommendations and guidelines can take effect under the statute, which necessarily means that they can be incorporated into the statutory obligations. The same statutory section that Plaintiffs challenge requires the Secretary to "establish a minimum interval between the date on which a recommendation described in subsection (a)(1) or (a)(2) or a guideline under subsection (a)(3) is issued and the plan year with respect to which the requirement described in subsection (a) is effective with respect to the service described in such recommendation or guideline." 42 U.S.C. § 300gg-13(b)(1). That interval must be "not be less than 1 year." § 300gg-13(b)(2). By laying out prospective restrictions on how new recommendations and guidelines can be incorporated into the statutory scheme, the law necessarily acknowledges that they will be relevant. Furthermore, the law cannot have been intended to incorporate only those recommendations and guidelines in existence at the time of enactment, as the "comprehensive guidelines" described in § 300gg-13(a)(4) did not yet exist. Instead, the statute was intended to incorporate guidelines that HRSA *would* develop with respect to women's preventive care. 77 Fed. Reg. at 8725–26.

Other points in the ACA likewise establish that the statute does not automatically peg its provisions to the date of enactment by using the word "current." If the word "current" unambiguously has the meaning ascribed to it by Plaintiffs, then other provisions of the ACA are undermined. For example, the ACA calculates an employer's size by looking at the number of employees it employed in the preceding year, but if the employer didn't exist in the preceding year, the statute asks how many employees are expected to be employed "in the current calendar year."

42 U.S.C. § 18024(b)(4)(B). Under Plaintiffs' theory, even for a new employer in 2020, that provision would require looking at the number of employees expected to be employed in 2010. Instead, that statutory provision shows that the very same Act at issue in this case often spoke of what was "current" as what was current at the time of application.

Furthermore, when Congress intended the ACA to refer to the time of the statute's enactment, it made that intention explicit. As the Court recognized in *Carcieri*, the use of temporal specificity in one part of a statute raises the inference that the lack of qualifying language in another part was a deliberate choice to convey a different meaning. 555 U.S. at 389–90; *see also Barnhart v. Sigmon Coal Co.*, 534 U.S. 438, 452 (2002) ("[W]hen Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion." (internal quotation marks omitted)). Numerous provisions in the ACA specify that they speak to "the date of enactment" or an equivalent phrase, which has been translated into "March 23, 2010" in the U.S. Code. *See, e.g.*, 42 U.S.C. § 18011(a)(1) ("Nothing in this Act . . . shall be construed to require that an individual terminate coverage under a group health plan or health insurance coverage in which such individual was enrolled on March 23, 2010"); 42 U.S.C. § 300gg-4(k) ("Nothing in this section shall prohibit a program of . . . disease prevention that was established prior to March 23, 2010, . . . that is operating on such date, from continuing to be carried out . . . .").

Although this discussion has focused on the word "current," the analysis applies even more strongly to the other provisions, which lack language that even arguably incorporates a temporal element. For § 300gg-13(a)(2), Plaintiffs are necessarily arguing that the phrase "have in effect a recommendation" should be amended to include the phrase "at the time of enactment." But other provisions in the ACA that are similarly phrased to § 300gg-13(a)(2) would not make sense with

that interpretation. For example, § 1301 of the ACA—codified at 42 U.S.C. § 18021(a)(1)—defines a "qualified health plan" as one that "has in effect a certification . . . that such plan meets the criteria for certification described in section 18031(c) [of the ACA]." That provision would make no sense if it requires that the health plan "has in effect *at the time of enactment* a certification," because a health plan could not have such a certification at the time of enactment—it was section 1311(c) of the ACA itself, codified at 42 U.S.C. § 18031(c), that directed the Secretary to develop the certification process. Plaintiffs' interpretation of "have in effect" would render the category of "qualified health plan" a nullity. Plaintiffs can offer nothing in the statute that shows Congress intended to silently append a temporal limitation in § 300gg-13(a)(2).

Finally, the remaining two provisions—referring to coverages "provided for" in HRSA's "comprehensive guidelines"—contain nothing that resembles a temporal limitation. Plaintiffs' challenges thus face all of the same textual and structural shortcomings as their first two. Merely acknowledging that HRSA develops guidelines and might already have done so relating to some of the provisions' subject matter does not indicate that Congress intended to forgo incorporating any further agency expertise and medical advancement into the ACA's requirements. That is especially clear for HRSA's guidelines for women's preventive care, which did not exist until after passage of the ACA. Had Congress intended instead to incorporate only particular recommendations, they could have identified them more specifically—as they did, for example, just one provision later in specifically *excluding* PSTF's November 2009 recommendations relating to "breast cancer screening, mammography, and prevention." 42 U.S.C. § 300gg-13(a)(5).

Even if this Court concludes that the statutory provisions are ambiguous or silent regarding the temporal scope of the effective recommendations, the agencies responsible for executing the challenged provisions have interpreted them to incorporate later-enacted provisions. 80 Fed. Reg.

at 41,322. The agencies' interpretations of the statutes are entitled to deference under *Chevron USA, Inc. v. Natural Resources Defense Council*, 467 U.S. 837 (1984). Under the *Chevron* doctrine, if a statute is "ambiguous or silent as to the question at issue," and the agency's decision is "based on a reasonable interpretation of the statute," the courts must "defer to the agency's construction." *Tex. Coal. of Cities for Utility Issues v. FCC*, 324 F.3d 802, 807 (5th Cir. 2003). As discussed above, Plaintiffs cannot show that the ACA unambiguously limits the incorporated recommendations and guidelines to those in effect when the ACA was enacted. And, even if there were some ambiguity, the agencies could reasonably interpret the challenged provisions to permit incorporation of recommendations and guidelines that came about after the statute was enacted. This Court must therefore defer to that reasonable interpretation put forth by the agencies.

To avoid *Chevron*, Plaintiffs invoke the avoidance canon. But avoidance has no applicability here. That doctrine allows a court, "when statutory language is susceptible of multiple interpretations," to "shun an interpretation that raises serious constitutional doubts and instead [] adopt an alternative that avoids those problems." *Jennings v. Rodriguez*, 138 S. Ct. 830, 836 (2018). But as discussed above, *supra* Parts IV-V, Plaintiffs' constitutional claims could not raise any "serious" doubts.

VII. PLAINTIFFS FAIL TO ALLEGE A VIOLATION OF THE RELIGIOUS FREEDOM RESTORATION ACT

Plaintiffs assert a RFRA claim only as to the requirement that PrEP medications be covered without cost sharing, and do not assert that any other preventive care requirement violates RFRA. *See* FAC ¶¶ 108-111. Plaintiffs Kelley, Starnes, Zach Maxwell, Ashley Maxwell, Kelley Orthodontics, and Braidwood have failed to allege a violation of RFRA.[12] Under RFRA,

[12] Plaintiffs Scheideman, Miller, and both Plaintiffs Riddle cannot assert a RFRA claim, because they allege no religious objection to the PrEP mandate, or indeed either any religious objection to the preventive care mandates in general or any specific objection to the PrEP mandate at all. *See*

"Government shall not substantially burden a person's exercise of religion even if the burden results from a rule of general applicability." 42 U.S.C. § 2000bb-1. "To claim RFRA's protections, a person must show that (1) the relevant religious exercise is grounded in a sincerely held religious belief and (2) the government's action or policy substantially burdens that exercise by, for example, forcing the plaintiff to engage in conduct that seriously violates his or her religious beliefs." *United States v. Comrie*, 842 F.3d 348, 351 (5th Cir. 2016) (cleaned up).

But Plaintiffs' allegations fail to satisfy RFRA's requirements, as they fail to allege that Plaintiffs have any sincerely held religious belief that the government is substantially burdening. Plaintiffs Kelley, Starnes, and both Plaintiffs Maxwell allege merely that they "do not want or need," coverage of PrEP drugs, because they are "not engaged in behavior that transmits HIV." FAC ¶ 36. There is likewise no allegation that Plaintiff Kelley Orthodontics has any *religious* objection to any of the challenged services—only that it "*wishes* to provide insurance for its employees that excludes coverage of" the challenged services. *Id.* ¶ 55 (emphasis added). But wishes and lack of need do not constitute "sincerely held religious belief[s]" protected by RFRA. *Comarie*, 842 F.3d at 351.

Plaintiffs allege that Dr. Hotze, Braidwood's principal, is "unwilling to allow Braidwood's self-insured plan to cover PrEP drugs . . . because these drugs facilitate or encourage homosexual behavior," because this behavior "is contrary to [his] sincere religious beliefs." FAC ¶ 63. But while "homosexual behavior" may be contrary to Dr. Hotze's sincere religious beliefs, Dr. Hotze is not being compelled to engage in any such activity, and Braidwood nowhere alleges that providing or purchasing insurance coverage for medication to prevent an infectious disease—even

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FAC ¶¶ 40, 42, 45, 47, 50, 51; 42 U.S.C. § 2000bb-1 (preventing government from "substantially burden[ing] a person's exercise of religion"); *see generally id.* ¶¶ 39-52 (addressing these four Plaintiffs' specific allegations).

an infectious disease Dr. Hotze may associate with those activities—is contrary to his or Braidwood's sincere religious beliefs. Accordingly, these allegations fail to state a claim for a violation of RFRA.[13]

CONCLUSION

For the reasons set forth above, Defendants' motion to dismiss should be granted.

Respectfully submitted,

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[13] Plaintiffs Kelley (and through him Kelley Orthodontics), Starnes, and the Maxwells' allegations that they are "Christian, and therefore unwilling to purchase health insurance that subsidizes" medication or "encourage[s] and facilitates" certain activities likewise fails to satisfy RFRA's requirements for similar reasons. While they may be "unwilling" to purchase such insurance, they do not allege that doing so would violate any of their sincere religious beliefs. FAC ¶ 36.

Certificate of Service

On August 7, 2020, 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
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