

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' REPLY IN SUPPORT OF MOTION TO DISMISS
FIRST AMENDED COMPLAINT PURSUANT TO RULES 12(B)(1) AND 12(B)(6)**

ERIN NEALY COX
United States Attorney

Brian W. Stoltz
Assistant United States Attorney
Texas Bar No. 24060668
1100 Commerce Street, Third Floor
Dallas, Texas 75242-1699
Telephone: 214-659-8626
Facsimile: 214-659-8807
brian.stoltz@usdoj.gov

JEFFREY BOSSERT CLARK
Acting Assistant Attorney General

MICHELLE R. BENNETT
Assistant Branch Director

CHRISTOPHER M. LYNCH
(D.C. Bar # 1049152)
Trial Attorney
U.S. Department of Justice
Civil Division
1100 L Street, NW
Washington, D.C. 20005
Telephone: (202) 353-4537
Fax: (202) 616-8460
Email: Christopher.M.Lynch@usdoj.gov

Attorneys for Federal Defendants Alex M. Azar,
Steven T. Mnuchin, Eugene Scalia, and the United States

TABLE OF CONTENTS

INTRODUCTION	1
ARGUMENT	1
I. PLAINTIFFS LACK STANDING	1
II. <i>RES JUDICATA</i> BARS THE CHALLENGES OF <i>DEOTTE</i> CLASS MEMBER PLAINTIFFS TO THE CONTRACEPTIVE MANDATE	4
III. PLAINTIFFS’ CONSTITUTIONAL AND ACA CLAIMS ARE TIME BARRED	5
IV. PLAINTIFFS FAIL TO STATE A CLAIM FOR VIOLATION OF THE APPOINTMENTS CLAUSE OR THE VESTING CLAUSE.....	6
V. THE ACA’S PREVENTIVE SERVICES PROVISIONS DO NOT VIOLATE NONDELEGATION PRECEDENTS.....	11
VI. THE CHALLENGED PROVISIONS INCORPORATE RECOMMENDATIONS AND GUIDELINES ISSUED AFTER THE STATUTE’S ENACTMENT.....	12
VII. PLAINTIFFS FAIL TO ALLEGE A VIOLATION OF RFRA	13
CONCLUSION.....	14

TABLE OF AUTHORITIES

Cases

<i>Barr v. American Association of Political Consultants</i> , 140 S. Ct. 2335 (2020).....	7
<i>Big Time Vapes, Inc. v. Food & Drug Admin.</i> , 963 F.3d 436 (5th Cir. 2020)	12
<i>Clapper v. Amnesty Int’l USA</i> , 568 U.S. 398 (2013)	2
<i>Colonial Oaks Assisted Living Lafayette, LLC v. Hannie Dev., Inc.</i> , --- F.3d ---, 2020 WL 5015453 (5th Cir. Aug. 25, 2020).....	4, 5
<i>Diamond v. Charles</i> , 476 U.S. 54 (1986)	3
<i>In re Kosmos Energy Ltd. Sec. Litig.</i> , 955 F. Supp. 2d 658 (N.D. Tex. 2013)	2, 13
<i>Jennings v. Rodriguez</i> , 138 S. Ct. 830 (2018).....	12
<i>Little Sisters of the Poor v. Pennsylvania</i> , 140 S. Ct. 2367 (2020).....	11
<i>Lucia v. SEC</i> , 138 S. Ct. 2044 (2018).....	9, 10
<i>Resident Council of Allen Parkway Vill. v. U.S. Dep’t of Hous. & Urban Dev.</i> , 980 F.2d 1043 (5th Cir. 1993)	3
<i>Riley v. St. Luke’s Episcopal Hosp.</i> , 252 F.3d 749 (5th Cir. 2001)	8
<i>Rodriguez de Quijas v. Shearson/Am. Express, Inc.</i> , 490 U.S. 477 (1989)	11
<i>Texas v. Rettig</i> , 968 F.3d 402 (5th Cir. 2020)	6
<i>United States v. Comrie</i> , 842 F.3d 348 (5th Cir. 2020)	12

<i>Whitman v. Am. Trucking Ass'ns</i> , 531 U.S. 457 (2001)	11
--	----

<i>Whole Women's Health v. Hellerstedt</i> , 136 S. Ct. 2922 (2016).....	3, 4, 5
---	---------

Statutes

5 U.S.C. app. § 3(2)	9
28 U.S.C. § 2401(a)	6
42 U.S.C. § 299b-4(a)(1)	10
42 U.S.C. § 299b-4(a)(2)	10, 11
42 U.S.C. § 299b-4(a)(3)	11
42 U.S.C. § 300gg-13(a)	9
42 U.S.C § 300gg-13(a)(1)	6, 11
42 U.S.C. § 300gg-13(a)(2)	3, 8, 11
42 U.S.C. § 300gg-13(a)(3)	3, 8, 11
42 U.S.C § 300gg-13(a)(4)	4, 6, 11
42 U.S.C. § 300gg-13(b)(1)	7

Regulations

45 C.F.R. § 147.130(a)(1)	8
76 Fed. Reg. 46,621 (Aug. 3, 2011).....	7
85 Fed. Reg. 711 (Jan. 7, 2020)	9

Other Authorities

Charter of the Advisory Committee on Immunization Practices, https://www.cdc.gov/vaccines/acip/committee/acip-charter.pdf	8
--	---

Officers of the United States within the Meaning of the Appointments Clause, 31 Op. Off. Legal Counsel 73, 2007 WL 140549 (Apr. 16, 2007)	9
--	---

INTRODUCTION

In a grab bag of claims, various Plaintiffs collectively contend that they challenge *all* the numerous preventive services insurance coverage requirements established pursuant to four subsections of the Affordable Care Act, despite asserting a putative injury from only two individual requirements—the so-called Contraceptive Mandate and the PrEP coverage requirement. As to the former, Plaintiffs assert no cognizable injury and the claims of many Plaintiffs are barred by *res judicata* as a result of this Court’s enjoining that requirement as to them in a previous case. Plaintiffs’ claims as to both requirements also fail both procedurally and on the merits, flying in the face of both established Supreme Court and Fifth Circuit precedent. The Complaint should be dismissed.

ARGUMENT

I. PLAINTIFFS LACK STANDING

For the *DeOtte* class members, Plaintiffs’ own allegations establish that they lack Article III standing to challenge the Contraceptive Mandate, because this Court has already granted them all possible relief against Defendants. The *DeOtte* injunction exempts these Plaintiffs from the Contraceptive Mandate—meaning the government permits insurers to offer exactly what the *DeOtte* class-member Plaintiffs want. See FAC ¶¶ 27, 37, ECF No. 14. And Plaintiffs do not go so far as to allege that it is impossible for them to obtain those plans. See FAC ¶ 37 (alleging that “few if any insurance companies are offering insurance of this sort”). Indeed, one *DeOtte* class-member Plaintiff, Braidwood Management, “acknowledge[s]” it “is no longer suffering injury in fact from the continued enforcement of the Contraceptive Mandate.” Opp’n 1 n.1. Plaintiffs’ grievance is instead with the business choices of insurers, who have declined to offer a larger number of insurance plans on terms that Plaintiffs find acceptable even though the *DeOtte*

injunction expressly permits them to.¹ These Plaintiffs’ alleged harm cannot be attributed to Defendants.

Further, redressability for those class members relies on speculative predictions about the future actions of third parties, which need not be accepted as true, and in any event are insufficient to establish standing. *See Clapper v. Amnesty Int’l USA*, 568 U.S. 398, 414 (2013) (refusing to “endorse standing theories that rest on speculation about the decisions of independent actors”). Because those Plaintiffs’ theory of redressability is that third-party insurers will offer additional plans that federal law already allows them to offer, they have not met their burden of pleading redressability. These Plaintiffs’ PrEP-related claims fail for the same reason.²

For Plaintiffs not members of the *DeOtte* class—those without a religious objection to contraceptive coverage—they have failed to allege an Article III injury from the Contraceptive Mandate, because the presence of contraceptive coverage in their plans does not harm them. Only Schneiderman speculatively alleges—contrary to the cost-saving purpose of the preventive care

¹ To the extent that Plaintiffs have been unable to obtain desirable contraceptive-free insurance in Texas notwithstanding the *DeOtte* injunction, Plaintiffs’ counsel has made clear why they believe that to be true in a substantively similar case also pending in this District: Texas law “mak[es] it impossible for individuals and employers with religious objections to purchase health insurance that excludes contraceptive coverage unless they forego all coverage of prescription drugs.” Complaint, *Leal v. Azar*, 20-cv-185-Z (N.D. Tex.), ¶ 51. This, too, is no fault of Defendants.

² To avoid the necessary conclusion from the FAC’s allegations that any inability of Plaintiffs to secure insurance without PrEP drugs is not based on insurers’ market-based choices, Plaintiffs contend in a footnote of their Opposition that their FAC alleges that they *someday* will not be able to acquire insurance without covering this drug. Opp’n at 7 n.5. But the FAC itself plainly says otherwise. *See* FAC ¶ 35 (alleging in present tense that ACA “*makes* it impossible” to obtain their desired insurance) (emphasis added); *cf. In re Kosmos Energy Ltd. Sec. Litig.*, 955 F. Supp. 2d 658, 676 (N.D. Tex. 2013) (“[A] plaintiff may not amend its complaint in [a] response to a motion to dismiss.”)

provision—that the inclusion of the whole set of preventive care mandates raises his premiums. But he does not allege that he objects to *any* specific preventive care service or that he would decline coverage for such services for his employees if he had the option. *See* FAC ¶¶ 49-52. And his cost increase theory is grounded on the purely speculative assumption that, absent these preventive care mandates, third party insurers would choose to offer him a lower priced plan. *Cf. Clapper*, 568 U.S. at 414 & n.5. Scheiderman therefore has not suffered a redressable injury, nor have the other Plaintiffs who pleaded even less than him.

For the preventive services mandates other than the Contraceptive Mandate and PrEP, no Plaintiff has alleged a cognizable Article III injury, because no Plaintiff has alleged that the inclusion of those coverages hurts it (with the exception of Schneiderman’s general and insufficient complaint of higher premiums). Plaintiffs allege merely that they don’t need and don’t want the coverage. Indeed, no Plaintiff identifies *any* specific requirement established pursuant to either 42 U.S.C. §§ 300gg-13(a)(2) (relating to immunizations) or 300gg-13(a)(3) (relating to pediatric care) to which he, she, or it objects.³ Plaintiffs argue they can “free-ride off” Plaintiff Braidwood’s desire to “control” the coverage in its insurance plan, Opp’n 10, but Braidwood does not allege that, given the choice, it would exclude *any* preventive care item or service from its plan other than PrEP drugs. *See* FAC ¶¶ 58-65. Without some further allegation that they are actually harmed by, *inter alia*, any specific immunization or pediatric care coverage requirement, Plaintiffs offer nothing more than a disagreement with the law. And for Article III standing, Plaintiffs must

³ Plaintiffs note that certain Plaintiffs refer in passing to not needing “free STD testing . . . because they are in monogamous relationships” but do not identify any specific test to which they object or that any such coverage requirement was established under either section 300gg-13(a)(2) or section 300gg(a)(3). Nor is it plausible, without more, that either a provision regarding immunizations or a provision regarding pediatric medicine would cover to STD tests applicable to Plaintiffs. Opp’n at 9 (citing FAC ¶ 35). This allegation is insufficient to establish standing under either subsection.

“show more than the presence of a disagreement.” *Resident Council of Allen Parkway Vill. v. U.S. Dep’t of Hous. & Urban Dev.*, 980 F.2d 1043, 1050 (5th Cir. 1993) (quoting *Diamond v. Charles*, 476 U.S. 54, 62 (1986)). This Court should dismiss Plaintiffs’ claims for lack of standing.

II. **RES JUDICATA BARS THE CHALLENGES OF DEOTTE CLASS MEMBER PLAINTIFFS TO THE CONTRACEPTIVE MANDATE**

In their Motion, Defendants established that certain Plaintiffs’ claims are barred by *res judicata*, easily satisfying the Fifth Circuit test. Mot. 14-17, ECF No. 20. Plaintiffs’ only contention in response is that the Supreme Court’s decision in *Whole Women’s Health v. Hellerstedt*, 136 S. Ct. 2922 (2016), saves their claims. Opp’n 14-20. It does not.

First, *Hellerstedt* did not abrogate the Fifth Circuit test for *res judicata*, which the court has applied on numerous occasions since. *See, e.g., Colonial Oaks Assisted Living Lafayette, LLC v. Hannie Dev., Inc.*, --- F.3d ---, 2020 WL 5015453 at *5 (5th Cir. Aug. 25, 2020).

Second, Plaintiffs cannot draw a material distinction between *DeOtte* and the instant case. Plaintiffs claim that their current challenge is to the statute codified at 42 U.S.C § 300gg-13(a)(4), while *DeOtte* was a challenge to the “agency rules that codify the Contraceptive Mandate,” Opp’n 12. This argument is premised on both a misreading of *Hellerstedt* and a misstatement of the FAC. The language from *Hellerstedt* on which Plaintiffs rely notes the unremarkable proposition that “two different statutory provisions” “with two different, independent requirements” and “that serve two different functions” can be challenged in separate suits. *Hellerstedt*, 136 S. Ct. at 2308; Opp’n 12 (quoting same). This language does *not* purport to authorize a second challenge to a single requirement—the Contraceptive Mandate—by bringing new legal arguments that were just as available to Plaintiffs at the time of the first challenge. Indeed, Plaintiffs’ own allegations make clear that the subject of their complaint is the Contraceptive Mandate established pursuant to HRSA’s guidelines, just as it was in *DeOtte*. Compare FAC at 1 (“In 2011 . . . [HRSA] issued an

edict that compels private insurance to cover all forms of FDA-approved contraceptive methods . . .”) with *DeOtte* Am. Compl., at 1 (“Federal regulations require health insurance to cover all FDA-approved contraceptive methods.”); see also FAC ¶¶ 21-28 (section entitled “HRSA’s Contraceptive Mandate”); *id.* ¶ 37 (“The federal Contraceptive Mandate continues to inflict injury in fact on these plaintiffs and other religious objectors . . .”). Plaintiffs here simply challenge the same law under new theories that they could just as easily have brought as part of *DeOtte*.⁴ This is squarely precluded by *res judicata*.

Plaintiffs’ putative distinction between *DeOtte*’s challenge to “the behavior of executive branch officials” and their current challenge to “the legislature’s action” enacting the enabling statute fails for the same reason. Opp’n 13-14. In each case, Plaintiffs challenge only the Contraceptive Mandate, promulgated under authority granted by statute. To the extent Plaintiffs did not challenge the statutory basis for the Contraceptive Mandate in *DeOtte*, they unquestionably “could have . . . raised” those claims there. *Colonial Oaks*, 2020 WL 5015453 at *5. Such claims are thus part of the same nucleus of operative facts.

III. PLAINTIFFS’ CONSTITUTIONAL AND ACA CLAIMS ARE TIME BARRED

Plaintiffs do not dispute their failure to bring their claims within eight years of the time the Contraceptive Mandate took effect, nine years after it was established, and ten years after the enabling statute was passed. Each is well beyond the relevant limitations period. Nor do they dispute that the statutes cited in Defendants’ motion to dismiss are applicable here. They instead claim they can bring this litigation at any time on the theory that their claims “‘accrue[]’ each

⁴ Nor can Plaintiffs claim that any “factual developments” since *DeOtte* newly permit their claim. *Hellerstedt*, 136 S. Ct. 2306. The only relevant change since *DeOtte* is that it is now undisputable that the Contraceptive Mandate does *not* apply to religious objectors like Plaintiffs. See FAC ¶¶ 24, 25, 27.

day” the Mandate is enforced because it imposes an “ongoing” violation of constitutional rights. Opp’n 15. But the mandate is not being enforced against *DeOtte* class member Plaintiffs; they can thus bring only a facial challenge to the statute’s enforcement upon *others*. But the time to bring a facial challenge to the statute’s enforcement against others is long past. For similar reasons, the other Plaintiffs’ purely speculative assertion that they might pay lower premiums if there were no Contraceptive Mandate (or other preventive coverage mandate) is inadequate to support any newly-accruing injury to them.⁵

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

Plaintiffs’ Opposition likewise fails to save their Appointments Clause and Vesting Clause claims. First, as Defendants have explained, Plaintiffs forfeited this claim by failing to present it to the agencies. Mot. 19-21. Plaintiffs do not dispute that they failed to present these claims to the agencies in the first instance. Instead, they implausibly assert that they are simply targeting a statute, not agency action, and thus need not have presented these claims to the agencies. The FAC refutes this contention. It makes clear that Plaintiffs’ challenge is to the specific requirements that contraceptives and PrEP drugs be covered by insurance, pursuant to HRSA’s guidelines and PSTF’s recommendations, respectively. *See, e.g.*, FAC at 1-2; *id.* ¶¶ 21-31 (sections entitled “The HRSA’s Contraceptive Mandate” and “The U.S. Preventive Services Task Force’s PrEP Mandate”); 42 U.S.C. § 300gg-13(a)(1) & (a)(4). Their challenge is not to the enabling statute—which does not itself act on Plaintiffs—in the abstract. Indeed, Plaintiffs themselves frame their Appointments Clause claim as a challenge to the way members of PSTF, ACIP, and HRSA are

⁵ Nor are Plaintiffs correct that the statute of limitations does not apply to claims against cabinet secretaries. *Texas v. Rettig*, 968 F.3d 402, 413 (5th Cir. 2020), cited in Defendants’ motion, is but one recent example in which claims against cabinet secretaries were dismissed pursuant to 28 U.S.C. § 2401(a)).

appointed in light of their authority, resulting in Plaintiffs’ request that the Court “declare that” preventive care mandates “based on a rating, recommendation, or guideline issued by the U.S. Preventive Services Task Force, the Advisory Committee on Immunization Practices, or the Health Resources and Services Administration” after March 2010 are unconstitutional. *FAC* ¶ 77; *see id.* ¶¶ 66-80.

Plaintiffs cite one case, *Barr v. American Association of Political Consultants*, 140 S. Ct. 2335 (2020), to attempt to refute the extensive authority cited by Defendants. That case has nothing to do with the Appointments Clause and is inapposite for that reason alone. It also has no bearing because plaintiffs in *Barr* challenged a statute that directly forbade them from taking certain actions while permitting others to do so. *See id.* at 2344 (addressing the validity of “the TCPA’s prohibit[ion of] almost all robocalls to cell phones” which is “codified in . . . the U.S. Code” in light of the decision of “Congress [to] carve[] out a new . . . exception to [this] restriction”) (emphasis added). Because *Barr* turned in no way on agency action, it does not speak to the claim at issue here, which challenges what an *agency* did and whether it had the authority to do it.

Plaintiffs also fail to refute the Secretary of Health and Human Services’ ratification of the Contraceptive Mandate or the CDC Director’s ratification of ACIP’s recommendations. First, Plaintiffs do not dispute that either the Secretary or the CDC Director was constitutionally appointed, nor do they contend that neither ratified the relevant guidelines. Instead, they claim the statute does not provide the Secretary or CDC Director with the authority to do so and that it in any event “empowers HRSA or ACIP to dictate the preventive care that private insurers must cover *until* an ‘officer of the United States’ acts to approve or revoke their decisions.” Opp’n 18. But Plaintiffs’ argument fails for the fundamental problem that the HHS Secretary *did* ratify the Contraceptive Mandate before it took effect, so the hypothetical of whether some other guideline

not discussed in the FAC could take effect without ratification is not at issue here. *See* 76 Fed. Reg. 46,621 (Aug. 3, 2011) (interim final regulations “[a]pproved” by the “Secretary” of HHS permitting Contraceptive Mandate to take effect but authorizing religious exemption to the Contraceptive Mandate). And their argument is even more baseless with regard to ACIP, whose charter expressly makes clear that the CDC Director must “adopt[]” its recommendations before they are “in effect” as required for coverage under the preventive services provision.⁶ Charter of the Advisory Committee on Immunization Practices⁷ at 1; 42 U.S.C. § 300gg-13(a)(2); *see also* Compl. Ex. 2 (45 C.F.R. § 147.130(a)(1)(ii)) (ACA implementing regulations providing that immunization recommendations must be “in effect” to have an insurance coverage requirement and that “for this purpose, a recommendation from the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention is considered in effect after it has been adopted by the Director of the Centers for Disease Control and Prevention”).

Next, Plaintiffs ask this Court to disregard the binding authority of *Riley v. St. Luke’s Episcopal Hosp.*, 252 F.3d 749 (5th Cir. 2001), which requires that a position have “at a minimum, a continuing and formalized relationship of employment with the United States Government” to qualify as an “officer” for purposes of the Appointments Clause, by reading this requirement out of existence. *Id.* at 757. Specifically, Plaintiffs contend that this Court should “interpret[]” (Opp’n 20) *Riley*’s standard to not require an individual to draw a salary to be an “officer of the United States,” despite the Court in *Riley* explicitly concluding that qui tam plaintiffs do not meet this

⁶ The arguments in Plaintiffs’ standalone section regarding ACIP (Opp’n 24-25) are misplaced for this reason. ACIP does not have the power to “dictate” insurance coverage. The CDC Director must approve ACIP’s recommendations for coverage to be required; for that reason, (a) it remains “advisory” and (b) whatever its members’ status, the CDC Director is unquestionably their “superior” officer.

⁷ <https://www.cdc.gov/vaccines/acip/committee/acip-charter.pdf>.

standard and are thus not officers of the United States on the sole grounds that they “*do not draw a government salary* and are not required to establish their fitness for public employment.” *Riley*, 252 F.3d at 758 (emphasis added). Such a contorted “interpretation” is simply a request by Plaintiffs that the Court improperly refuse to follow this binding precedent, and Plaintiffs’ criticism of the government for bringing binding circuit authority to the attention of the Court is extraordinary.⁸ Even if Plaintiffs’ strained reading of *Riley*’s “continuing and formalized relationship of employment” test not requiring payment of a salary were correct, it would still not bring the members of PSTF and ACIP within this language. As a Federal Advisory Committee, ACIP’s members by definition cannot all be “full-time, or permanent part-time, officers or employees of the Federal Government.” 5 U.S.C. app. § 3(2). Whatever *Riley*’s standard may require, ACIP’s members by definition do not meet it. Similarly, PSTF members are not just unpaid volunteers, but also meet only “three times a year for two days,” which likewise cannot satisfy the “minimum” under *Riley* whether or not payment is necessary to that standard. 85 Fed. Reg. 711, 712 (Jan. 7, 2020).

But even if the Court were to take up Plaintiffs’ implied request to turn a blind eye to *Riley*, it would not help them. As Plaintiffs note, in *Lucia v. SEC*, 138 S. Ct. 2044, 2051 (2018), the Supreme Court has held that an “officer of the United States” must “occupy a ‘continuing’ position established by law” and “‘exercise[e] significant authority pursuant to the laws of the United States.’” *Id.* (citation omitted). Of course, this test is consistent with *Riley* and this Court must

⁸ Plaintiffs argue that a 2007 Office of Legal Counsel Opinion (“OLC”) containing an analysis of the Appointments Clause that differs from *Riley* requires rejecting the substance of that decision. See Opp’n 21-23 (citing 31 Op. Off. Legal Counsel 73 (Apr. 16, 2007)). In fact, as the cited OLC opinion acknowledges the OLC has itself taken conflicting positions over the years about whether employment “is considered essential” to the definition of “officer” under the Appointments Clause. See 31 Op. Off. Legal Counsel 73, 2007 WL 140549, at *4. But to the extent the OLC’s opinions conflict with the Circuit precedent in *Riley*, it is the latter, not the former, that binds this Court.

follow both. But the relevant expert bodies do not meet this test even disregarding *Riley*, because as made clear in Defendants' motion, these bodies do not "exercise significant authority pursuant to the laws of the United States." In pressing the contrary conclusion, Plaintiffs fundamentally misunderstand the role of the expert bodies who provide the preventive care guidelines and recommendations that, pursuant to ACA, must be covered by insurance. In 42 U.S.C. § 300gg-13(a), *Congress* made the determination that standard contemporary preventive care practices should be covered by insurance without cost sharing. The authority of the expert bodies referenced in the statute is limited, and this limited nature of their authority is not changed by the statute's incorporation of their work by reference. Specifically, their limited role is to set forth what contemporary preventive care practices are the prevailing medical standard at a given time. In other words, these expert bodies are not "unilaterally dictat[ing] the scope of preventive care that all private insurers must cover," because Congress has already made that determination. Opp'n 21. The expert bodies simply have the task of setting forth, in a world where medical science is evolving daily, what practices qualify in the medical field as the current standard of care.

Plaintiffs concede, as they must, that Congress can constitutionally incorporate the evolving standards established by outside bodies into the laws of the United States. Opp'n 20. But they implausibly claim that doing so becomes permissible only if such outside bodies are *not* associated with the federal government in any way. This proposition is absurd: if Congress can appropriately incorporate the expert standards of wholly non-federal entities like state governments, foreign governments, or nongovernmental organizations, who are unquestionably not "officers of the United States," then the creation of such standards cannot be the exercise of "significant authority pursuant to the laws of the United States" that would require appointment

pursuant to the Appointments Clause. *Lucia*, 138 S. Ct. at 2051. Plaintiffs’ vesting clause claim, which relates only to PSTF’s recommendations, fails for the same reason.

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

In claiming the only intelligible principle governing the PSTF’s recommendations are PSTF’s “own criteria” and not Congress’s (Opp’n 27), Plaintiffs ignore that the statute governing the PSTF itself states that the PSTF’s recommendations regarding “clinical preventive services” must be made on the basis of “the scientific evidence related to the effectiveness, appropriateness, and cost-effectiveness of clinical preventive services.” Mot. at 27 (quoting 42 U.S.C. § 299b-4(a)(1)). If that is not guidance on how PSTF exercises its discretion, it is unclear what would satisfy Plaintiffs.

And for all of the challenged provisions, instead of arguing that the statute lacks an intelligible principle, Plaintiffs essentially argue that every intelligible principle should have additional subsidiary principles. This is not the law. Plaintiffs cannot and do not dispute that each challenged provision, in entrusting the relevant entity with the discretion to make recommendations, instructs those entities regarding the nature of the recommendations they are empowered to make. For PSTF, those are “evidence-based items or services that have in effect a rating of ‘A’ or ‘B.’” 42 U.S.C. § 300gg-13(a)(1). For ACIP, the recommendations must be “immunizations that have in effect a recommendation . . . with respect to the individual involved.” *Id.* § 300gg-13(a)(2). For HRSA, they are either “evidence-informed preventive care or screenings” “with respect to infants, children, and adolescents,” or they are “additional preventive care and screenings” “with respect to women . . . as provided for in comprehensive guidelines.” *Id.* §§ 300gg-13(a)(3), (4). Those terms all instruct the relevant entities in exercising their discretion.

Although Plaintiffs contend that the agencies should have further instructions about how to follow those broader instructions, nondelegation precedents expressly permit even statutory delegations that allow extremely broad discretion within very general guidelines, such as the authority to recoup “excess profits” without defining what profits are “excess.” *Whitman v. Am. Trucking Ass’ns*, 531 U.S. 457, 475 (2001) (citation omitted). And here Congress has not empowered PSTF, ACIP, or HRSA to set standards that “affect the entire national economy,” but instead has given each entity the power to define a term in a cabined regulatory scheme. *See id.*

Plaintiffs essentially ask this Court to anticipate a change in Supreme Court nondelegation caselaw, citing *Little Sisters of the Poor v. Pennsylvania*. But the *Little Sisters* Court expressly disavowed making any conclusion on nondelegation. 140 S. Ct. 2367, 2382 (2020). Current Supreme Court and Fifth Circuit precedents permit the level of guidance offered in §§ 300gg-13(a)(1) through (4), and this Court should not act in anticipation of a change in binding precedents. *See Rodriguez de Quijas v. Shearson/Am. Express, Inc.*, 490 U.S. 477, 484 (1989); *Big Time Vapes, Inc. v. Food & Drug Admin.*, 963 F.3d 436, 447 (5th Cir. 2020) (“The Court might well decide—perhaps soon—to reexamine or revive the nondelegation doctrine. But ‘[w]e are not supposed to ... read tea leaves to predict where it might end up.’”) (citation omitted).

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

Plaintiffs essentially concede their argument on this point, explicitly “agree[ing]” that the “most natural” reading of the challenged provisions is that they incorporate post-enactment recommendations and guidelines and “would compel any court to adopt the government’s construction of the statute” in the absence of constitutional doubt. Opp’n 30. Plaintiffs’ sole argument is that the avoidance canon compels courts to adopt “unnatural or unpalatable” or “exceedingly dubious interpretations.” *Id.* But the Supreme Court has flatly rejected this argument,

expressly holding in *Jennings v. Rodriguez* that it was error for the Ninth Circuit to invoke the avoidance canon to adopt “interpretations of the . . . provisions at issue [that] are implausible.” 138 S. Ct. 830, 842 (2018). Instead, the Supreme Court has limited the avoidance canon only to those situations where, “after the application of ordinary textual analysis, the statute is found to be susceptible of more than one construction.” *Id.* If there is not “more than one plausible construction, the canon simply ‘has no application.’” *Id.* (citation omitted). Here, the ordinary tools of statutory construction lead inexorably to the conclusion that the statute means what Plaintiffs concede it means—that the statute incorporates post-enactment guidelines and recommendations. The avoidance canon is inapplicable.

VII. PLAINTIFFS FAIL TO ALLEGE A VIOLATION OF RFRA

Plaintiffs claim that they assert “complicity-based objections” to the requirement that insurance cover PrEP drugs in certain cases, which must be accepted if sincere. Opp’n 32. But the allegations in the FAC do not make any such complicity-based assertions, and Plaintiffs cannot amend their FAC with statements in their Opposition. *See, e.g., In re Kosmos Energy Ltd. Sec. Litig.*, 955 F. Supp. 2d at 676. Braidwood simply alleges that “homosexual behavior . . . is contrary to [its owner] Dr. Hotze’s sincere religious beliefs” and the individual religious objector Plaintiffs simply claim that they are “unwilling” to purchase health insurance that subsidizes PrEP drugs. *Id.* at 31 (quoting FAC at ¶¶ 36, 63). And Kelley Orthodontics does not allege any religious objection to the requirement that insurance plans cover PrEP drugs in certain cases at all. In short, the FAC does not allege that providing or purchasing insurance coverage for PrEP drugs is contrary to Plaintiffs’ sincere religious beliefs. Because Plaintiffs do not allege that any of their “religious exercise [that] is grounded in a sincerely held religious belief” is “substantially burdened” by the requirement that PrEP drugs be covered by insurance in certain cases, they have failed to state a RFRA claim. *United States v. Comrie*, 842 F.3d 348, 351 (5th Cir. 2016).

CONCLUSION

For the reasons set forth above, Defendants' motion to dismiss (ECF No. 20) should be granted.

Respectfully submitted,

ERIN NEALY COX
United States Attorney

JEFFREY BOSSERT CLARK
Acting Assistant Attorney General

/s/ Brian W. Stoltz
Brian W. Stoltz
Assistant United States Attorney
Texas Bar No. 24060668
1100 Commerce Street, Third Floor
Dallas, Texas 75242-1699
Telephone: 214-659-8626
Facsimile: 214-659-8807
brian.stoltz@usdoj.gov

MICHELLE R. BENNETT
Assistant Branch Director

/s/ Christopher M. Lynch
CHRISTOPHER M. LYNCH
(D.C. Bar # 1049152)
Trial Attorney
U.S. Department of Justice
Civil Division
1100 L Street, NW
Washington, D.C. 20005
Telephone: (202) 353-4537
Fax: (202) 616-8460
Email: Christopher.M.Lynch@usdoj.gov

Attorneys for Federal Defendants Alex M. Azar II,
Steven T. Mnuchin, Eugene Scalia, and the United States

Certificate of Service

On October 5, 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
Christopher M. Lynch
Trial Attorney