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
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, claiming, *inter alia*, they violate the Religious Freedom Restoration Act ("RFRA"). Yet nearly two years ago, several of the same Plaintiffs brought a challenge before this Court under RFRA to the requirement that all health insurance cover all FDA-approved methods of birth control for women without cost sharing (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 purchase and establish insurance that excluded contraceptive coverage.

Plaintiffs today bring a hodgepodge of new challenges to *all* of the ACA's preventive care coverage requirements, including the Contraceptive Mandate that this Court has already held does not apply to them. Their claims must fail. First, they have no standing to bring their new Contraceptive Mandate claims, and those claims are also barred by *res judicata*. Second, their Complaint fails to state a claim with respect to each of their new claims, many of which are forfeited, untimely, and/or sketched out in only conclusory allegations. Fundamentally, most of Plaintiffs' Complaint rests on the basic misunderstanding that the ACA's preventive care requirements are established through 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 only 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* Plaintiff's Complaint (Compl.) ¶ 15 (ECF No. 1). 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.* ¶ 16. 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 ¶ 18 of the Complaint). 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 "ensur[ing] that individual religious objectors would have the option to purchase health insurance that excludes contraception from any willing health insurance issuer." Compl. ¶ 19. Although enforcement of the 2018 final rule was enjoined on the day it was to take effect, *see* Compl. ¶ 20, litigation was filed before this Court contending that the 2018 final rule's accommodation to religious objectors was required by RFRA. Compl. ¶ 20; *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 its sincerely held religious beliefs, to . . . providing . . . coverage or payments for some or all contraceptive services," Compl. Ex. 5 at 1, and "permanently enjoined federal officials from enforcing the Contraceptive Mandate against any religious objector protected by the [2018] final rule." Compl. ¶ 21.

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." Compl. 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. Compl. Intro.

Four plaintiffs now bring this action challenging the PSTF recommendations, ACIP recommendations, and HRSA guidelines—including the Contraceptive Mandate—on multiple grounds. Plaintiffs John Kelley and Joel Starnes sue because each "has no desire to purchase health insurance that includes contraceptive coverage," "does not want or need STD testing covered," and "does not want or need health insurance that covers Truvada or PrEP drugs." Compl. ¶¶ 29, 36. Each is "a Christian, and . . . therefore unwilling to purchase health insurance that subsidizes abortifacient contraception or PrEP drugs that encourage homosexual behavior and intravenous drug use." Compl. ¶¶ 30, 37. Each contends that, despite the *DeOtte* injunction permitting issuance of coverage that excludes contraceptive coverage, "few insurance companies are offering health insurance of this sort." Compl. ¶ 31; *see id.* ¶ 38.

Plaintiff Kelley Orthodontics "wants 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." Compl. ¶¶ 43–44.

Plaintiff Braidwood Management Inc. ("Braidwood") employs the people who work at three business entities, each of which is owned by Steven Hotze. Compl. ¶ 47–49. Hotze is also the sole trustee and beneficiary of the trust that owns Braidwood. Compl. ¶ 48. Braidwood is self-insured and must offer ACA-compliant health insurance. Compl. ¶ 50. Hotze "is a Christian," and alleges he is unwilling to allow Braidwood's self-insured plan to cover PrEP drugs "because those drugs facilitate behaviors such as homosexual sodomy, prostitution, and intravenous drug use."

Compl. ¶¶ 51–52. Hotze also "objects to other preventive-care mandates that require Braidwood's plan to cover STD screenings and counseling for those engaged in non-marital sexual behavior." Compl. ¶ 53. 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 HAVE NO 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, "Plaintiffs" refers only to Plaintiffs Kelley, Starnes, and Kelley Orthodontics. Plaintiff Braidwood Management, Inc. does not allege the Contraceptive Mandate is causing it any injury. For that reason alone, it fails to establish standing. To the extent the Complaint can be read to assert a claim against the Contraceptive Mandate by Braidwood Management, Inc., that Plaintiff does not have standing for the same reasons as the other Plaintiffs; in fact, Braidwood

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," Compl. ¶ 33, 40, 46, 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.* ¶ 21, *see id.* ECF No. 1-5. 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* Compl. ¶¶ 18, 19, 21 & ECF No. 1-5; *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 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 "*limit[s] the scope* of available health insurance that excludes . . . unwanted contraceptive coverage," because "*few* insurance companies are offering health insurance of that sort." Compl. ¶ 31 (emphasis added); *see also id.* ¶ 38. But Plaintiffs' allegations that their options to choose health insurance coverage are narrower than they

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

would prefer are insufficient to establish a 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." Compl. ¶ 21. 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.* ¶¶ 18, 19, 21. 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 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.* ¶ 31; *see id.* ¶ 38. 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; Compl. ¶¶ 31, 38. Although "few . . . are currently" choosing to do so, *id.* ¶ 31; *see id.* ¶ 38, 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* Compl. ¶¶ 21, 31, 38. 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]

II. PLAINTIFFS' CHALLENGES TO THE CONTRACEPTIVE MANDATE ARE BARRED BY *RES JUDICATA*

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 of purchasing 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." Compl. ¶¶ 18, 19, 21. 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 regulations as in the prior suit for identical reasons. Pursuant to the judgment in *DeOtte*, these regulations can no longer be applied to them;

[2] Plaintiffs' claims regarding the requirement that insurance cover PrEP medications fail for the same reason. The Complaint alleges that it is "impossible" for both Plaintiffs Kelley and Starnes "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." Compl. ¶¶ 25, 29, 36. 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.

they cannot raise new legal theories to attack them 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, Compl. ¶ 41) and Braidwood Management, Inc. were named plaintiffs in that case.[4] Plaintiffs allege, in substance, that they are "religious objectors who wish to purchase health insurance" who are "injur[ed]" by the Contraceptive Mandate." Compl. ¶¶ 31, 38; *see id.* ¶¶ 41 & 44. 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. ECF No. 1-5 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 Complaint and attach the judgment as an exhibit to their Complaint. 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 grounds 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, 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.").

Compl. 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 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 have been ratified 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," they do not allege that they raised their contention that these provisions violate the Appointments Clause before the agencies 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*, --- F.3d ---, 2020 WL 3167896, at *1 (10th Cir. June 15, 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 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). And a draft version of the PSTF's PrEP recommendation "was posted for public comment" on the PSTF's website in November 2018. Compl. 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 has been cured by the Secretary of Health and Human Services' ratification of the mandate through the rulemaking implementing it. "[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, the action by the Secretary of Health and Human Services—who was unquestionably constitutionally appointed—to promulgate regulations for purposes of implementing the Contraceptive Mandate constitute her ratification of the mandate, curing any conceivable defect in the appointment of the administrator of HRSA. *See, e.g.*, 78 Fed. Reg. 39,870, 39,872 (July 2, 2013) (notice of final regulations "[a]pproved" by the "Secretary, Department of Health and Human Service" noting "[t]hese final regulations promote . . . [the] important policy goal[]" of "provid[ing] women with access to contraceptive coverage without cost sharing.").

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)[6] ("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.

[6] 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."[7] *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.[8] *Riley*, 252 F.3d at 757.

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

[8] 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 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 in doing so they exercise "significant authority pursuant to the laws of the United States." Compl. ¶ 61 (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.

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

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

Plaintiffs also fail to state a nondelegation claim. First, as discussed below, *infra* Part V, 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 agency discretion. "[W]hen Congress confers decisionmaking authority upon agencies 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*, ---F.3d ---, 2020 WL 3467973, at *4 (5th Cir. June 25, 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 *7.

Notably, the Court has even "blessed delegations that authorize regulation in the 'public interest' or to 'protect the public health.'" *Id.* at *4 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."[9] 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,

[9] 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' expert analysis. *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.

V. THE CHALLENGED COVERAGE REQUIREMENTS DO NOT VIOLATE THE APA'S NOTICE-AND-COMMENT REQUIREMENTS

Plaintiffs' challenges under the APA fail for numerous reasons. First, the statutory incorporation of clinical recommendations and guidelines does not make those recommendations and guidelines "rules" subject to the APA. Second, even if they were rules, Congress has prescribed an alternative procedure for promulgating them. Third, the agencies complied with any notice-and-comment requirements in promulgating the regulations for those statutory commands, so the APA is satisfied regardless. Fourth, even if there were a procedural defect in adopting those regulations, the Plaintiffs' claim is barred by the statute of limitations. Finally, even if this Court concludes that the incorporation of each new recommendation and guideline had to follow APA procedures, Plaintiffs' claims still all fail, because many of those recommendations follow notice-and-comment procedures or cannot overcome harmless error.

Plaintiffs contend that the PSTF, ACIP, and HRSA recommendations and guidelines needed to go through notice-and-comment procedures. They did not. Plaintiffs misapprehend the nature of the statute and of the recommendations and guidelines. The APA's notice-and-comment requirements apply only to rulemaking, 5 U.S.C. § 553(b), and a "rule" is defined in the APA, in

relevant part, as being "designed to implement, interpret, or prescribe law or policy," *id.* § 551(4). The recommendations and guidelines neither do nor are designed to do any such thing, and as such they do not constitute "rules" within the meaning of the APA. The substantive obligations that are imposed on group health plans and health insurance issuers were imposed by Congress, in 42 U.S.C. § 300gg-13(a), which expressly and automatically imports the content of various "recommendations" and "guidelines"—not rules—including HRSA guidelines for preventive health that would be developed later, and other recommendations and guidelines by PSTF, ACIP, and HRSA that might be issued or updated after a specified period of time.[10]

Even if these were considered "rules" in some fashion, Congress has overridden the APA's default notice-and-comment procedures in this case. A statute can substitute different procedures than those that the APA might otherwise require. *See Asiana Airlines v. FAA*, 134 F.3d 393, 398 (D.C. Cir. 1998). The PSTF, ACIP, and HRSA all existed prior to the ACA's passage, made recommendations regarding preventive care that corresponded to the categories outlined in §§ 300gg-13(a)(1) through (a)(3), and would have continued to do so even in the absence of the ACA. Congress took then-existing recommendations and guidelines as it found them—expert clinical recommendations and guidelines that may not have gone through notice and comment—and further made clear its intent to incorporate recommendations and guidelines those entities issued going forward. Under Plaintiffs' theory, even as Congress was adopting those recommendations and guidelines wholesale, its enthusiastic reception was also meant to silently

[10] In contrast, other provisions of the ACA use clear language when referring to the promulgation of substantive rules. *See, e.g.*, 42 U.S.C. § 300gg-1(b)(3) ("The Secretary shall promulgate regulations with respect to enrollment periods under paragraphs (1) and (2)."); *id.* § 300gg-14(b) ("The Secretary shall promulgate regulations to define the dependents to which coverage shall be made available under subsection (a)."). That Congress explicitly did not use such language here indicates that it did not intend the PSTF and ACIP recommendations and HRSA guidelines to be "rules" within the meaning of the APA.

rebuke PSTF, ACIP, and HRSA for any deviations from notice and comment. There is no support in the statute for such a radical rejection of Congress's choice to take those entities' recommendation-making processes as it found them. Indeed, Congress is considering a proposal to make PSTF follow procedures of notice-and-comment rulemaking, such as publishing recommendations in the Federal Register. *See* H.R. 3534, 116th Cong. (2019). This Court should enforce Congress's decision not to require notice-and-comment rulemaking.

Even if the incorporation of new recommendations and guidelines were subject to the APA's notice-and-comment requirements, the challenged provisions all satisfy the APA's requirements. The agencies' implementing regulations for the challenged statutory provisions went through notice-and-comment procedures that fully complied with the APA. On July 19, 2010, the agencies issued their interim final rules for 42 U.S.C. § 300gg-13(a). 75 Fed. Reg. 41,726. Those interim final rules detailed the process by which a PSTF, ACIP, or HRSA recommendation or guideline would be considered final and thus incorporated into the statute's mandated coverage going forward, and included charts with the then-active recommendations by the PSTF, ACIP, and the HRSA, with the exception of the HRSA guidelines for women's preventive care, which had not yet been issued. The interim rules gave an opportunity for comments. On August 1, 2011, HRSA issued its comprehensive guidelines referenced in § 300gg-13(a)(4), which required coverage for "[a]ll Food and Drug Administration [(FDA)] approved contraceptive methods, sterilization procedures, and patient education and counseling for all women with reproductive capacity." 77 Fed. Reg. 8725, 8725 (Feb. 15, 2012). Thereafter, the agencies amended the interim final rules, acknowledged that the women's preventive health guidelines had been issued, and extended the comment period. 76 Fed. Reg. 46,622 (Aug. 3, 2011). And the agencies' final rule in 2013 addressed comments on HRSA's decision to include contraceptive coverage as women's

preventive care, from commenters who argued that "contraceptive services should not be considered preventive health services." 78 Fed. Reg. 39,870, 39,872 (July 2, 2013). Another final rule issued in 2015 finalized other matters, such as the effective date that would be used for determining when insurers must provide coverage relating to changes to the recommendations and guidelines. 80 Fed. Reg. 41,318 (July 14, 2015). Plaintiffs have not identified any procedural defects that would render those rulemakings ineffective.

Furthermore, the statute of limitations bars any notice-and comment challenge to the agencies' regulations. A claim that an agency violated the APA is subject to a six-year statute of limitations. *Dunn-McCampbell Royalty Interest, Inc. v. Nat'l Park Service*, 112 F.3d 1283, 1286 (5th Cir. 1997). That statute of limitations begins to run from the final agency action being challenged. *Id.* To qualify as "final agency action," (1) "the action must mark the consummation of the agency's decisionmaking process" and (2) "the action must be one by which rights or obligations have been determined, or from which legal consequences will flow." *Bennett*, 520 U.S. at 177–78 (citations and internal quotations marks omitted). For a procedural challenge to a regulation, such as a failure to follow notice-and-comment procedures, the limitations period begins to run from the publication of the rule. *See, e.g.*, *Dunn-McCampbell Royalty Interest*, 112 F.3d at 1287 ("On a facial challenge to a regulation, the limitations period begins to run when the agency publishes the regulation in the Federal Register.").

Plaintiffs do not identify with precision which final regulatory actions they challenge, but many or all of them will fail the statute of limitations. The interim final rule that designated the PSTF, ACIP, and HRSA recommendations and guidelines that would apply going forward for §§ 300gg-13(a)(1) through (a)(3) was published in 2010. 75 Fed. Reg. 41,726 (July 19, 2010). The HRSA guidelines requiring—with certain exceptions not relevant here—coverage of all FDA-

approved contraceptive options were published on August 1, 2011. 77 Fed. Reg. 8725, 8725 (Feb. 15, 2012). The agencies gave notice of the same in the Federal Register just a few days later, *see* 76 Fed. Reg. 46,622. And it was 2013 when the agency issued a final rule responding to and rejecting the argument that contraceptives were not "preventive care." 78 Fed. Reg. at 39,872–73. Plaintiffs therefore has waited too long to challenge any alleged procedural errors in the regulations relating to the recommendations and guidelines.

If Plaintiffs are instead suggesting that PSTF, ACIP, and HRSA themselves are required to follow notice-and-comment procedures in considering individual adjustments to recommendations and guidelines before the statute can mandate coverage, the guidelines and recommendations still stand for numerous reasons. At the outset, the statute of limitations would still bar many of the claims, as any recommendations in place for more than six years—including the HRSA guideline to cover all FDA-approved contraceptives—would be beyond procedural objection now.

Plaintiffs' Complaint otherwise fails to make out a challenge to any category of coverage. First, as discussed, the HRSA guidelines required coverage of "[a]ll Food and Drug Administration [(FDA)] approved contraceptive methods, sterilization procedures, and patient education and counseling for all women with reproductive capacity." 77 Fed. Reg. at 8725; *see also* Compl. ¶ 15. And the resulting rules went through notice-and-comment rulemaking. Compl. ¶ 16. It is therefore inaccurate to state that the coverage of contraceptive products and services post-dates the regulatory process.

For ACIP, it is not clear whether Plaintiffs challenge any recommendation that post-dates the ACA. The only immunization they list—the immunization for the human papillomavirus—has been covered by an ACIP recommendation since the ACA was enacted. *See* 75 Fed. Reg. at 41,746. But even if Plaintiffs could challenge unidentified ACIP recommendations, this challenge would

fail, because ACIP's recommendations comply with notice and comment. ACIP publishes a notice in the Federal Register at least sixty days before meetings at which there will be a vote on recommendations. *See* Advisory Committee on Immunization, Practices Policies and Procedures 6–7 (Dec. 2018), https://www.cdc.gov/vaccines/acip/committee/downloads/Policies-Procedures-508.pdf. Those notices identify the subjects to be discussed and voted upon, and they invite written and oral comment. *Id. See, e.g.*, 85 Fed. Reg. 26,474 (May 4, 2020). Once a vote is taken at the ACIP meeting and the CDC Director adopts it, the recommendation is published in CDC's Morbidity and Mortality Weekly Report and incorporated into the CDC's immunization schedules. That process satisfies the procedures laid out in 5 U.S.C. § 553.

For HRSA's guidelines relating to infants, children, and adolescents, Plaintiffs likewise have not identified what guidelines they object to that post-date the initial preventive services rulemaking. The first interim final rule incorporated two documents that HRSA uses for its comprehensive guidelines in accordance with that statutory provision, and it reproduces those charts in the regulation itself while also specifying where on the HRSA website it will be posting the most up-to-date version. 75 Fed. Reg. at 41,729 (identifying website), 41,740 (identifying charts), 41,733-35 (reproducing charts). Plaintiffs thus had an opportunity to comment on these guidelines through the initial rulemaking.

Finally, to the extent Plaintiffs challenge the PSTF recommendations, they fail to identify which provisions they challenge as allegedly violating the APA. The 2010 interim final rule listed then-current PSTF recommendations. *Id.* at 41,741–44. And even if new PSTF recommendations had to go through notice-and-comment procedures on a recommendation-by-recommendation basis (they do not), any failure to comply with the exact procedures described by the APA is harmless. Technical failures in the notice-and-comment process are harmless where adequate

public notice has been provided and adequate opportunity for comment has been provided. *See, e.g., Cal-Almond, Inc. v. U.S. Dept. of Agric.*, 14 F.3d 429, 442 (9th Cir. 1993) (failure to engage in notice-and-comment procedures was harmless where the challenged decisions were reached at an open meeting at which the agency receives public comments and gave notice of decisions). The PSTF publicly posts draft recommendations on its website and accepts public comment for at least four weeks. *See* U.S. Preventive Services Task Force, Procedure Manual 52 (Dec. 2015).[11] As discussed earlier, the PrEP recommendation was posted publicly for over a month for public comment. Plaintiffs have not identified how they were harmed by the notifications' not being published in the Federal Register, nor have they explained what sorts of comments they might have offered in evaluating those expert clinical recommendations. Any shortcoming in meeting the technical requirements of notice-and-comment is therefore harmless.

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

[11] https://www.uspreventiveservicestaskforce.org/uspstf/sites/default/files/inline-files/procedure-manual2017_update.pdf.

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, they 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 some relating to some of the provisions' subject matter does not indicate that Congress intended to forego 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, *infra* Parts III–IV, Plaintiffs' constitutional claims could not raise any "serious" doubts.

VII. CONTRACEPTIVE CARE CAN QUALIFY AS "PREVENTIVE CARE" UNDER THE STATUTE

In enacting § 300gg-13(a)(4), Congress incorporated comprehensive guidelines to be developed by HRSA regarding preventive care for women. The Supreme Court stated outright that Congress "did not specify what types of preventive care must be covered." *Burwell v. Hobby Lobby Stores, Inc.*, 573 U.S. 682, 697 (2014). HRSA determined that contraceptive services were one type of preventive care that its guidelines would cover. Plaintiffs cannot identify anything in the text, history, or structure of the ACA that precludes that choice.

There is nothing in the term "preventive care" to suggest that it excludes contraceptive services. Neither of Plaintiffs' limiting constructions has any purchase in the text of the statute.

See Compl. ¶¶ 105–06. First, they identify no definition that limits "preventive care" solely to the prevention of disease and illness. If medical care can have as its purpose the prevention of the medical condition of pregnancy—and any health consequences associated with that condition—then the HRSA guidelines to that effect fall within § 300gg-13(a)(4)'s terms. Second, there is no suggestion in the statute that a particular treatment is "preventive care" only if the insured cannot otherwise achieve the pursued health outcome. Presumably Plaintiffs do not dispute that other pregnancy-related preventive services within the HRSA guidelines count as legitimate preventive care even if they could be avoided with abstinence.

Plaintiffs assert that constitutional avoidance should be applied to avoid the alleged Equal Protection problems with the coverage of contraceptive services for women. Constitutional avoidance is inapplicable here for two reasons. First, as discussed *infra* Part IX, Plaintiffs' Equal Protection challenge is not sufficiently persuasive to raise doubts about the mandate's constitutionality. And second, the alleged Equal Protection problem does not relate to the question whether "preventive care" includes contraceptive coverage—but rather to whether contraceptive coverage can be limited to women. Plaintiffs do not contend that the coverage of contraceptives as "preventive care" violates the Constitution, nor do they contend that the alleged Equal Protection problems in the statutory and regulatory scheme would disappear if "preventive care" were interpreted as they desire. Accordingly, Plaintiffs' desired interpretation of the phrase would not avoid the constitutional questions raised in this case.

Finally, to the extent there were any doubt that contraceptive coverage could be included in HRSA guidelines supported for the purpose of the preventive services mandate, the agencies' interpretation of that statutory provision would be entitled to *Chevron* deference. Plaintiffs cannot hope to show that the term "preventive care" unambiguously excludes the coverage of

contraceptive care for the reasons discussed above. *See Chevron*, 467 U.S. at 842-43. Nor can Plaintiffs show that the agencies' construction of the term to include contraceptive coverage is unreasonable.

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

Plaintiffs have failed to allege a violation of the RFRA. Under RFRA, "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). Here, Plaintiffs challenge the requirements that insurance cover a variety of services to screen for and prevent serious illnesses that are often sexually-transmitted. *See* Compl. ¶ 118 (challenging coverage for, *inter alia*, HIV screening and preventive medication, HPV testing and immunization, and Hepatitis screening).

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 and Starnes allege merely that they "do[] not want and do[] not need," this coverage, because they are "monogamous" and "not engaged in behavior that transmits HIV. Compl.¶¶ 28-29, 35-36. 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. Compl. ¶ 43 (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, Plaintiff Braidwood Management, Inc.'s principal, is "unwilling to allow his health plan to encourage" "drug use, prostitution, homosexual conduct, or sexual promiscuity," and that these activities "are contrary to [his] sincere religious beliefs." Compl. ¶ 119; *see id.* ¶¶ 52-53. But while drug use, prostitution, homosexual conduct, and sexual promiscuity may be contrary to Dr. Hotze's sincere religious beliefs, Dr. Hotze is not being compelled to engage in any such activity, and Plaintiffs nowhere allege that providing or purchasing insurance coverage for screenings and therapy for infectious diseases—even infectious diseases Dr. Hotze may associate with those activities—is contrary to his sincere religious beliefs. Accordingly, these allegations fail to state a claim for a violation of RFRA.[12]

Plaintiffs Kelley, Starnes, and Kelley Orthodontics also appear to challenge the Contraceptive Mandate pursuant to RFRA. This claim, too, must fail. Plaintiffs allege that the Contraceptive Mandate "imposes a substantial burden on the exercise of religion" because it "mak[es] it impossible for religious individuals and employers to purchase health insurance that excludes objectionable coverage." Compl. ¶ 114. But this Court in *DeOtte* "permanently enjoined federal officials from enforcing the Contraceptive Mandate against any religious objector," thus giving "full force and effect" to "the protections conferred by the Trump Administration's final rule" which "ensure[s] individual religious objectors . . . have the option to purchase 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." Compl. ¶¶ 18, 19, 21.

[12] Plaintiffs Kelley and Starnes' allegations that they are "Christian, and therefore unwilling to purchase health insurance that subsidizes" 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 it would violate any of their sincere religious beliefs. Compl. ¶¶ 30, 37.

Although Plaintiffs Kelley, Starnes, and Kelley Orthodontics effectively concede that they are in fact able to obtain insurance that excludes contraceptive coverage, *see id.* ¶¶ 32, 38 (alleging only that "few" insurance companies are offering the type of health insurance Plaintiffs would like), assuming *arguendo* that it is "impossible" for them to do so (*id.* ¶¶ 122, 124), that does not constitute a violation of RFRA, which limits only the actions of government. *See* 42 U.S.C. § 2000bb-1. The choice of private insurers not to offer Plaintiffs as wide an array of potential plans that exclude contraceptive coverage as they wish does not implicate RFRA at all.

IX. THE CONTRACEPTIVE MANDATE DOES NOT VIOLATE EQUAL PROTECTION PRINCIPLES

Plaintiffs further lack standing with respect to the equal protection claim. Plaintiffs contend that the Contraceptive Mandate discriminates against men by compelling coverage for women but "denying equivalent coverage of contraception and sterilization for men." Compl. ¶ 111. But Kelley and Starnes are both men who do not want their health insurance to provide them with contraceptive coverage. Compl. ¶¶ 29, 36. Neither has been injured by the law, as it allows each to continue purchasing health insurance that does not cover contraceptives for himself. Each therefore lacks Article III standing to bring this claim, because—to the extent each is "den[ied] equivalent coverage of contraception and sterilization", Compl. ¶ 111—he is getting what he wants. *See, e.g.*, *In re Gee*, 941 F.3d 153, 163 (5th Cir. 2019) (plaintiffs had not been injured "to the extent the challenged regulations require Plaintiffs to do what they've already been doing and want to keep doing"). To the extent either of them wants even more—namely, also to exclude contraceptive coverage for woman—his alleged injury is not related to alleged discrimination against him as a man, and so he cannot rest his challenge on equal protection principles. "[S]tanding is not dispensed in gross." *Lewis v. Casey*, 518 U.S. 343, 358 (1996).

And for Kelley Orthodontics and Braidwood,[13] those companies likewise have no desire to provide contraceptive coverage for their male employees, and they have not alleged the right to proceed on behalf of any employee allegedly denied equal protection. They cannot proceed merely by showing that someone has suffered an injury in fact—"they must 'be [themselves] among the injured.'" *McMahon v. Fenves*, 946 F.3d 266, 270 (5th Cir. 2020) (alteration in original). Even if one of those entities believes that it has a male employee who wants contraceptive coverage, these Plaintiffs have not identified a theory under which they can proceed on behalf of that employee. In short, Plaintiffs are all by their own admission glad that the Contraceptive Mandate does not require them to obtain or provide contraceptive coverage for men, and they therefore have not been injured by the law's licensing their continued ability to abide by that preference.

The next shortcoming of Plaintiffs' theory is that the Contraceptive Mandate does not impermissibly distinguish between the sexes. Although HRSA follows the statutory instruction to identify certain preventive care "with respect to women" and thus covers only contraceptive care for women and not for men, that distinction in the treatment of contraceptive care reflects the difference in medical needs between men and women—only women can get pregnant, and thus women are the only people for whom access to contraceptive care will affect their *own* medical condition. Plaintiffs contend that it is an impermissible sex-based classification for the law to "compel[] health insurance to cover contraception and sterilization for women but not for men." Compl. ¶ 110. But Plaintiffs are urging this Court to treat as identical two separate and incommensurate types of medical care—medical care that affects the health of the person receiving it, and medical care that does not. Many types of medical treatment are specific only to one sex, and there is nothing in equal protection doctrine that requires legislation to act as though non-

[13] To the extent the latter seeks to challenge the Contraceptive Mandate, *but see* Compl. ¶ 117.

equivalent medical services are equivalent. *See, e.g.*, *Women Prisoners of the D.C. Dept. of Corrs. v. District of Columbia*, 93 F.3d 910, 924 (D.C. Cir. 1996) ("The Constitution . . . does not require things which are different in fact or opinion to be treated in law as though they were the same." (quoting *Plyler v. Doe*, 457 U.S. 202, 216 (1982))).

Even if the contraceptive mandate were a classification on the basis of sex, it would easily satisfy intermediate scrutiny. To withstand such scrutiny, classifications by sex "must serve important governmental objectives and must be substantially related to achievement of those objectives." *Craig v. Boren*, 429 U.S. 190, 197 (1976). "Reduction of the disparity in economic condition between men and women caused by the long history of discrimination against women has been recognized as such an important governmental objective." *Califano v. Webster*, 430 U.S. 313, 317 (1977) (per curiam). Although "the mere recitation of a benign, compensatory purpose is not an automatic shield which protects against any inquiry into the actual purposes underlying a statutory scheme," sex distinctions are permissible when the statutory structure and history show that a classification was enacted to compensate for past discrimination. *Id.* (quotation marks and citation omitted) (collecting cases). *See also Kahn v. Shevin*, 416 U.S. 351 (1974).

In enacting the ACA, including the requirement that preventive services for women be covered without cost-sharing, Congress intended to end the "practices of the private insurance companies in their gender discrimination" against women, who "paid more for the same health insurance coverage available to men." *Priests for Life v. U.S. Dep't of Health & Human Servs.*, 772 F.3d 229, 263 (D.C. Cir. 2014) (citing 155 Cong. Rec. 28,842 (2009) (statement of Sen. Mikulski)) (cleaned up), *vacated on other grounds sub nom.*, *Zubik v. Burwell*, 136 S. Ct. 1557 (2016). Remedying this past discrimination, rather than penalizing men or validating stereotypical assumptions about women, is the purpose of the statute's focus on preventive services for women.

Under the Supreme Court's cases, the requirement of coverage of contraceptive care without cost-sharing for women is a constitutional means of furthering that governmental interest.

Furthermore, sex classifications are permissible when they are not invidious, but instead reflect the "demonstrable fact" that men and women "are not similarly situated" in some circumstances. *Schlesinger v. Ballard*, 419 U.S. 498, 508 (1975). In *Schlesinger*, the Supreme Court upheld a statutory distinction between male and female naval officers that gave female officers a longer period of commissioned service before mandatory discharge for want of promotion, reasoning that, given restrictions on women officers' participation in combat and sea duty, Congress could have "believed that women line officers had less opportunity for promotion . . . and that a longer period of tenure for women officers would, therefore, be consistent with the goal to provide women officers with 'fair and equitable career advancement programs.'" *Id.* at 508.

Indeed, the Supreme Court has specifically recognized that women and men are differently situated with respect to pregnancy and childbirth and that these differences can support a sex-based distinction under equal protection principles. In *Tuan Anh Nguyen v. INS*, 533 U.S. 53 (2001), the Court upheld an immigration statute that makes it more difficult for a child born abroad and out of wedlock to one United States parent to claim citizenship if the citizen parent was a father. As the Court recognized, "[f]athers and mothers are not similarly situated with regard to the proof of biological parenthood." *Id.* at 63. "[G]iven the unique relationship of the mother to the event of birth," *id.* at 64, the more favorable treatment afforded to children of a U.S. citizen mother complies with equal protection. *See id.* at 61-65, 70-71.

Here, as in *Tuan Anh Nguyen*, the different circumstances of men and women with respect to many medical conditions, including pregnancy, likewise justifies a sex-based distinction with

respect to coverage for certain preventive care and screenings not included in the other preventive-services provisions of the ACA. Prior to enactment of the ACA and the preventive-services mandate, "'women of childbearing age spen[t] 68 percent more in out-of-pocket health care costs than men,'" "in part because services more important or specific to women have not been adequately covered by health insurance." *Priests for Life*, 772 F.3d at 263 (quoting 155 Cong. Rec. 28,843 (2009) (statement of Sen. Gillibrand)). "[W]omen have different health needs than men, and these needs often generate additional costs." 155 Cong. Rec. 29,070 (2009) (statement of Sen. Feinstein). The Contraceptive Mandate aims to equalize access to health-care outcomes by providing insurance coverage that is disproportionately needed by women.

CONCLUSION

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

Respectfully submitted,

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Certificate of Service

On June 29, 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).

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