

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.

Case No. 4:20-cv-00283-O

BRIEF IN OPPOSITION TO DEFENDANTS' MOTION TO DISMISS

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The government seeks dismissal on numerous grounds. We will address its arguments in the order they appear in its brief.

I. THE PLAINTIFFS HAVE ALLEGED ARTICLE III STANDING

At the pleading stage, a plaintiff needs only to allege and not prove the elements of Article III standing. *See Lujan v. Defenders of Wildlife*, 504 U.S. 555, 561 (1992) (“[E]ach element [of the Article III standing inquiry] must be supported in the same way as any other matter on which the plaintiff bears the burden of proof, *i.e.*, with the manner and degree of evidence required at the successive stages of the litigation.”). Detailed factual allegations are not required; a complaint needs only to provide a plausible basis for believing that Article III standing can be established. *See Ashcroft v. Iqbal*, 556 U.S. 662, 677–78 (2009); *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555–56 (2007). The first amended complaint does more than enough to plausibly allege the components of Article III standing for each of the claims.

A. Mr. Kelley, Mr. Starnes, Mr. and Mrs. Maxwell, and Kelley Orthodontics Have Alleged Standing To Challenge The Contraceptive Mandate

In *DeOtte v. Azar*, 393 F. Supp. 3d 490, 509 (N.D. Tex. 2019), this Court enjoined the defendants from enforcing the Contraceptive Mandate against insurers who are willing to offer policies that exclude contraceptive coverage to individuals who oppose such coverage based on religious belief. Several of the plaintiffs in this case, including Mr. Kelley, Mr. Starnes, Mr. and Mrs. Maxwell, and Kelley Orthodontics, are members of the *DeOtte* class and have the prerogative to purchase contraceptive-free health insurance from insurers willing to provide it.¹ The government denies that

1. We will refer to these plaintiffs collectively as “the *DeOtte* class members.” Plaintiff Braidwood Management Inc. is a member of the employer class protected by the *DeOtte* injunction, but the plaintiffs acknowledge that Braidwood is no longer suffering injury in fact from the continued enforcement of the Contraceptive Mandate.

anyone protected by the *DeOtte* injunction can allege standing to challenge the continued enforcement of the contraceptive mandate, but the government's argument is mistaken.

1. The *DeOtte* Class Members Have Alleged Injury In Fact

The *DeOtte* class members allege that the continued enforcement of the Contraceptive Mandate inflicts Article III injury—even though the *DeOtte* injunction allows insurers to offer contraceptive-free policies to individual religious objectors—because “few if any” insurance companies are currently offering policies of this sort:

Despite the *DeOtte* injunction, few if any insurance companies are currently offering health insurance that excludes coverage for contraception, and the continued existence of the Contraceptive Mandate restricts the options available to those who wish to purchase health insurance but who do not need or want contraceptive coverage.

First Amended Complaint (ECF No. 14) at ¶ 28; The complaint goes on to allege:

Although the *DeOtte* injunction permits issuers of health insurance to issue group or individual health-insurance coverage that excludes abortifacient contraception to religious objectors, few if any insurance companies are offering health insurance of this sort. And even if a health insurer were willing to create and offer a policy that excludes abortifacient contraceptive coverage solely for religious objectors, the Contraceptive Mandate drastically restricts the available options on the market to consumers who hold religious objections to abortifacients. The Mandate requires any policy that covers anyone who lacks a sincere religious objection to contraception to cover all forms of FDA-approved contraceptive methods, without any deductibles or co-pays. Without the federal Contraceptive Mandate, insurers will have the freedom to offer policies that exclude contraceptive coverage to the general public, just as they did before the Contraceptive Mandate, which will expand the health-insurance options available to consumers who oppose abortifacient contraceptive coverage for sincere religious reasons.

Id. at ¶ 37. How does this fail to allege injury in fact? Injury can surely arise from regulations that reduce the number of contraceptive-free health-insurance policies that are available on the market. *See Center for Auto Safety v. National Highway Traffic Safety Administration*, 793 F.2d 1322, 1332–34 (D.C. Cir. 1986) (holding that a

reduced opportunity to purchase fuel-efficient vehicles established injury in fact); *id.* at 1332 (“NHTSA’s low CAFE standards will diminish the types of fuel-efficient vehicles and options available. Without the threat of civil penalties, manufacturers will not be prodded to install as many fuel-saving devices, nor to install them as promptly. As a result, petitioners’ members will have less opportunity to purchase fuel-efficient light trucks than would otherwise be available to them.”); *Orangeburg, South Carolina v. FERC*, 862 F.3d 1071, 1078 (D.C. Cir. 2017) (“The lost opportunity to purchase a desired product is a cognizable injury, even though Orangeburg *can* purchase, and *has* purchased, wholesale power from another source. . . . [E]ven though Orangeburg can and does purchase wholesale power from another source, the city cannot purchase wholesale power from the provider of its choice *nor* on its preferred terms”). If a pregnant woman alleged that federal or state abortion regulations had reduced the number of available providers, that would surely qualify as an Article III injury. See *Whole Woman’s Health v. Hellerstedt*, 136 S. Ct. 2292, 2307 (2016). It is hard to understand how a different result can obtain here. The government cites no authority that denies that an injury of this sort can confer standing. And its argument flies in the face of *Center for Auto Safety* and *Orangeburg*, which specifically hold that Article III injury arises when regulations reduce the available options from which to purchase a desired product.

The government also asserts that “there is no legally protected right to an unfettered choice in health insurance coverage.” Mot. to Dismiss (ECF No. 20) at 9. But the injury-in-fact test does not turn on whether one is alleging the invasion of a “legally protected right.” See *Ass’n of Data Processing Serv. Organizations, Inc. v. Camp*, 397 U.S. 150, 153 (1970) (specifically rejecting the notion that a plaintiff must allege the invasion of a “legally protected right” to establish standing); *id.* (“The ‘legal interest’ test goes to the merits. The question of standing is different.”). A plaintiff needs only to allege an injury *in fact*. See *id.* at 152 (“The first question is whether

the plaintiff alleges that the challenged action has caused him injury in fact, economic or otherwise.”). And an “identifiable trifle” is all that is needed—not the identification of a “legally protected right.” See *United States v. Students Challenging Regulatory Agency Procedures (SCRAP)*, 412 U.S. 669, 690 n.14 (1973); see also *American Legion v. American Humanist Ass’n*, 139 S. Ct. 2067 (2019) (unwanted contact with a religious display sufficient to confer standing); *Czyzewski v. Jevic Holding Corp.*, 137 S. Ct. 973, 983 (2017) (“For standing purposes, a loss of even a small amount of money is ordinarily an ‘injury.’”); *New York Republican State Committee v. SEC*, 927 F.3d 499, 504 (D.C. Cir. 2019) (“As we have long held, even a slight injury is sufficient to confer standing; the size of the harm therefore poses no jurisdictional barrier to the NYGOP’s claim.”).

2. The *DeOtte* Class Members Have Alleged Traceability

The *DeOtte* class members have specifically alleged that their inability to purchase health insurance that excludes contraceptive coverage is traceable to the defendants’ continued enforcement of the Contraceptive Mandate. See First Amended Complaint (ECF No. 14) at ¶ 37 (“[T]he Contraceptive Mandate drastically restricts the available options on the market to consumers who hold religious objections to abortifacients. The Mandate requires any policy that covers anyone who lacks a sincere religious objection to contraception to cover all forms of FDA-approved contraceptive methods, without any deductibles or co-pays.”). And it is hard to fathom how the government can deny that this injury is “fairly traceable” to the Contraceptive Mandate.² The entire reason for the Contraceptive Mandate’s existence was that some private insurers were *not* providing contraceptive coverage on their own initiative or in

2. See *Lexmark Int’l, Inc. v. Static Control Components, Inc.*, 572 U.S. 118, 134 n.6 (2014) (“Proximate causation is not a requirement of Article III standing, which requires only that the plaintiff’s injury be fairly traceable to the defendant’s conduct.”).

response to market forces; that is why the Obama Administration issued regulations to *force* every insurer to provide this coverage regardless of whether the beneficiary wanted or needed it. The present-day absence of contraceptive-free health-insurance policies is a direct result of the federal Contraceptive Mandate and the defendants' continued enforcement of it.

The defendants appear to be arguing that the failure of insurance companies to suddenly provide contraceptive-free health-insurance policies in response to the *DeOtte* injunction proves that the absence of these policies is attributable to market forces rather than government regulation. *See* Mot. to Dismiss (ECF No. 20) at 10. Hardly. The *DeOtte* injunction allows insurance companies to offer contraceptive-free health insurance *only* to individual religious objectors and not to the public at large. *See DeOtte v. Azar*, 393 F. Supp. 3d 490, 513–15 (N.D. Tex. 2019). So it is not at all surprising that insurers are slow to create new policies that can only be offered or sold to a narrow slice of the population.

But more importantly, the complaint *specifically alleges* that the continued enforcement of the Contraceptive Mandate makes it untenable for insurers to offer contraceptive-free health-insurance policies to the general public. *See* First Amended Complaint (ECF No. 14) at ¶ 37 (“The Mandate requires any policy that covers anyone who lacks a sincere religious objection to contraception to cover all forms of FDA-approved contraceptive methods, without any deductibles or co-pays. Without the federal Contraceptive Mandate, insurers will have the freedom to offer policies that exclude contraceptive coverage to the general public, just as they did before the Contraceptive Mandate, which will expand the health-insurance options available to consumers who oppose abortifacient contraceptive coverage for sincere religious reasons.”). This allegation *must* be assumed true at the motion-to-dismiss stage, even if the government disputes it, and that is all that is needed to *allege* traceability at this

stage of the litigation. *See Leatherman v. Tarrant County Narcotics Intelligence & Coordination Unit*, 507 U.S. 163, 164 (1993) (“We review here a decision granting a motion to dismiss, and therefore must accept as true all the factual allegations in the complaint.”).

3. The *DeOtte* Class Members Have Alleged Redressability

The *DeOtte* class members have alleged redressability by specifically asserting that an injunction against the continued enforcement of the Contraceptive Mandate “will expand” the availability of contraceptive-free health insurance:

Without the federal Contraceptive Mandate, insurers will have the freedom to offer policies that exclude contraceptive coverage to the general public, just as they did before the Contraceptive Mandate, *which will expand the health-insurance options available to consumers who oppose abortifacient contraceptive coverage for sincere religious reasons.*

First Amended Complaint (ECF No. 14) at ¶ 37 (emphasis added). These statements go beyond merely alleging that the plaintiffs’ injuries are “likely” to be redressed by relief that invalidates the Contraceptive Mandate across the board.³ These statements allege that the plaintiffs’ injuries *will in fact* be redressed by the requested relief—and these factual assertions must be accepted as true at this stage of the litigation. *See Leatherman*, 507 U.S. at 164.

The government argues that the willingness of private insurers to offer contraceptive-free health insurance is speculative rather than certain.⁴ *See Mot. to Dismiss* (ECF No. 20) at 10–11. But those are factual questions that cannot be resolved on a motion to dismiss. The plaintiffs are not required to *prove* that insurance companies actually will offer contraceptive-free health insurance in response to their lawsuit at this stage of the litigation, nor are they required to prove that their requested relief

3. *See Lujan v. Defenders of Wildlife*, 504 U.S. 555, 561 (1992) (holding that a plaintiff needs only to allege that it is “likely” that his injury will be redressed by the requested relief).

4. *See Mot. to Dismiss* (ECF No. 20) at 10–11.

will reduce premiums for health insurance. And if the defendants want to dispute the plaintiffs' claim that insurers "will expand" the availability of contraceptive-free health insurance in response to the requested injunction, they can do so at summary judgment. The plaintiffs have asserted that this will occur, and that is all that is needed to *allege* redressability under the rules of notice pleading.⁵

B. Mr. and Mrs. Riddle, Mr. Miller, and Dr. Scheideman Have All Alleged Standing

The government's brief incorrectly states that Mr. Miller and Mr. and Mrs. Riddle object "only" to the Contraceptive Mandate and not the other preventive-care coverage mandates. Mr. Miller and Mr. and Mrs. Riddle—along with the other plaintiffs—are seeking to enjoin the enforcement of *all* the preventive-care coverage mandates that issued after March 23, 2010, so they can choose for themselves the extent of coverage that they want:

The preventive-care coverage mandates, however, make it impossible for Mr. and Mrs. Riddle to purchase health insurance unless they agree to pay for contraceptive coverage *and other preventive-care coverage that they do not want and do not need.*

First Amended Complaint ¶ 41 (emphasis added); *see also id.* at ¶ 46 (same allegation with respect to Mr. Miller). The Contraceptive Mandate is one *example* of the unneeded and unwanted coverage compelled by the defendants' enforcement of 42 U.S.C. § 300gg-13(a), but it is not the only one, and the plaintiffs do not need to provide a detailed recitation in their pleading of the preventive-care coverage they want or do not want to pay for. The plaintiffs' objection is to the compulsion and lack of choice imposed by 42 U.S.C. § 300gg-13(a), and their requested relief will remedy

5. The complaint does *not* allege (or concede) that every private insurer is currently covering PrEP drugs, as the government suggests in its brief. *See* Mot. to Dismiss (ECF No. 20) at 11 n.2. The PrEP mandate does not take effect until 2021, and when it takes effect it will become impossible for the plaintiffs to purchase or obtain health insurance that excludes this coverage.

that by enjoining the enforcement of any coverage mandate based upon an agency rating, recommendation, or guideline that issued after March 23, 2010.

Mr. and Mrs. Riddle, Mr. Miller, and Dr. Scheideman are suffering the same “injury in fact” as the *DeOtte* class members: The inability (or reduced ability) to purchase a desired product or service. Each of these plaintiffs wants to purchase health insurance that excludes coverage of contraception (and other unneeded and unwanted preventive care), and each of them is unable to do so on account of 42 U.S.C. § 300gg-13(a). Indeed, each of the plaintiffs has alleged that it is “impossible” for them to purchase contraceptive-free health insurance (and other forms of stripped-down health coverage) in the current regulatory climate. *See* First Amended Complaint (ECF No. 14) at ¶¶ 41, 46, 50. It is not merely that the enforcement of the Contraceptive Mandate (and the other preventive-care mandates) “drastically restricts the available options on the market.” *Id.* at ¶ 37. It is that the plaintiffs are *unable* to obtain insurance that excludes coverage of some or all of the government-mandated preventive care. If a woman alleged that she could not obtain an abortion because federal and state regulations had chased out willing providers and made it “impossible” for her to access the procedure, that would qualify as an Article III injury. *See Roe v. Wade*, 410 U.S. 113, 124–25 (1973). So too here; the inability to purchase a desired product or service will always constitute injury in fact. *See Consumer Federation of America v. FCC*, 348 F.3d 1009, 1012 (D.C. Cir. 2003) (“[T]he inability of consumers to buy a desired product may constitute injury-in-fact ‘even if they could ameliorate the injury by purchasing some alternative product.’” (citation omitted)).

The government questions whether its preventive-care mandates actually lead to higher premiums. *See* Mot. to Dismiss (ECF No. 20) at 12–13. But the complaint specifically alleges that the preventive-care mandates have led to “higher premiums for health insurance that must cover preventive care free of charge as decreed by the

U.S. Preventive Services Task Force, the Advisory Committee on Immunization Practices, and the Health Resources and Services Administration.” First Amended Complaint (ECF No. 14) at ¶ 51. That allegation *must* be accepted as true at the motion-to-dismiss stage. *See Leatherman*, 507 U.S. at 164. Whether the plaintiffs are actually paying higher premiums for this unnecessary and unwanted coverage is a disputed factual question that cannot be resolved on a motion to dismiss. *See id.* The mere allegation is enough to establish traceability and redressability at the motion-to-dismiss stage.

C. The Plaintiffs Have Alleged Standing To Challenge All Preventive-Care Coverage Mandates That That Issued After March 23, 2010

The plaintiffs have alleged throughout their complaint that they oppose and are harmed by more than just the Contraceptive Mandate and the compulsory coverage of PrEP drugs. *See, e.g.*, First Amended Complaint ¶ 35 (“Mr. Kelley, Mr. Starnes, Mr. Maxwell, and Ms. Maxwell . . . do not want or need free STD testing covered by their health insurance because they are in monogamous relationships with their respective spouses.”); *id.* at ¶ 41 (“The preventive-care coverage mandates, however, make it impossible for Mr. and Mrs. Riddle to purchase health insurance unless they agree to pay for contraceptive coverage *and other preventive-care coverage that they do not want and do not need.*” (emphasis added)); *id.* at ¶ 46 (same allegation with respect to Mr. Miller); *id.* at ¶ 51 (“The preventive-care coverage mandates . . . deprive[] Dr. Scheideman of the option of purchasing less expensive health insurance for his employees with less extensive coverage of preventive care.”); *id.* at ¶ 55 (“Kelley Orthodontics wishes to provide health insurance for its employees that excludes coverage of contraception, PrEP drugs, *and other preventive care* required by the defendants’ current interpretation and enforcement of 42 U.S.C. § 300gg-13.” (emphasis added)); *id.* at ¶ 64 (“Dr. Hotze *objects to the other preventive-care coverage mandates* imposed by the defendants because Dr. Hotze wants the freedom to decide the extent to which

Braidwood’s plan will cover preventive care, and whether it will charge copays or require preventive care to count toward an annual deductible.” (emphasis added)). We cannot understand how the government can insist that the plaintiffs have failed to allege injury from the remaining preventive-care mandates in light of these specific allegations.

More importantly, only one of the plaintiffs needs to establish standing to seek declaratory and injunctive relief against the continued enforcement of the preventive-care coverage mandates. See *Little Sisters of the Poor Saints Peter & Paul Home v. Pennsylvania*, 140 S. Ct. 2367, 2379 n.6 (2020) (“Under our precedents, at least one party must demonstrate Article III standing for each claim for relief.”); *Town of Chester v. Laroe Estates, Inc.*, 137 S. Ct. 1645, 1651 (2017) (“At least one plaintiff must have standing to seek each form of relief requested in the complaint.”); *Bowsher v. Synar*, 478 U.S. 714, 721 (1986). Braidwood obviously has standing to challenge each of the preventive-care mandates (apart from the Contraceptive Mandate) because it wants to control the coverage decisions in its self-insured plan. Any other plaintiff in this case can free-ride off Braidwood’s undisputed standing and seek the same relief against the continued enforcement of 42 U.S.C. § 300gg-13(a).

II. RES JUDICATA DOES NOT BAR THE CLAIMS ASSERTED BY MEMBERS OF THE DEOTTE CLASSES

The government insists that res judicata precludes members of the *DeOtte* classes from “challenging” the “Contraceptive Mandate.” But the plaintiffs in this case are challenging the constitutionality of the underlying statutes that authorize HRSA (and other entities) to impose preventive-care coverage mandates on private insurers. This is not the “same claim” or the “same cause of action” that was asserted in *DeOtte*, which concerned only the failure of the Contraceptive Mandate to provide sufficient exemptions for religious objectors. The government’s res judicata argument is also incompatible with *Whole Woman’s Health v. Hellerstedt*, 136 S. Ct. 2292 (2016),

which it never cites. *Hellerstedt* allows the *DeOtte* class members to challenge the constitutionality of 42 U.S.C. § 300gg-13(a)(4) because it is a separate and distinct provision from the agency rules that were challenged in *DeOtte*. *See id.* at 2308. And even apart from *Hellerstedt*, the plaintiffs’ constitutional challenge to 42 U.S.C. § 300gg-13(a)(4) involves an entirely different “nucleus of operative fact” from the RFRA claims presented by the *DeOtte* litigants.

A. *Hellerstedt* Allows The *DeOtte* Class Members To Challenge The Constitutionality Of 42 U.S.C. § 300gg-13(a)(4)

Hellerstedt holds that res judicata applies *only* when the same parties seek to relitigate “the very same claim.” *See id.* at 2305 (“The doctrine of claim preclusion . . . prohibits ‘successive litigation of the very same claim’ by the same parties. Petitioners’ postenforcement as-applied challenge is not ‘the very same claim’ as their preenforcement facial challenge.” (quoting *New Hampshire v. Maine*, 532 U.S. 742, 748 (2001)); *id.* at 2307 (“The challenge brought in this case and the one in *Abbott* are not the ‘very same claim,’ and the doctrine of claim preclusion consequently does not bar a new challenge to the constitutionality of the admitting-privileges requirement.” (citation omitted)). *Hellerstedt* also makes clear that a challenge to the constitutionality of 42 U.S.C. § 300gg-13(a)(4) is not “the very same claim” as the RFRA challenges in *DeOtte* because section 300gg-13(a)(4) is a “separate, distinct provision” from the agency rules that were challenged in the *DeOtte* litigation. *See id.* at 2308.

Hellerstedt holds that litigants may bring separate challenges to discrete provisions of the same statute—even when those separate provisions govern the same subject matter and are “part of one overarching government regulatory scheme.” The statute in *Hellerstedt* required abortions to be performed by doctors with hospital admitting privileges, and it also required abortions to be performed in ambulatory surgical centers. Yet the Court allowed abortion providers to challenge the admitting-privileges provision and the surgical-center provision in separate lawsuits—even though the

provisions appeared in the same statute, and even though the claims arose out of the same nucleus of operative facts. The Court explained:

The surgical-center provision and the admitting-privileges provision are separate, distinct provisions of H.B. 2. They set forth two different, independent requirements with different enforcement dates. This Court has never suggested that challenges to two different statutory provisions that serve two different functions must be brought in a single suit. And lower courts normally treat challenges to distinct regulatory requirements as “separate claims,” even when they are part of one overarching “[g]overnment regulatory scheme.”

That approach makes sense. The opposite approach adopted by the Court of Appeals would require treating every statutory enactment as a single transaction which a given party would only be able to challenge one time, in one lawsuit, in order to avoid the effects of claim preclusion. Such a rule would encourage a kitchen-sink approach to any litigation challenging the validity of statutes. That outcome is less than optimal—not only for litigants, but for courts.

Hellerstedt, 136 S. Ct. at 2308. All of this applies with equal or greater force to the challenges brought to 42 U.S.C. § 300gg-13(a)(4) and the agency rules that codify the Contraceptive Mandate.

First, section 300gg-13(a)(4) and the agency rules challenged in *DeOtte* are far more “separate” and “distinct” from each other than the abortion-related statutory provisions in *Hellerstedt*. Section 300gg-13(a)(4) is a statutory provision enacted in 2010 as part of the Affordable Care Act. The Contraceptive Mandate is a series of agency rules that post-date the enactment of section 300gg-13(a)(4). Second, the statute and the agency rules set forth “different, independent requirements.” Section 300gg-13(a)(4) is a delegation of authority to the Health Resources and Services Administration to impose preventive-care mandates on private insurers, while the Contraceptive Mandate specifically compels private insurers to cover FDA-approved contraceptive methods. Third, section 300gg-13(a)(4) and the Contraceptive Mandate have different effective dates. Section 300gg-13(a)(4) took effect immediately

upon the ACA’s enactment, while the Contraceptive Mandate’s requirements did not take effect until 2013. When all of this is combined with *Hellerstedt*’s explicit encouragement of separate lawsuits for separate provisions, it becomes impossible to sustain a res judicata defense against the plaintiffs’ constitutional challenges to section 300gg-13(a)(4).

B. The *DeOtte* Class Members Can Challenge The Constitutionality Of 42 U.S.C. § 300gg-13(a) (4) Under The “Same Nucleus Of Operative Facts” Test

The *DeOtte* class members do not even need to rely on *Hellerstedt* to challenge the constitutionality of section 300gg-13(a)(4). Even if one applies the “common nucleus of operative fact” test that the government proposes (but that *Hellerstedt* eschewed),⁶ the constitutional challenge to section 300gg-13(a)(4) is a different “claim” from the RFRA challenge to the Contraceptive Mandate.

The constitutional challenge to section 300gg-13(a)(4) alleges that *Congress* violated the Constitution by enacting this statute.⁷ It challenges the *legislature*’s action in enacting a law that confers authority on individuals who are not appointed in conformity with Article II, and that fails to provide an intelligible principle to guide the discretion of the Health Resources Services Administration. The “nucleus” of relevant facts concerns the text of this statute and the meaning of the Constitution—nothing more. The alleged constitutional violation occurred at the moment of the statute’s enactment,⁸ and the “nucleus” of relevant facts is centered around that event and nothing else. There is no concern with how HRSA decides to use its powers under

6. See Mot. to Dismiss (ECF No. 20) at 14.

7. See Nicholas Quinn Rosenkranz, *The Subjects of the Constitution*, 62 Stan. L. Rev. 1209, 1214 (2010) (“[E]very constitutional holding should start by saying *who* has violated the Constitution.”).

8. See Rosenkranz, *supra* at 1224 (“Every constitutional violation must be located in time.” (emphasis removed)).

the statute; that is irrelevant to the Appointments Clause and nondelegation challenges alleged in the first amended complaint. *See* First Amended Complaint (ECF No. 14) at ¶¶ 66–89.

The claims in *DeOtte*, by contrast, were challenging *only* the behavior of *executive-branch officials* who enforced the Contraceptive Mandate in a manner that violated the Religious Freedom Restoration Act. The relevant facts concerned the meaning of RFRA and the conduct of the executive branch, which have nothing to do with *any* of facts surrounding the plaintiffs’ constitutional challenges to section 300gg-13(a)(4). There is no overlap at all with these factual nuclei, and the government does not even present an argument for how the constitutional challenges to section 300gg-13(a)(4) rest on the same “nucleus” of operative facts that undergird the RFRA claims in *DeOtte*. Indeed, the government does not even acknowledge that the plaintiffs in this case are challenging the underlying statute that purports to authorize the Contraceptive Mandate, rather than the Mandate itself.

III. THE PLAINTIFFS’ CLAIMS ARE NOT TIME-BARRED

The plaintiffs have sued to enjoin an *ongoing* violation of the Constitution and the Affordable Care Act. They are asking only for declaratory and injunctive relief to stop these unlawful acts from continuing; they are not seeking any backward-looking relief to remedy or undo an action that occurred in the past. The statute of limitations is simply inapplicable to claims that seek only prospective relief against the continued enforcement of an unconstitutional statute—or against the continued enforcement of an agency rule that violates federal law. *See, e.g., Virginia Hospital Ass’n v. Baliles*, 868 F.2d 653, 663 (4th Cir. 1989) (“[T]he continued enforcement of an unconstitutional statute cannot be insulated by the statute of limitations.”), *aff’d in part on other grounds Wilder v. Virginia Hospital Ass’n*, 496 U.S. 498 (1990); *Kuhnle Brothers, Inc. v. County of Geauga*, 103 F.3d 516, 522 (6th Cir. 1997) (“A law that works an

ongoing violation of constitutional rights does not become immunized from legal challenge for all time merely because no one challenges it within two years of its enactment.”).

The government cites no case that holds that a plaintiff loses his right to seek prospective relief against the continued enforcement of an unconstitutional statute or an *ultra vires* agency rule unless he files suit within a specified time after its enactment. And we have been unable to locate any case that enforces a statute-of-limitations defense in these situations. It is common for litigants to challenge the continued enforcement of old statutes, including statutes that criminalize abortion or define marriage as an opposite-sex union, and the courts have never held that the statute of limitations prevents litigants from seeking prospective relief against these statutes’ enforcement. That is because the plaintiff’s “claims” accrue continually as the defendants persist in enforcing unconstitutional statutes (or *ultra vires* agency rules) in a manner that affects the plaintiff. See *Flynt v. Shimazu*, 940 F.3d 457, 462 (9th Cir. 2019) (“When the continued enforcement of a statute inflicts a continuing or repeated harm, a new claim arises (and a new limitations period commences) with each new injury.”). The same is true here: The defendants, by continuing to enforce 42 U.S.C. § 300gg-13(a)(1)–(4) and the preventive-care mandates imposed under the auspices of that statute, are engaged in an ongoing violation of the Constitution, and their intent to continue in this unconstitutional and unlawful conduct is what allows the plaintiffs to seek declaratory and injunctive relief. A new cause of action “accrues” each day the defendants continue to enforce the disputed statute and agency rules.⁹

9. The government cites *Palacios v. MedStar Health, Inc.*, 298 F. Supp. 3d 87 (D.D.C. 2018), but the plaintiff in that case was seeking compensatory and punitive damages over a health-care provider’s refusal to accommodate a transgender patient’s demands for breast-augmentation surgery. See Amended Complaint, *Palacios v. MedStar Health, Inc.*, No. 1:17-cv-00867-CRC (ECF No. 22) at 13. Lawsuits seeking retrospective relief of that sort are always subject to limitations defenses.

The government is also wrong to suggest that sovereign immunity could bar the plaintiffs' claims. *See* Mot. to Dismiss (ECF No. 20) at 17. The claims brought against Secretaries Azar, Mnuchin, and Scalia fall within the *Ex parte Young* exception to sovereign immunity, so the plaintiffs do not need to satisfy any statute of limitations to overcome a sovereign-immunity defense. *See Philadelphia Co. v. Stimson*, 223 U.S. 605, 619–20 (1912) (“The exemption of the United States from suit does not protect its officers . . . [when] acting in excess of [their] authority or under an authority not validly conferred.”). So the government’s attempt to link its limitations argument with sovereign immunity (and jurisdiction) runs headlong into the fact that sovereign immunity has no application to the *Ex parte Young* claims in this case.

IV. THE PLAINTIFFS HAVE ALLEGED A VIOLATION OF THE APPOINTMENTS CLAUSE

The government contends that the plaintiffs forfeited their Appointments Clause claims by failing to raise them before the agencies, and it says that any constitutional problems with the appointment of the ACIP and HRSA members have been “cured” because their decisions have been “ratified” by the Secretary of Health and Human Services or the Director of the Center for Disease Control and Prevention. *See* Mot. to Dismiss (ECF No. 20) at 19–22. Each of these arguments is meritless.

The plaintiffs are challenging the constitutionality of an Act of Congress and seeking to enjoin its continued enforcement. They are not petitioning for review of an agency rulemaking or adjudication, nor are they taking any type of appeal from an agency to a court. A litigant need not present his claims to an agency unless he is asking a court to directly review an agency’s work, in the same way that a litigant must preserve arguments before a district court when seeking appellate review of that court’s decision. Each of the cases that the government cites involves litigants who had petitioned for review of an agency action or had appealed an agency action under a statute that authorized judicial review. None of those cases have any relevance to

this situation, where the plaintiffs have sued to stop the enforcement of an unconstitutional statute without regard to how the agencies have used their statutory authority.

A litigant who is merely suing federal officers to stop them from enforcing an unconstitutional statute is not required to present his claims to agencies that might be affected by the constitutional pronouncement. In *Barr v. American Association of Political Consultants, Inc.*, 140 S. Ct. 2335 (2020), for example, the plaintiffs who challenged the constitutionality of statutes regulating robocalls were not required to present their constitutional claims to the FCC. They simply filed a declaratory judgment action directly against the Attorney General and the FCC, without any need to present their constitutional arguments in agency proceedings. *Id.* at 2345. The government does not cite a single case that enforces an agency-exhaustion requirement when a plaintiff sues to enjoin the continued enforcement of an allegedly unconstitutional statute, and we have not been able to find any.

The government's "ratification" argument is even more off-base. First, the statute *does not allow* the Secretary of Health and Human Services (or anyone else) to countermand HRSA's guidelines, and the Secretary is given no discretion to accept or reject the guidelines that HRSA produces. When HRSA announces the "preventive care and screenings" that private insurers must cover, the Secretary is *legally obligated* to issue rules and enforce preventive-care mandates in accordance with HRSA's guidelines. Yet the government is trying to pass off the Secretary's compulsory implementation of HRSA's decisions as a voluntary act of "ratification"—even though the text of section 300gg-13(a)(4) makes clear that HRSA holds the whip hand. *See Little Sisters of the Poor Saints Peter & Paul Home v. Pennsylvania*, 140 S. Ct. 2367, 2380 (2020) ("On its face, then, [section 300gg-13(a)(4)] grants sweeping authority to HRSA to craft a set of standards defining the preventive care that applicable health plans must cover."); *id.* ("HRSA has virtually unbridled discretion to decide what

counts as preventive care and screenings.”); *id.* at 2381 (“By its terms, the ACA leaves the Guidelines’ content *to the exclusive discretion of HRSA.*” (emphasis added)).

The statute likewise prohibits the Director of the CDC from overruling the recommendations of ACIP. It *requires* all insurers to cover “immunizations that have in effect a recommendation from the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention with respect to the individual involved.” 42 U.S.C. § 300gg-13(a)(2). The committee’s recommendations are final under the text of the statute, and the government cites no example where the CDC Director has overruled an ACIP recommendation since the enactment of the Affordable Care Act.

Second, even if the HHS Secretary or the CDC Director had the authority to veto or “ratify” HRSA’s guidelines or ACIP’s recommendations, section 300gg-13(a) would *still* violate the Appointments Clause because it 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. That constitutes “significant authority pursuant to the laws of the United States,” even if it remains subject to reversal by an “officer of the United States,” because the power to establish the default rule on matters of compulsory health-insurance coverage amounts to “significant authority” in and of itself. *See Lucia v. SEC*, 138 S. Ct. 2044, 2049 (2018) (holding that the SEC’s administrative law judges qualify as “officers of the United States,” even though their decisions are subject to review by the Commission itself).

Finally, the government insists that the members of the Preventive Services Task Force and the Advisory Committee on Immunization Practices cannot qualify as “officers of the United States” because they lack “a continuing and formalized relationship of employment with the United States government.” Mot. to Dismiss (ECF No. 20) at 23 (quoting *Riley v. St. Luke’s Episcopal Hospital*, 252 F.3d 749, 757 (5th Cir. 2001)). Both the major premise and the minor premise of this argument are wrong.

The Supreme Court has never held that an “officer of the United States” must hold a “formalized relationship of employment” with the federal government, and the Office of Legal Counsel has explicitly rejected this view in an opinion that binds the Department of Justice. *See Officers of the United States Within the Meaning of the Appointments Clause*, 31 Op. Off. Legal Counsel 73, 78 (Apr. 16, 2007) (“[F]ederal employment is not necessary for the Appointments Clause to apply.”); *id.* at 121 (specifically rejecting the notion that “the Appointments Clause does not apply to persons who are not employees of the federal government, even if they are delegated permanent federal authority to enforce federal law.”).

More importantly, the Supreme Court has established a two-part test for determining whether someone qualifies as an officer of the United States, and *that* is the standard that lower courts and litigants must apply when considering Appointments Clause claims. *See Lucia v. SEC*, 138 S. Ct. 2044, 2051 (2018) (holding that one qualifies as an “officer of the United States” if they (1) “occupy a continuing position established by law”; and (2) “exercise significant authority pursuant to the laws of the United States.”). Nowhere does this test purport to require an employer–employee relationship, and the government does not attempt to explain how the members of PSTF and ACIP fail to qualify as “officers” under either prong of the *Lucia* test.

The members of PSTF and ACIP easily qualify as “officers of the United States” under *Lucia*. First, each of these members occupies “a continuing position established by law.” The Preventive Services Task Force was established by an Act of Congress in 1984, and the Advisory Committee on Immunization Practices was established pursuant to 42 U.S.C. § 217a, which authorizes the Secretary of Health and Human Services to establish “advisory councils or committees.” Each of these entities has therefore been “established by law.” And each of these entities has remained in continued existence since they were first established in 1984 (PSTF) and 1964 (ACIP).

The members of PSTF and ACIP therefore occupy “continuing positions” that are also “established by law.”¹⁰

This is what distinguishes PSTF and ACIP from private institutions or state or foreign governments whose decisions are sometimes incorporated by reference into federal statutes. The government correctly notes that federal laws incorporate by reference recommendations of the American National Standards Institute (ANSI), and some federal criminal offenses are defined by reference to state or foreign law. *See* Mot. to Dismiss (ECF No. 20) at 25 (citing 4 U.S.C. § 119(a)(2), 16 U.S.C. § 3372(a)(2)(A), 18 U.S.C. § 13(a), 42 U.S.C. § 6293(b)(8)). But none of this violates the Appointments Clause, because the members of ANSI and the state and foreign government officials do *not* occupy “a continuing position established by [federal] law.” *Lucia*, 138 S. Ct. at 2051. ANSI is a private, non-profit entity that was not created or established by a federal statute. And members of state and foreign governments are obviously not occupying “a continuing position established by [federal] law.” *Lucia*, 138 S. Ct. at 2051. One cannot be an “officer of the United States” unless there is a federal *office* to occupy—and the first part of the *Lucia* test ensures that there is a federal “office” that is held by the alleged “officer.”¹¹ There is no doubt,

10. *See Officers of the United States Within the Meaning of the Appointments Clause*, 31 Op. Off. Legal Counsel 73, 111 (Apr. 16, 2007) (“[A]n office exists where a position that possesses delegated sovereign authority is permanent, meaning that it is not limited by time or by being of such a nature that it will terminate ‘by the very fact of performance.’ ”).

11. *See Officers of the United States Within the Meaning of the Appointments Clause*, 31 Op. Off. Legal Counsel 73, 73–74 (Apr. 16, 2007) (“We conclude that any position having the two essential characteristics of a federal “office” is subject to the Appointments Clause. That is, a position, however labeled, is in fact a federal office if (1) it is invested by legal authority with a portion of the sovereign powers of the federal government, and (2) it is “continuing.” A person who would hold such a position must be properly made an “Officer[] of the United States” by being appointed pursuant to the procedures specified in the Appointments Clause.”).

however, that the members of PSTF and ACIP occupy federal offices, because each of these entities was created and established by federal law.

Second, the members of PSTF and ACIP exercise “significant authority pursuant to the laws of the United States.” *Lucia*, 138 S. Ct. at 2051. It is hard to conceive of “authority” more “significant” than the power to unilaterally dictate the scope of preventive care that all private insurers must cover, without any cost-sharing arrangements such as deductible or copays. And the members of PSFT and ACIP wield these powers “pursuant to the laws of the United States,” as 42 U.S.C. § 300gg-13(a)(1) and (a)(2) explicitly confer this authority upon them. The government does not even attempt to argue that these powers fail to qualify as “significant authority pursuant to the laws of the United States” under *Lucia*.

Rather than addressing the Supreme Court’s test for “officers of the United States,” the government hangs its hat on *Riley v. St. Luke’s Episcopal Hospital*, 252 F.3d 749 (5th Cir. 2001), which asserts that “the constitutional definition of an ‘officer’ encompasses, at a minimum, a continuing and formalized relationship of employment with the United States Government.” *Id.* at 757. *Riley*’s insistence on a formalized employment relationship finds no support in the rulings of the Supreme Court, which ask only whether the individual “occupies a continuing position established by law” and “exercises significant authority pursuant to the laws of the United States.” *See Lucia*, 138 S. Ct. at 2051. It also contradicts the opinions of the Office of Legal Counsel, which specifically hold that “federal employment is not necessary for the Appointments Clause to apply.” *Officers of the United States Within the Meaning of the Appointments Clause*, 31 Op. Off. Legal Counsel 73, 78 (Apr. 16, 2007). But *Riley* remains a precedent of the Fifth Circuit, so these statements in *Riley* cannot be dismissed as simply wrong. Instead, they should be interpreted in a manner that mitigates any inconsistency with the views expressed by Supreme Court and the Office of Legal Counsel.

The Court should hold that an individual has a “formalized relationship of employment with the United States government” under *Riley* whenever he “occupies a continuing position established by law”—regardless of whether he receives payment or emoluments for his work. This is a permissible (though not mandatory) interpretation of *Riley*, and this approach would eliminate any inconsistency between *Riley* and *Lucia* (and between *Riley* and the opinions of OLC). The words “employ” and “employment” can be used to describe work that does not involve payment,¹² and the notion that *paid* employment is required to make one an “officer of the United States” is flatly contradicted by original meaning and historical practice. As the Office of Legal Counsel explains:

[A]ny understanding of an ‘office’ that would require an ‘emolument’ akin to the compensation that a person on the regular payroll of the federal government receives would conflict with the original meaning of the Appointments Clause as revealed by earliest practice. In the first decade under the Constitution, most federal officers, particularly those outside the capital, received no compensation from the government, much less a regular one. Instead, they received authority to collect fees . . .”

Officers of the United States Within the Meaning of the Appointments Clause, 31 Op. Off. Legal Counsel 73, 120 (Apr. 16, 2007).¹³ And there is no need to construe the

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12. See, e.g., “employ.” *Merriam-Webster.com*. 2020. <https://www.merriam-webster.com/dictionary/employ> (September 12, 2020) (defining “stepfather” as “1a: to make use of (someone or something inactive) *employ* a pen for sketching; b: to use (something, such as time) advantageously a job that *employed* her skills; c(1): to use or engage the services of; (2): to provide with a job that pays wages or a salary; 2: to devote to or direct toward a particular activity or person *employed* all her energies to help the poor.”); see also *Officers of the United States Within the Meaning of the Appointments Clause*, 31 Op. Off. Legal Counsel 73, 121 (Apr. 16, 2007).
 13. See also *Officers of the United States Within the Meaning of the Appointments Clause*, 31 Op. Off. Legal Counsel 73, 119 (Apr. 16, 2007) (“[A]n emolument is also a common characteristic of an office, as *Hartwell* indicates, 73 U.S. at 393, but it too is not essential: ‘Like the requirement of an oath,’ provision for

word “employment” in *Riley* (or in other cases) as requiring *payment* from the federal government:

[T]he general language of these cases allows for an office that does not involve government employment in the modern sense. *Maurice*, for example, said that an office is “*a public charge or employment*,” 26 F. Cas. at 1214 (internal quotation marks omitted; emphasis added), and *Hartwell* defined an office as “*a public station, or employment*,” 73 U.S. at 393 (emphasis added). *Maurice*, among others, also does state that an “office is ‘an employment,’” 26 F. Cas. at 1214, but such a statement must be read in a contemporaneous rather than anachronistic sense, broadly to include anyone engaged by the government, whether an independent contractor, “employee,” or other agent. The pertinent definition of “employ” is:

To engage in one’s service; to use as an agent or substitute in transacting business; to commission and entrust with the management of one’s affairs. The president *employed* an envoy to negotiate a treaty. Kings and States *employ* ambassadors at foreign courts.

Noah Webster, *An American Dictionary of the English Language*, tit. Employ (1828). Thus, even an “agreement” to provide services (such as “to make hay” or “plough land”) was an “employment.

Officers of the United States Within the Meaning of the Appointments Clause, 31 Op. Off. Legal Counsel 73, 121 (Apr. 16, 2007). It is hard to understand how the Department of Justice can take a position in this Court that so flatly contradicts the pronouncements of the Office of Legal Counsel, and it is even harder to understand why it would not seek an interpretation of *Riley* that is consonant with OLC’s views.

pay ‘may aid in determining the nature of the position, but it is not conclusive. . . . As in the case of the oath, the salary or fees are mere incidents and form no part of the office.’ Mechem § 7, at 6; see *id.* at 6 n.3 (‘it is not a sine qua non’); Kennon, 7 Ohio St. at 559 (‘That compensation or emolument is a usual incident to office, is well known; but that it is a necessary element in the constitution of an office, is not true.’); *id.* at 120 (‘If Presidents were to serve without pay, as Benjamin Franklin had proposed, see James Madison, Notes of Debates in the Federal Convention of 1787, at 51–55 (June 2, 1787) (1987), they would no less hold an office.’).

It is undisputed that the members of PSTF and ACIP “occupy a continuing position established by law” and “exercise significant authority pursuant to the laws of the United States.” *Lucia v. SEC*, 138 S. Ct. at 2051. That is all that is needed to make them “officers of the United States.”

V. THE SECRETARY’S AUTHORITY TO APPOINT ACIP MEMBERS UNDER 42 U.S.C. § 217a(a) DOES NOT DEFEAT THE PLAINTIFFS’ APPOINTMENTS CLAUSE CLAIM

In a footnote, the government claims that members of ACIP are appointed consistent with the Appointments Clause because 42 U.S.C. § 217a empowers the Secretary to appoint members of “advisory councils or committees.” The government contends that ACIP members are appointed pursuant to this statutory authority, and that (in the government’s view) satisfies the Constitution’s requirement for appointing “inferior officers.” This argument is unavailing for three reasons.

First, ACIP is no longer an “advisory” council or committee within the meaning of 42 U.S.C. § 217a because the Affordable Care Act makes its recommendations mandatory and binding upon every insurer in the United States. *See* 42 U.S.C. § 300gg-13(a)(2) (requiring insurers to cover the immunizations “recommended” by ACIP). ACIP’s role *before* the enactment of the ACA was advisory, but it can no longer be passed off as an “advisory” committee under 42 U.S.C. § 217a now that it holds the power to dictate which immunizations private insurance must cover. So 42 U.S.C. § 217a does not qualify as a “law” that vests the appointment of ACIP members in the Secretary of HHS, because ACIP no longer falls within the definition of an “advisory committee.”

Second, 42 U.S.C. § 217a cannot qualify as a law that “vests” the appointment of any “inferior officer” in the Secretary of HHS, because members of “advisory” councils and committees will *never* qualify as “officers” under the Appointments Clause. *See Officers of the United States Within the Meaning of the Appointments*

Clause, 31 Op. Off. Legal Counsel 73, 77 (Apr. 16, 2007) (“[A]n individual who occupies a purely advisory position (one having no legal authority) . . . does not hold a position with delegated sovereign authority of the federal government and therefore does not hold a federal office.”); *The Constitutional Separation of Powers Between the President and Congress*, 20 Op. Off. Legal Counsel 124, 144 (1996) (“[T]he members of a commission that has purely advisory functions ‘need not be officers of the United States’ because they ‘possess no enforcement authority or power to bind the Government.’” (quoting *Proposed Commission on Deregulation of International Ocean Shipping*, 7 Op. Off. Legal Counsel 202, 202–03 (1983))). Any person appointed pursuant to 42 U.S.C. § 217a is by definition a non-officer of the United States who holds a purely “advisory” role, so 42 U.S.C. § 217a cannot be used to defeat a constitutional challenge to the appointment of someone who *does* qualify as an “officer of the United States” under *Lucia*.

Third, the members of ACIP cannot qualify as “inferior officers” because their recommendations are conclusive and final under 42 U.S.C. § 300gg-13(a)(2). *See Edmond v. United States*, 520 U.S. 651, 662–63 (1997) (“Whether one is an “inferior” officer depends on whether he has a superior. . . . [W]e think it evident that “inferior officers” are officers whose work is directed and supervised at some level by others who were appointed by Presidential nomination with the advice and consent of the Senate.”). The statute allows no one to override ACIP’s recommendations, and it compels private insurers to cover ACIP’s recommended immunizations without any appeal to a higher source of authority. Whatever ACIP says goes. So Congress lacks the authority to vest the appointment of ACIP members in the President alone, in the Courts of Law, or in the Heads of Department. They must be appointed as principal officers, who are subject to Presidential nomination and Senate confirmation.

VI. THE PLAINTIFFS HAVE ALLEGED A VIOLATION OF THE VESTING CLAUSE

The government denies that 42 U.S.C. § 300gg-13(a)(1) violates Article II’s vesting clause by empowering the Preventive Services Task Force to dictate the “items or services” that private insurers must cover, while simultaneously insulating the members of the task force from Presidential direction or control. *See* 42 U.S.C. § 299b-4 (“All members of the Task Force convened under this subsection, and any recommendations made by such members, shall be independent and, to the extent practicable, not subject to political pressure.”). The government denies that the PSTF is exercising *any* type of “legislative” or “executive” power—or even “quasi-legislative power”—because (in the government’s view) the PSTF is indistinguishable from the American National Standards Institute (ANSI), or the state and foreign governments whose decision are incorporated by reference into federal statutes. The government’s argument is untenable.

The Preventive Services Task Force is an entity of the federal government. It is funded by the Agency for Healthcare Research and Quality, which appoints its members and provides its support staff.¹⁴ And it was created and established by an Act of Congress in 1984. A government agency of this sort *must* comply with the constitutional rules established in Articles I and II; Congress cannot create independent entities and then empower them to make legally binding decisions independent of Presidential control. *See Seila Law LLC v. Consumer Financial Protection Bureau*, 140 S. Ct. 2183 (2020). ANSI is a private, non-profit entity that is not part of the federal government and was not created by the federal government. State and foreign governments are not part of the federal government either, so they do not need to comply with constitutional separation-of-powers rules—even when they exercise authority

14. *See* <https://www.ahrq.gov/cpi/about/otherwebsites/uspstf/index.html> (last visited on September 12, 2020).

pursuant to a federal statute. State judicial officers, for example, are not required to hold life tenure and salary protection, even when they decide cases arising under a federal statute, because they are entities of their state government and do not exercise “the judicial power of the United States.” *See* William Baude, *Adjudication Outside Article III*, 133 Harv. L. Rev. 1511 (2020). The Supreme Court has never allowed an entity that is part of the federal government to exempt itself from constitutional separation-of-powers rules, and the Court’s recent decision in *Seila Law* is an emphatic reminder that purely independent federal agencies of the type established in 42 U.S.C. § 300gg-13(a) have no place in our constitutional structure.

VII. THE PLAINTIFFS HAVE ALLEGED A VIOLATION OF THE NONDELEGATION DOCTRINE

Statutes that delegate authority to agencies must supply an “intelligible principle” to guide the agency’s discretion. *See Whitman v. American Trucking Associations*, 531 U.S. 457, 472 (2001). Yet there is *nothing* in the text of section 300gg-13(a) that purports to guide the discretion of PSTF, ACIP, or HRSA when choosing the preventive care that private insurance must cover. The statute does not even require these agencies to make these decisions based on the “public interest” or the “public health,” and it does not provide *any* factors or considerations that might influence the agency’s decisionmaking. Even the statutes that fall along the outermost boundary of constitutionally permissible delegations have at least *something* to guide the agency; this statute has *nothing at all*.

The government suggests that the statute provides an “intelligible principle” because the PSTF has established its *own criteria* for determining which “items or services” receive an “A” or “B” grade. *See* Mot. to Dismiss (ECF No. 20) at 27. But *Whitman* explicitly rejects the idea that an agency can cure the absence of an intelligible principle in a statute by supplying the intelligible principle that Congress failed to provide:

[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.” *J.W. Hampton, Jr., & Co. v. United States*, 276 U.S. 394, 409 (1928). We have never suggested that an agency can cure an unlawful delegation of legislative power by adopting in its discretion a limiting construction of the statute. . . . The idea that an agency can cure an unconstitutionally standardless delegation of power by declining to exercise some of that power seems to us internally contradictory. The very choice of which portion of the power to exercise—that is to say, the prescription of the standard that Congress had omitted—would *itself* be an exercise of the forbidden legislative authority. Whether the statute delegates legislative power is a question for the courts, and an agency’s voluntary self-denial has no bearing upon the answer.

Whitman, 531 U.S. at 472 (emphasis added). The “intelligible principle” must appear in the statute itself, not in any agency-created guidelines.

The government also suggests that the statute provides an “intelligible principle” by allowing PSTF to compel coverage only of “evidence-based items and services,”¹⁵ by allowing ACIP to compel coverage only of “immunizations,”¹⁶ and allowing HRSA to compel coverage only of “preventive care and screenings,”¹⁷ and then only of preventive care and screenings for “infants, children, and adolescents,”¹⁸ or “for women.”¹⁹ *See* Mot. to Dismiss (ECF No. 20) at 27. This argument confuses a statutory boundary on an agency’s authority with the “intelligible principle” needed to guide the agency’s discretion within those boundaries. Limiting the scope of HRSA’s powers to “preventive care and screenings,” for example, does nothing to provide guidance when HRSA is deciding *which* “preventive care” and *which* “screenings” will be covered. *That* is where the absence of an intelligible principle is felt, and the government cannot point to anything in the statute that alleviates this problem.

15. 42 U.S.C. § 300gg-13(a)(1).

16. 42 U.S.C. § 300gg-13(a)(2).

17. 42 U.S.C. § 300gg-13(a)(3)–(4).

18. 42 U.S.C. § 300gg-13(a)(3).

19. 42 U.S.C. § 300gg-13(a)(4).

Finally, the Supreme Court’s recent opinion in *Little Sisters* indicates that the justices have at least some discomfort with the delegation in section 300gg-13(a)(4). Consider this passage, which seems to go out of its way to call out the statute as a unique (and uniquely troublesome) delegation:

On its face, then, [section 300gg-13(a)(4)] grants sweeping authority to HRSA to craft a set of standards defining the preventive care that applicable health plans must cover. But the statute is completely silent as to *what* those “comprehensive guidelines” must contain, or how HRSA must go about creating them. The statute does not, as Congress has done in other statutes, provide an exhaustive or illustrative list of the preventive care and screenings that must be included. See, *e.g.*, 18 U.S.C. § 1961(1); 28 U.S.C. § 1603(a). It does not, as Congress did elsewhere in the same section of the ACA, set forth any criteria or standards to guide HRSA’s selections. See, *e.g.*, 42 U.S.C. § 300gg-13(a)(3) (requiring “*evidence-informed* preventive care and screenings” (emphasis added)); § 300gg-13(a)(1) (“evidence-based items or services”). It does not, as Congress has done in other contexts, require that HRSA consult with or refrain from consulting with any party in the formulation of the Guidelines. See, *e.g.*, 16 U.S.C. § 1536(a)(1); 23 U.S.C. § 138. This means that HRSA has virtually unbridled discretion to decide what counts as preventive care and screenings. But the same capacious grant of authority that empowers HRSA to make these determinations leaves its discretion equally unchecked in other areas, including the ability to identify and create exemptions from its own Guidelines.

Congress could have limited HRSA’s discretion in any number of ways, but it chose not to do so. Instead, it enacted ““expansive language of-fer[ing] no indication whatever” that the statute limits what HRSA can designate as preventive care and screenings or who must provide that coverage.

Little Sisters, 140 S. Ct. at 2380 (some citations omitted). Of course, the Supreme Court did not go so far as to say that section 300gg-13(a)(4) actually violates the nondelegation doctrine. But the Court *did* make clear that the doctrine continues to exist—and that they will continue policing the boundary between permissible and impermissible delegations of lawmaking power. See *Gundy v. United States*, 139 S. Ct. 2116 (2019). If the provisions of section 300gg-13(a)(1)–(4) are held to pass muster

under the “intelligible principle” standard, then one must wonder how any statute could possibly fail this court-imposed test.

VIII. 42 U.S.C. § 300gg-13(a)(1)–(4) SHOULD BE CONSTRUED, AS A MATTER OF STATUTORY INTERPRETATION, TO REFER TO THE RATINGS, RECOMMENDATIONS, OR GUIDELINES THAT EXISTED ON THE DATE THAT THE AFFORDABLE CARE ACT BECAME LAW

The canon of constitutional avoidance counsels in favor of interpreting 42 U.S.C. § 300gg-13(a)(1)–(4) to require coverage only of the ratings, recommendations, or guidelines that existed on the date that the Affordable Care Act was enacted into law. It is at least *possible* to read the statutory language this way, and this construction will obviate the serious constitutional problems with the government’s interpretation of statute. The plaintiffs need *only* to show that: (1) Their proposed interpretation of the statute is possible; and (2) The government’s interpretation of the statute presents serious constitutional questions.

The government argues (and we agree) that section 300gg-13(a)(1)–(4) is “most naturally read” to incorporate the agencies’ future ratings, recommendations, and guidelines, especially when the statute is considered alongside other provisions such as section 300gg-13(a)(5) and section 300gg-13(b). *See* Mot. to Dismiss (ECF No. 20) at 29–32. And in the absence of any constitutional doubt, these structural arguments (when combined with *Chevron* deference) would compel any court to adopt the government’s construction of the statute. But the constitutional-avoidance canon allows courts to adopt unnatural or unplausible interpretations of statutory language, so long as the contrary interpretation would present a serious constitutional question. Indeed, the Supreme Court has adopted some exceedingly dubious interpretations of statutory language in the name of constitutional avoidance—sometimes going so far as to contradict an unambiguous statutory text. *See, e.g., INS v. St. Cyr*, 533 U.S. 289, 299–300 (2001); *Northwest Austin Municipal Utility District No. One v. Holder*, 557

U.S. 193, 204–06 (2009); *Bond v. United States*, 572 U.S. 844 (2014). So the statutory-interpretation question turns on whether the plaintiffs have presented constitutional challenges serious enough to trigger the canon of constitutional avoidance.

The government denies that the constitutional-avoidance canon should apply, insisting that the plaintiffs’ constitutional arguments are not only mistaken but not even colorable enough to present a “serious” constitutional question. Although we respect the government’s views, we think it impossible to deny that the constitutional claims presented in this case are at least serious enough to implicate the avoidance canon, especially given the Supreme Court’s recently expressed concerns about the constitutionality of 42 U.S.C. § 300gg-13(a)(4). *See Little Sisters*, 140 S. Ct. at 2380.

IX. THE PLAINTIFFS HAVE ALLEGED A VIOLATION OF RFRA

Plaintiffs Kelley, Starnes, Zach and Ashley Maxwell, Kelley Orthodontics, and Braidwood each hold sincere religious objections to the compulsory coverage of PrEP drugs, and this explained clearly in the complaint:

Mr. Kelley, Mr. Starnes, Mr. Maxwell, and Ms. Maxwell also object to contraceptive coverage *and the coverage of PrEP drugs on religious grounds*. Each of these plaintiffs is a Christian, and they are unwilling to purchase health insurance that subsidizes abortifacient contraception *or PrEP drugs that encourage and facilitate homosexual behavior*.

First Amended Complaint (ECF No. 14) at ¶ 36 (emphasis added). The complaint also states that Mr. Kelley is the owner of Kelley Orthodontics, *see id.* at ¶ 53, and the Kelley Orthodontics “wishes to provide health insurance for its employees that excludes coverage of . . . PrEP drugs.” And the complaint specifically explains Braidwood’s religious objections to the compulsory coverage of PrEP drugs:

Dr. Hotze is therefore unwilling to allow Braidwood’s self-insured plan to cover PrEP drugs such as Truvada and Descovy because these drugs facilitate or encourage homosexual behavior, which is contrary to Dr. Hotze’s sincere religious beliefs.

First Amended Complaint (ECF No. 14) at ¶ 63.

All of these allegations make clear that the plaintiffs are asserting a complicity-based objection to the coverage of PrEP drugs, because they do not wish to subsidize or provide drugs that “encourage and facilitate homosexual behavior.” *Id.* at ¶ 36. That unquestionably qualifies as a “substantial burden” on the exercise of their religion, and the Supreme Court has repeatedly held that courts *must* accept a religious objector’s complicity-based objections to unwanted health-insurance coverage—no matter how attenuated the complicity may seem to an opposing party or a federal judge. The Court’s only task is to determine whether a complicity-based objection is sincere; it may not dismiss a religious objector’s sincere complicity objections as unreasonable or “too attenuated.” See *Burwell v. Hobby Lobby Stores, Inc.*, 573 U.S. 682, 725 (2014); *Little Sisters of the Poor Saints Peter & Paul Home v. Pennsylvania*, 140 S. Ct. 2367, 2383 (2020). Each of these plaintiffs has clearly alleged a complicity-based objection to the compulsory coverage of PrEP drugs that is rooted in their sincere religious beliefs (or in the case of Braidwood and Kelley Orthodontics, in the sincere religious beliefs of their owners). And the sincerity of those beliefs must be accepted as true at this stage of the litigation.

CONCLUSION

The defendants' motion to dismiss should be denied.

Respectfully submitted.

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CERTIFICATE OF SERVICE

I certify that on September 12, 2020, I served this document through CM/ECF

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