

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

JOHN KELLEY, *et al.*,

Plaintiffs,

v.

XAVIER BECERRA, *et al.*,

Defendants.

Civil Action No. 4:20-cv-00283-O

**DEFENDANTS' REPLY IN SUPPORT OF
CROSS-MOTION FOR SUMMARY JUDGMENT**

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SUMMARY

Plaintiffs would prefer that the Preventive Services Provision, 42 U.S.C. §§ 300gg-13—which provides that certain preventive services be covered without cost sharing by group health plans and health insurers offering group and individual health insurance coverage—were not the law.¹ But they have failed to provide evidence demonstrating that the provision has any material real world effect on them that would be redressable by this Court. Instead, they simply express the desire to deny this guarantee of cost-free medical care, which they need not use themselves, to others who want and need it. But absent showing some actual effect of the provision on *them*, for example an increase in the price of their *own* insurance or a concrete and imminent expectation of being required to pay for objected-to services—none of which *any* Plaintiff has shown—they cannot meet their burden of establishing that this Court has jurisdiction to hear their claims.

Plaintiffs’ arguments on the merits fare no better. They contend that the Preventive Services Provision is unconstitutional because it permits certain entities in and affiliated with the Public Health Service of the United States to act without the “direction and supervision” of the Secretary of Health and Human Services (the “Secretary”)—despite the explicit statutory grant of authority to the Secretary to “supervis[e] and direct[]” the administration of the Public Health Service. 42 U.S.C. § 202. And even if these entities had improperly acted without the requisite direction from the Secretary, the Secretary has now independently ratified all preventive services requirements currently in effect, which “resolves [Plaintiffs’] claim[s] 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) (second two alterations in original; internal quotation marks removed).

Finally, Plaintiffs’ only pleaded RFRA claim, which challenges the specific coverage requirement involving PrEP medications that prevent the spread of HIV, fails because Plaintiffs have not provided evidence that the law imposes any burden on the religious beliefs in which they

¹ Hereafter, Defendants will refer to “health insurance” as a shorthand that also includes self-insured plans.

ground their claims, and because the requirement is necessary to advance the government's compelling interest in preventing the spread of a potentially fatal virus, HIV.

ARGUMENT

I. PLAINTIFFS LACK STANDING TO CHALLENGE THE PREVENTIVE SERVICES PROVISION

In their opening brief, Defendants showed that no Plaintiff had met its burden of demonstrating with evidence that it had Article III standing, as required at the summary judgment stage to establish the Court's jurisdiction. Defs.' Br. in Response to Pls.' Mot. for Summ. J. and Cross-Mot. for Summ. J. ("Defs.' Br.") at 9-26, ECF No. 64 at 20-37. Plaintiffs essentially argue that they have standing because they say so, and need establish no facts beyond their own disagreement with the challenged law to demonstrate their own standing. But this is not the law. Rather, the "observation of conduct with which one disagrees . . . is not an injury sufficient to confer standing under Art. III," *Valley Forge Christian Coll. v. Americans United for Separation of Church and State, Inc.*, 454 U.S. 464, 485-86 (1982), and to establish standing at summary judgment, a plaintiff "must 'set forth' by affidavit or other evidence 'specific facts'" to meet its burden. *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 561 (1992) (quoting Fed. R. Civ. P. 56(e)).

A. The Economic Objectors Have Failed to Establish Standing

Defendants previously demonstrated that Plaintiffs have failed to produce evidence sufficient to establish standing to the extent they premise their standing based on an objection to the Preventive Services Provision that is not religious in nature. Contrary to the allegations in their complaint, they have (1) failed to submit *any* evidence that they are *injured* by the provision of extra coverage that they do "not want or need," First Am. Compl. (FAC) ¶¶ 45, 50, ECF No. 14; *see* Defs.' Br. at 11-12; (2) failed to demonstrate that the Preventive Services Provision caused any increase to their premiums—and indeed admitted they had "no knowledge" of any such increase, *see* Defs' Br. at 12-16 (citing APP 167-78, 225-236, 261-273, 206-220, 279-294, & 183-200); and (3) failed to establish that enjoining the Preventive Services Provision would redress their purported injury because they failed to provide evidence showing that insurers would lower

premiums as a result of such an injunction and because a favorable ruling on their claims would undisputedly leave nearly all of the objected-to coverages in place, *see* Defs.’ Br. 16-20.

In response, Plaintiffs do not dispute that they have failed to show any of these elements or contest the facts presented by Defendants, although this was the theory of standing they had previously asserted in this case. *See* FAC ¶¶ 45, 50; Order of 2/25/21, ECF No. 35 (“[T]he Free-Market Plaintiffs object to paying higher prices for health insurance that provides coverage they do not wish to purchase. This type of economic injury involving compulsion to purchase a product or service is sufficient to show that the Free-Market Plaintiffs have suffered an injury in fact.”). Instead, they pivot to the claim that they need not do so because, in their view, so-called “purchaser standing” “allows litigants to sue whenever a statute or agency deprives them of the opportunity to purchase a desired product,” and thus obviates any need to show economic injury. Response to Defs.’ Mot. for Summ. J and Reply Br. In Support of Pls.’ Mot. for Summ. J. (“Pls.’ Reply”) at 3, ECF No. 74. But the Fifth Circuit has never adopted the purchaser standing doctrine, and the D.C. Circuit has made clear that the “purchaser standing” doctrine is far more limited than Plaintiffs contend and does not afford standing in the circumstances here.

In *Weissman v. National Railroad Passenger Corp.*, 21 F.4th 854 (D.C. Cir. 2021), the D.C. Circuit recently explained that the purchaser standing doctrine applies in limited circumstances. It first noted that the court has “assumed” that doctrine permits standing “only in the context of a challenge . . . under the APA”—circumstances not at issue here. *Id.* at 859. But *Weissman* more generally rejects the premise behind Plaintiffs’ maximalist construction of the purchaser standing doctrine, making clear that “[e]ven assuming” that the purchaser standing doctrine “could apply beyond [the APA] context,” it would still not apply here. *Id.* In *Weissman*, plaintiffs sought to challenge Amtrak’s decision to modify the terms and conditions governing its rail service to include a mandatory arbitration provision. *Id.* at 856. To contest the claim that they had no standing, the *Weissman* plaintiffs—like Plaintiffs here— “rel[ie]d on [the D.C. Circuit’s] precedent that consumers have standing to challenge government action that ‘prevented the consumers from purchasing a desired product.’” *Id.* at 857 (quoting *Coal. for Mercury-Free Drugs*

v. *Sebelius*, 671 F.3d 1275, 1281 (D.C. Cir. 2012)). The court rejected plaintiffs' contention, analyzing the very cases on which Plaintiffs rely here to explain the limits of the purchaser standing doctrine:

In each case, the court analyzed the injury-in-fact requirement by considering whether government action had meaningfully abridged a concrete interest of the plaintiff in accessing the desired product. That inquiry has focused on two considerations: whether the challenged action made a consumer's desired product, *as defined by its core features*, "not readily available," and whether it rendered the product "unreasonably priced."

Weissman, 21 F.4th at 858 (quoting *Coal. for Mercury-Free Drugs*, 671 F.3d at 1282) (emphasis added). In *Weissman*, as here, plaintiffs did not and could not show that the challenged decision made the product at issue more expensive or unreasonably priced. *See id.* at 859; Defs.' Br. 11-20; *see also* Pls.' Reply at 3-4; *id.* at 6 ("The allegations of the plaintiffs' complaint are not relevant at this stage of the litigation."); *see also* Coverage of Certain Preventive Services Under the Affordable Care Act, 78 Fed. Reg. 39,870 (July 2, 2013) ("Use of preventive services results in a healthier population and reduces health care costs by helping individuals avoid preventable conditions and receive treatment earlier."). Instead—again, like Plaintiffs here, who argue that health insurance without certain preventive services coverage is no longer on the market, Br. in Support of Pls.' Mot. for Summ. J. ("Pls.' Br.") at 9-10, ECF No. 45—the *Weissman* plaintiffs "maintain[ed] that, . . . they are prevented from purchasing their desired product because an Amtrak rail ticket without an arbitration clause is no longer on the market as a result of Amtrak's new term of service." 21 F.4th at 859.

But, the Court explained, this was not sufficient to establish standing. Rather, where standing was permitted under the purchaser theory, "the product at issue was differentiated from available alternatives by its core features," not ancillary ones. *Id.* Thus, the *Weissman* plaintiffs, the court explained, "adequately alleged a 'primary,' concrete consumer interest in traveling on Amtrak, but not in purchasing an Amtrak ticket without an arbitration provision." *Id.* at 860. So too, here, where Plaintiffs may have a primary interest in obtaining health insurance, but not in

obtaining health insurance that provides no coverage for ancillary preventive services that they have no intention of using.

The *Weissman* court further explained that “[c]onsumers proceeding on a desired-products theory must still allege a concrete invasion of a cognizable interest,” and that, again like Plaintiffs, the *Weissman* plaintiffs “failed to do so” because they did not demonstrate how any harm from the mere existence of this ancillary term of service is “actual or imminent, not ‘conjectural’ or ‘hypothetical.’” *Id.* at 859.

In short, Plaintiffs’ “approach would contrive standing simply by redefining any sweeping ‘gripe’ as the inability to obtain a product that negates that ‘gripe,’ which would contravene a central purpose of Article III standing doctrine to channel “generalized dissatisfaction with government policy” into the political process, not the courts.” *Id.* at 860 (quoting *Coal. for Mercury-Free Drugs*, 671 F.3d at 1278). Their “unbounded expansion of the desired-products theory, then, would circumvent much of modern standing doctrine, allowing abstract and speculative interests to find a footing for standing merely by reframing their injury as a lost opportunity to purchase a product.” *Id.* at 861. This is not the law. Plaintiffs cannot meet their burden of establishing Article III jurisdiction merely because a statute or regulation establishes that a product they consume (health insurance) will contain ancillary features that they do “not want or need,” FAC ¶¶ 45, 50, for the benefit of others who may want to use them. *Cf. Coal. for Mercury-Free Drugs*, 671 F.3d at 1277 (Kavanaugh, J.) (“[Plaintiffs] do not have standing to challenge FDA’s decision to allow *other people* to receive thimerosal-preserved vaccines.”). Having failed to demonstrate a concrete injury here, they do not have standing to bring their claims.

B. The Religious Objectors Have Failed to Establish Standing

Defendants also previously showed that the religious objector Plaintiffs failed to establish standing. As to the individual religious objector Plaintiffs John Kelley, Joel Starnes, Zach Maxwell, and Ashley Maxwell, none provided any evidence that they sought to obtain a plan that did not cover PrEP before the PrEP requirement took effect or that health insurers would be willing

to offer them PrEP-free insurance in the absence of a government-enforced PrEP requirement.² *See* Defs.’ Br. at 21-24. Defendants also demonstrated that Plaintiffs Kelley Orthodontics, John Kelley, and Joel Starnes have no standing because they conceded that they do not provide or purchase health insurance for reasons other than the challenged requirements. *See* Defs’ Br at. 24-26.

Perhaps recognizing that the other Plaintiffs have failed to establish standing, Plaintiffs claim that Plaintiff Braidwood has standing to assert all claims because it is self-insured and, as a result, no other plaintiffs need to demonstrate standing. Both premises are false. Regarding Plaintiffs’ first premise, Braidwood’s status as a self-insured entity does not, alone, establish standing. To establish standing, a plaintiff must demonstrate that its complained-of injury is “actual or imminent, not ‘conjectural’ or ‘hypothetical.’” *Lujan*, 504 U.S. at 560 (quoting *Whitmore v. Arkansas*, 495 U.S. 149, 155 (1990)). And “[i]n response to a summary judgment motion,” it “can no longer [do so by] rest[ing] on . . . ‘mere allegations,’ but must ‘set forth’ by affidavit or other evidence ‘specific facts,’” which for purposes of the summary judgment motion will be taken to be true.” *Lujan*, 504 U.S. at 561 (quoting Fed. R. Civ. P. 56(e)). Braidwood has not done so.

As Defendants previously explained, Defs’ Br. at 23, Braidwood self-insures and thus does not pool risk with other insureds, instead paying out claims itself, so Braidwood does not contribute financially to offsetting the risk of any insureds outside of its own employees. Braidwood therefore does not pay to offset the risk of future claims for PrEP, but instead merely bears the risk itself that a claim for PrEP may one day be filed and that Braidwood will then have to pay it. Yet Braidwood has presented no evidence that it has been required to make any payment related to PrEP so far. Nor has Braidwood offered evidence that any Braidwood employee has sought, intends to seek, or will seek to obtain PrEP medications—let alone that they meet medical criteria such that a physician would prescribe PrEP medications to them. Braidwood cannot sustain this case on the hypothetical possibility that it may one day have to make a payment towards PrEP treatment,

² Indeed, the only evidence in the record suggests otherwise. *See* APP 452-53, ECF No. 65.

without any evidence that such an event will or likely will happen. Until then, as a self-insured plan, Braidwood operates only under a legal obligation to cover PrEP if such a claim is submitted, and an abstract legal obligation, without any real world effect on Braidwood or Dr. Hoetze, its principal, is insufficient to establish standing. *See, e.g., Barber v. Bryant*, 860 F. 3d 345, 357 (5th Cir. 2017).

Plaintiffs do not contest any of the above or provide contrary evidence. Instead, Plaintiffs attempt to avoid the straightforward consequence of their failure to submit evidence to support their standing by citing the Supreme Court’s decision in *Burwell v. Hobby Lobby*, 573 U.S. 682, 720 (2014), effectively contending that *Hobby Lobby* grants religious objectors automatic Article III standing to challenge coverage requirements under the ACA, without making any showing of injury, causation, or redressability. *Hobby Lobby* does no such thing: The decision does not even address Article III standing and cannot be read to make a statement about how Article III standing must be demonstrated here, particularly in the context of summary judgment, where standing must be established by evidence rather than “plausible” allegations. *Lujan*, 504 U.S. at 561. When it comes to *that* question, the factual differences between Hobby Lobby’s challenge to contraceptive coverage and Braidwood’s challenge to PrEP coverage are significant and render the factual question of whether the parties have standing to be wholly distinct. Hobby Lobby had over 13,000 employees at the time of the case, 573 U.S. 702, while the other plaintiffs in that case had nearly 1,000, *id.* at 700. Those plaintiffs challenged a requirement that they provide contraception, medical services available to most women and actually used around the time of the case by 64.9% of American women aged 15-49, a total of 46.9 million women.³ Although the *Hobby Lobby* plaintiffs did not seek to exclude coverage for all forms of contraception, given their number of employees and the ubiquity of contraception use, it was more likely than not—if not a virtual

³ National Center for Health Statistics, Current Contraceptive Status Among Women Aged 15-49,; United States, 2015-2017, NCHS Data Brief No. 327, (Dec. 2018) [https://www.cdc.gov/nchs/products/databriefs/db327.htm#:~:text=of%20Family%20Growth-,In%202015%E2%80%932017%2C%20approximately%2065%25%20of%20women%20aged%2015,of%20contraception%20\(Figure%201\).](https://www.cdc.gov/nchs/products/databriefs/db327.htm#:~:text=of%20Family%20Growth-,In%202015%E2%80%932017%2C%20approximately%2065%25%20of%20women%20aged%2015,of%20contraception%20(Figure%201).)

certainty—that they would be required to pay for the undesired contraception as part of their self-insured plans.

By contrast, Braidwood has made no similar showing with respect to its challenge to PrEP. In contrast to the 13,000 Hobby Lobby employees, Braidwood employs “approximately 70 individuals.” FAC ¶ 60; Pls.’ APP 67 ¶ 5. And PrEP medications are far from ubiquitous: Only approximately one million individuals in the United States have clinical indications for PrEP medications, and less than 25% of those individuals were actually using them at the time the coverage requirement took effect. APP 383, ¶ 12. In other words, fewer than 250,000 Americans are currently prescribed or using PrEP medications. There is no indication in the record that any of these individuals are qualified for, in the geographic region of, or interested in working for Braidwood, let alone that any are currently employed by it or are dependents of its employees.

But even the above understates the likelihood that Braidwood may experience any actual impact from the PrEP coverage requirement. Given Plaintiffs’ publicly expressed statements in this litigation that Dr. Hoetze, Braidwood’s principal, “operates his business according to Christian principles and teaching,” FAC ¶ 62, which he interprets as requiring opposition to “facilitat[ing] or encourag[ing] homosexual behavior, intravenous drug use, and sexual activity outside of marriage between one man and one woman” APP 70, ¶ 16, it is difficult to imagine that individuals eligible to be prescribed PrEP medications would choose to work for Braidwood, given that the “principles and teaching” on which the business is “operate[d]” are openly opposed to their various lifestyles or the lifestyles of their intimate partners or dependent children. In any event, Plaintiffs have not identified any employee of Braidwood’s (or even any prospective employee of Braidwood’s) who is eligible for or intends to seek reimbursement for PrEP medications. Accordingly, it would require a logical leap beyond what is permissible on summary judgment to conclude that Braidwood has any more than speculative risk of the PrEP coverage requirement affecting it at all. *See Lujan*, 504 U.S. at 560. The burden is on Plaintiffs to demonstrate otherwise, and they have failed to do so. Absent a concrete, non-speculative, imminent injury, Braidwood does no more than express disagreement with the law. This does not confer standing. *See, e.g., Md.*

Shall Issue, Inc. v. Hogan, 963 F.3d 356, 362 (4th Cir. 2020) (“MSI’s alleged injury is no more than a mere disagreement with the policy decisions of the Maryland legislature, which is insufficient to meet the constitutional threshold for an injury in fact.”); *see also Coal. for Mercury-Free Drugs*, 671 F.3d at 1278-79 (“Standing protects democratic government by requiring citizens to express their generalized dissatisfaction with government policy through the Constitution’s representative institutions, not the courts.”); *Valley Forge Christian Co.*, 454 U.S. at 485-86.

Nor are Plaintiffs correct that only Braidwood must establish standing for the Court to adjudicate the claims of all Plaintiffs. Even if Braidwood had standing, the other Plaintiffs would still not be entitled to relief on *their* claims. As the Supreme Court has explained, “‘standing is not dispensed in gross’”; instead “a plaintiff must demonstrate standing for each claim he seeks to press and for each form of relief that is sought.” *Town of Chester, N.Y. v. Laroe Ests., Inc.*, 137 S. Ct. 1645, 1650 (2017) (citations omitted); *see also Arizona v. Biden*, 31 F.4th 469, 483 (6th Cir. 2022) (Sutton, C.J., concurring) (“A valid Article III remedy ‘operates with respect to specific parties,’ not with respect to law in the abstract,” which “is why courts generally grant relief in a party-specific and injury-focused manner.”). Thus, even if the Court can consider the merits of each claim as to which one Plaintiff has demonstrated standing, the Court cannot grant relief that is personal to Plaintiffs who have not themselves established standing. *See Warth v. Seldin*, 422 U.S. 490, 499 (1975) (A plaintiff “must assert his own legal rights and interests, and cannot rest his claim to relief on the legal rights or interests of third parties.”); *Gill v. Whitford*, 138 S. Ct. 1916, 1933-34 (2018) (explaining that “[a] plaintiff’s remedy must be tailored to redress the plaintiff’s particular injury,” and that “[t]he Court’s constitutionally prescribed role is to vindicate the individual rights of the people appearing before it”). Consistent with those equitable principles, the Fifth Circuit has repeatedly vacated or stayed universal relief that applies to nonparties. *See Louisiana v. Becerra*, 20 F.4th 260, 264 (5th Cir. 2021) (“This vaccine rule is an issue of great significance currently being litigated throughout the country. Its ultimate resolution will benefit from ‘the airing of competing views’ in our sister circuits.” (citation omitted)); *see also Texas v.*

United States, 14 F.4th 332, 341 (5th Cir. 2021); *Marshall v. Goodyear Tire & Rubber Co.*, 554 F.2d 730, 735 (5th Cir. 1977).

While this applies to all claims in this case, it has particular significance with respect to Plaintiffs' RFRA claims. The RFRA claims asserted here do not (and cannot) seek invalidation of any law; instead, Plaintiffs ask the Court to "enjoin the defendants from enforcing the PrEP mandate" against particular parties. FAC ¶ 111. Thus, the only parties who can seek the "form of relief" of an injunction preventing enforcement of the PrEP requirement against Starnes, John Kelley, Kelley Orthodontics, and the Maxwells, are Starnes, John Kelley, Kelley Orthodontics, and the Maxwells, respectively. Indeed, this is not a class action, and there is no dispute that only the parties who are properly before the Court may obtain relief on their RFRA claims. *See* Defs.' Br. at 60 n.41; Pls.' Reply at 40 n.38. Accordingly, judgment must be entered for Defendants with respect to all other Plaintiffs' RFRA claims regardless of whether Braidwood has established standing (which it has not).⁴

⁴ Plaintiffs also contend that they can assert new claims in their motion for summary judgment. That assertion—which is unsupported and contrary to the law—is addressed primarily in Part IV below. *See infra* at 30-31; *see generally Sloan ex rel. Juergens v. Urban Title Servs., Inc.*, 652 F. Supp. 2d 51, 62 (D.D.C. 2009) ("Plaintiff cannot amend her complaint by merely . . . filing a motion for summary judgment."). But Plaintiffs' further contention that they can establish *standing in particular* based on unasserted claims also is false. *See* Pls.' Reply at 6-7. Because "standing is not dispensed in gross," and "a plaintiff must demonstrate standing for each claim he seeks to press and for each form of relief that is sought," *Town of Chester*, 137 S.C. at 1650 (quoting *Davis v. Fed. Elec. Com'n*, 554 U.S. 724, 734 (2008)), a plaintiff cannot claim standing based on one claimed injury—e.g., that the HPV vaccine coverage requirement causes injury—to provide standing to assert a wholly different claim and request for relief—e.g., that the PrEP coverage requirement violates RFRA and must be enjoined. *See, e.g., Fednav, Ltd. v. Chester*, 547 F.3d 607, 614 (6th Cir. 2008) ("Our determination of standing is both plaintiff- and provision-specific. That one plaintiff has standing to assert a particular claim does not mean that all of them do."); *cf.* Pls.' Reply at 6-7. In addition, Plaintiffs' contention that "[D]efendants do not claim that they have been prejudiced by the absence of these RFRA claims and standing argument in the complaint" is mistaken. Pls' Reply at 7. Defendants made clear in their opening brief that Plaintiffs' newly asserted claims did prejudice them by eliminating their ability to obtain discovery about those claims. *See, e.g.,* Def's Br. at 54 n. 37.

II. DEFENDANTS ARE ENTITLED TO SUMMARY JUDGMENT ON PLAINTIFFS' APPOINTMENTS CLAUSE AND VESTING CLAUSE CLAIMS

Plaintiffs' constitutional claims, at their core, rest on the presumption that the Preventive Services Provision radically reshapes the structure of the Department of Health and Human Services, without explicitly saying so. But none of the text of the Preventive Services Provision, other statutes, binding authority from the Supreme Court and the Fifth Circuit, numerous courts of appeals decisions, or the basic principles of statutory interpretation support Plaintiffs' reading. Because the Secretary has plenary authority to direct and supervise the Public Health Service, the Preventive Services Provision is constitutional. And to the extent any appointment of personnel affiliated with the entities referenced in that provision has been defective, the Secretary's January 21, 2022 ratification of all current guidelines and recommendations subject to that provision cures it, wholly resolving Plaintiffs' constitutional claims.

A. The Secretary's Ratification of the Current Preventive Services Coverage Requirements Defeats Plaintiffs' Appointments Clause Claim

As Defendants established in their opening brief, the Secretary of Health and Human Services' January 21, 2022 ratification cured any constitutional defect in the appointment or vesting of authority under the Preventive Services Provision (though there was no such defect). *See* Defs.' Br. 26-35, 46-47; APP001-35. In response, Plaintiffs do not question the adequacy of the Secretary's own appointment or his status as a principal officer, the form of the January 21, 2022 ratification, the scope of the ratification, or the caselaw establishing that ratification by a properly empowered official cures any putative violations resulting from the initial action of an official with a defect in his or her authority to take the act in question. *See, e.g., Guedes*, 920 F.3d at 13 (ratification "resolves [Appointments Clause] claim[s] on the merits by remedy[ing] [the] defect (if any) from the initial appointment."); *Advanced Disposal Servs. E., Inc. v. NLRB*, 820 F.3d 592, 605 (3d Cir. 2016) (upholding ratification of appointment and ratification of the appointed official's conduct of a union election); *NLRB v. Newark Elec. Corp.*, 14 F.4th 152 (2d Cir. 2021) (upholding ratification of complaint issued by officer lacking an appointment); *cf. CFPB v. Seila Law LLC*, 997 F.3d 837, 846 (9th Cir. 2021) (upholding ratification of filing of

complaint to enforce a civil investigative demand).

Plaintiffs contend only that the Secretary has no authority to ratify the specific coverage decisions of the entities mentioned in the Preventive Services Provision. But Plaintiffs' argument—which is based exclusively on *assumptions* about the Preventive Services Provision—cannot be squared with (1) the text of the Preventive Services Provision itself, (2) the statutory background establishing HHS's structure on which the Preventive Services Provision is overlaid, or (3) basic principles of statutory interpretation.

First, citing dicta in *Myers v. United States*, 272 U.S. 52, 135 (1926), Plaintiffs argue that Congress may vest authority wholly in subordinate officials, without the oversight of their superiors. Pls.' Reply at 15. Plaintiffs then simply presume, without any analysis of the statutory text at issue, that because Congress *may* do so, it must have done so here. But that is contrary to the way statutes must be read, and nothing in the text of the Preventive Services Provision supports this assumption, much less compels it. *See, e.g., Jama v. Immigrations and Customs Enf't*, 543 U.S. 335, 341 (2005) (“We do not lightly assume that Congress has omitted from its adopted text requirements that it nonetheless intends to apply[.]”).

Although Plaintiffs refer to the “clear and unambiguous text” that they claim supports their argument, they do not analyze the statutory text itself at all. Pls.' Reply at 14. This is telling. All that the Preventive Services Provision requires is that certain health insurance plans cover, without cost-sharing,

- (1) evidence-based items or services that have in effect a rating of “A” or “B” in the current recommendations of the United States Preventive Services Task Force;
- (2) 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; and
- (3) with respect to [certain populations] preventive care and screenings provided for in . . . comprehensive guidelines supported by the Health Resources and Services Administration.

42 U.S.C. § 300gg-13(a)(1)-(3); *see id.* § 300gg-13(a)(4). Nothing in the text explicitly addresses the chain of command above the three entities mentioned, which officers of the United States have authority to supervise or direct those entities' decisionmaking, or what authority those officers

may have to do so.

Although the text of the Preventive Services Provision itself does not speak to the precise question at issue, Congress does not legislate in a vacuum, and resolving the question requires analyzing the provisions that *do* address this question. *See, e.g., Robinson v. Shell Oil Co.*, 519 U.S. 337, 341 (1997) (“The plainness or ambiguity of statutory language is determined by reference to the language itself, the specific context in which that language is used, and the broader context of the statute as a whole.”); *Abramski v. United States*, 573 U.S. 169, 179 (2014) (quoting *Maracich v. Spears*, 570 U.S. 48, 75 (2013)) (“[W]e must (as usual) interpret the relevant words not in a vacuum, but with reference to the statutory context, ‘structure, history, and purpose.’”). In light of the Preventive Services Provision’s failure to speak on the question of what oversight the Secretary has over the entities mentioned in that provision, the specific statutes setting forth the Secretary’s authority over the Department of Health and Human Services govern here. *See, e.g., Bostock v. Clayton Cty.*, 140 S. Ct. 1731, 1747 (2020) (“Nor is there any such thing as a ‘canon of donut holes,’ in which Congress’s failure to speak directly to a specific case that falls within a more general statutory rule creates a tacit exception. Instead, when Congress chooses not to include any exceptions to a broad rule, courts apply the broad rule.”). Those laws make clear that the Secretary retains control of the Public Health Service, including the guidelines and recommendations of the entities referenced in the Preventive Services Provision.

Multiple statutes explicitly vest the Secretary with the authority to control the work of the Public Health Service. Indeed, the Secretary is explicitly authorized by statute to “supervis[e] and direct[]” the work of the Public Health Service, 42 U.S.C. § 202—in which all agencies relevant to Plaintiffs’ Appointments Clause claim, HRSA, the CDC, and AHRQ—are organizationally located, assigned functions, and delegated authority by the Secretary. *See, e.g., Office of the Secretary and Public Health Services; Statement of Organization, Functions, and Delegations of Authority*, 60 Fed. Reg. 56605 (November 9, 1995). Section 202’s text is not surplusage. *See Knight v. United Land Ass’n*, 142 U.S. 161, 177–78 (1891) (“The phrase, ‘under the direction of the secretary of the interior,’ as used in these sections of the statutes, is not meaning-less, but was

intended as an expression in general terms of the power of the secretary to supervise and control the extensive operations of the land department, of which he is the head. . . . The statutes, in placing the whole business of the department under the supervision of the secretary, invest him with authority to review, reverse, amend, annul, or affirm all proceedings in the department”) (internal quotation marks omitted). All of the Public Health Service is, by law, doing the Secretary’s work and carrying out his functions under his authority.⁵ See Reorganization Plan. No. 3 of 1966, 5 U.S.C. app 1 (transferring to the Secretary “all functions of the Public Health Service, . . . and of all . . . officers and employees of the Public Health Service, and all functions of all agencies of or in the Public Health Service”). Thus, every action taken by these entities, absent explicit statutory command to the contrary, is an action of the Secretary, under his control, which *he takes through* his subordinates. See, e.g., 42 U.S.C. § 299(a) (“The Secretary shall carry out this subchapter acting through the Director [of AHRQ].”).

Because nothing in the Preventive Services Provision’s text purports to modify these grants of authority to the Secretary, it must be presumed that these other statutes passed by Congress retain their effect. See *Maine Comty. Health Options v. United States*, 140 S. Ct. 1308, 1323 (2020) (citations omitted) (“‘[R]epeals by implication[s] are not favored,’ and are a ‘rarity.’ ‘Presented with two statutes, the Court will ‘regard each as effective’—unless Congress’ intention to repeal is ‘clear and manifest,’ or the two laws are ‘irreconcilable.’”). Plaintiffs’ position requires imposing the opposite rule—their contention is effectively that despite *not* saying so, the Preventive Services Provision implicitly repeals these other statutes. This reading is impermissible. See *Cty. of Yakima v. Confederated Tribes and Bands of the Yakima Indian Nation*, 502 U.S. 251, 265-66 (1992) (quoting *Morton v. Mancari*, 417 U.S. 535, 551 (1974)) (“Judges ‘are not at liberty to pick and choose among congressional enactments, and when two [or more] statutes are capable

⁵ Plaintiffs erroneously claim that “defendants cannot identify any statute that empowers the Secretary to review, ratify, countermand, or revoke a coverage mandate imposed by” the entities at issue in the Preventive Services Provision. Pls.’ Reply at 15. But Defendants’ opening brief identifies both Section 202 and Reorganization Plan No. 3 of 1966 as relevant authorities. See Defs.’ Br at 5-6, 29, 36-37.

of co-existence, it is the duty of the courts, absent a clearly expressed congressional intention to the contrary, to regard each as effective.”).

But Plaintiffs’ position also cannot be squared with basic presumptions of administrative law, which should be assumed to inform Congress’s intent. *See Bond v. United States*, 572 U.S. 844, 857 (2014) (“Part of a fair reading of statutory text is recognizing that ‘Congress legislates against the backdrop of certain unexpressed presumptions.’”). More than a century of caselaw recognizes that

[a]s a general proposition of administrative law, the head of an administrative agency has the power to review and revise acts of subordinates where, as here, the powers in question are vested in the subordinate under the supervision and direction of the superior or the power to administer is vested in the superior. To hold otherwise would create havoc in the administration of our laws.

Chevron Oil Co. v. Andrus, 588 F.2d 1383, 1388 (5th Cir. 1979); *see Knight*, 142 U.S. at 176-78 (citations omitted).

If Congress had wished to vest unreviewable authority to establish particular forms of preventive services coverage requirements in particular entities, removing for this one purpose the supervisory authority it has clearly and repeatedly vested in the Secretary in multiple statutes in a manner inconsistent with the standard presumptions of administrative law, it could and would have done so expressly. *See Banister v. Davis*, 140 S. Ct. 1698, 1707 (2020) (citing *TC Heartland LLC v. Kraft Foods Group Brands LLC*, 521 U.S. 1514, 1519 (2017)) (“When Congress ‘intends to effect a change’ in existing law . . . it usually provides a clear statement of that objective.”). This is so particularly when the change would be as radical and contrary to the established law and presumptions regarding administrative authority as the one urged by Plaintiffs, as “Congress does not hide elephants in mouseholes.” *Cyan, Inc. v. Beaver Cty. Employees Ret. Fund*, 138 S. Ct. 1061, 1071-72 (2018). But nowhere does the text explicitly provide that any authority conferred by the Preventive Services Provision is unreviewable by the Secretary, and Plaintiffs’

strained interpretation must be rejected.⁶

Even if the question were close—and the above makes clear it is not—the Preventive Services Provision *still* must be read as Defendants urge. “[W]here a statute is susceptible of two constructions, by one of which grave and doubtful constitutional questions arise and by the other of which such questions are avoided, our duty is to adopt the latter.” *Jones v. United States*, 526 U.S. 227, 239 (1999) (quoting *United States ex rel. Attorney General v. Delaware & Hudson Co.*, 213 U.S. 366, 408 (1909)). Plaintiffs assert that the statute unambiguously supports their interpretation, but as demonstrated above, that assertion is belied by the statutory text, the rules of statutory construction, and other statutes that must be read in conjunction with the Preventive Services Provision to understand its meaning. Rather than follow the basic rules of statutory construction, Plaintiffs urge this Court instead to go out of its way to contort the law’s meaning for the purpose of finding it unconstitutional. This is not permitted.

In seeking to avoid the clear implications of the avoidance canon, Plaintiffs assert a second time that “the defendants have failed to identify any statutory language that could be construed to give the Secretary a ratification power over” the entities referenced in the Preventive Services Provision. Pls’ Reply at 17. But this proposition remains false no matter how many times it is repeated. As Defendants have made clear, more than one statute confers this power, but 42 U.S.C. § 202 expressly places the entire Public Health Service, including all three entities at issue, “under the supervision and direction of the Secretary.” 42 U.S.C. § 202; *see, e.g., supra* note 5.

⁶ Indeed, the *only* textual restriction on the authority of the Department’s hierarchy related to the entities at issue in the Preventive Services Provision that has been pointed to by either party in this litigation—42 U.S.C. § 299b-4(a)(6)’s admonition that the PSTF’s recommendations shall be “to the extent practicable, not subject to political pressure”—comes outside the Preventive Services Provision itself. This conclusively demonstrates that (1) Congress is capable of expressing its intentions about how the entities function within HHS’s hierarchy expressly; (2) Congress did not view the Preventive Services Provision as speaking to how these entities function within HHS’s hierarchy; and (3) Congress understood that the rules it created *outside* the Preventive Services Provision would govern how these entities operated for purposes of this provision. Of course, for the reasons explained below and in Defendants’ opening brief, Section 299b-4(a)(6) does not help Plaintiffs here. *See* Defs’ Br. at 39-47; *infra* Part II.B.2.

Plaintiffs' arguments directed at the remedy of ratification fare no better than their textual claims about the Secretary's authority under the Preventive Services Provision. Plaintiffs start by repeating the claim from their opening brief—for which they still offer no authority—that the Secretary's ratification is ineffective because the entities mentioned in the Preventive Services Provision may issue *future* guidelines and recommendations that the Secretary may choose not to ratify, or may not ratify before they would otherwise take effect. But this novel argument fails for numerous reasons, even beyond the lack of any authority supporting it. First, as set forth elsewhere herein, the Secretary's ratification is not necessary, because there is no constitutional infirmity with the structure of the Preventive Services Provision even absent Secretarial ratification. *See also* Defs.' Br. at 35-45.

Second, any hypothetical infirmity of future guidelines is not at issue in this case, and Plaintiffs have no standing to assert claims about guidelines that do not exist yet. Plaintiffs do not dispute that the Secretary's January 21, 2022 ratification encompasses all guidelines subject to the Preventive Services Provision currently in existence. Accordingly, any infirmity with the existing guidelines has been cured. *See Guedes*, 920 F.3d at 13. Whatever guidelines may be issued in the future, whether some Plaintiff may object to them, whether or not they are ratified, and, if they are ratified, what the timing of ratification is relative to the issuance of the guidelines, can only be the subject of speculation and have no bearing on these Plaintiffs' claims in this case.

Plaintiffs' related argument that the statute violates the Appointments Clause because it "makes the imposition of any preventive care mandate contingent on" ACIP or PSTF's proposal or HRSA's support, even if the Secretary subsequently approves it, is similarly misguided. Pls.' Reply at 18-19. It is unremarkable that the statute authorizes a principal officer to take action through a particular subordinate official, or authorizes particular subordinate officials to start the administrative process under the supervision of a principal officer—which the principal has plenary authority to subsequently review and overturn or to affirm and ratify. Courts have recognized and upheld analogous statutory schemes since at least the nineteenth century. For example, in *Knight v. United Land Ass'n*, 142 U.S. 161, 177-78 (1891), the Supreme Court

recognized the authority of the Secretary of the Interior to overturn a decision of the commissioner of the general land office, even after the administrative proceeding overseen by the commissioner was concluded, where a statute provided that “[t]he commissioner of the general land-office shall perform, *under the direction of the secretary of the interior*, all executive duties appertaining to the surveying and sale of the public lands of the United States, or in any wise respecting such public lands, . . . and the issuing of patents for all [grants] of land under the authority of the government.”

Plaintiffs cite only *Lucia* in support of this argument, but that is inapposite to the question of ratification, which is not addressed anywhere in that opinion. Moreover, the remedy in *Lucia* is different from the appropriate remedy here because the context was different. Although Plaintiffs dismiss the distinction between adjudications and other administrative decisions (though without providing any reasoning), the distinction is material for remedial purposes. To be sure, in certain contexts “the appropriate remedy *for an adjudication* tainted with an appointments violation is a new hearing before a properly appointed official.” *Lucia v. S.E.C.*, 138 S. Ct. 2044, 2055 (2018) (emphasis added) (internal quotation marks omitted). But Plaintiffs cite no authority suggesting this remedy is warranted or even practicable outside the context of adjudications. To the contrary, Plaintiffs’ approach is inconsistent with the well-established and consistent authority permitting ratification in the context of alleged Appointments Clause violations outside the adjudicative context. *See, e.g., Guedes*, 920 F.3d 1, 13. The distinction between certain adjudications and the issuance of rules and guidance supported by the caselaw makes sense: In the context of an adjudication, an initial hearing officer may take or preclude oral testimony or make credibility findings that cannot be fully cured by a reviewing authority considering the paper record. *See, e.g., Lucia*, 138 S. Ct. at 2049 (SEC ALJs’ powers include “hearing and examining witnesses”). By contrast, in rulemakings or similar processes like the issuance of guidelines and recommendations at issue here, a constitutionally appointed officer can make an “independent and considered review” that fully cures any constitutional defect in the appointment of an official who initially considered the matter. APP001; *see, e.g., Moose Jooce v.*

Food & Drug Admin., 981 F.3d 26, 28-30 (D.C. Cir. 2020). That review cures any problem with respect to the Appointments Clause, because a properly appointed official has redone the work with his proper authority, so there is no longer harm from an improperly appointed official issuing the rule or guidance.⁷

But Plaintiffs’ argument—and resulting proposed remedy—fails for a more basic reason: It violates the Supreme Court’s command in *Arthrex* to draw the narrowest remedy possible to undo the (alleged) constitutional problem. See *United States v. Arthrex*, 141 S. Ct. 1970, 1985 (2021) (“[W]hen confronting a constitutional flaw in a statute, we try to limit the solution to the problem” and where there is “a conflict between the Constitution and a statute, we give ‘full effect’ to the Constitution and to whatever portions of the statute are ‘not repugnant’ to the Constitution, effectively severing the unconstitutional portion of the statute.”). Indeed, *Arthrex* applied this rule to permit a constitutionally appropriate officer’s review of its subordinate’s decision to cure an Appointments Clause violation in the context of an adjudication. Thus, even in the adjudication context, it is not necessary to start over with a new slate of subordinates when the work can be adequately reviewed by a principal officer. Plaintiffs identify nothing barring the Secretary’s independent and complete review of the current guidelines at issue here. Thus, to the extent it is required that a principal officer have a say in the guidelines at issue in the Preventive Services Provision, that has already occurred here.

Plaintiffs proffer three reasons that they believe this Court should reject the Supreme Court’s directly applicable remedial holding in *Arthrex*. None is persuasive. First, plaintiffs contend that *Arthrex* is different because there the Court permitted the Director to review *every*

⁷ *Lucia* is also inapposite in light of the difference between the powers and duties of the entities involved from those at issue here. The SEC ALJs in *Lucia* had numerous, broad powers, including to sanction parties before them, ultimately “issu[ing] decisions containing factual findings, legal conclusions, and appropriate remedies”; their “authority [is] ‘comparable to’ that of a federal district judge conducting a bench trial.” *Lucia v. S.E.C.*, 138 S. Ct. 2044, 2049, 2053 (2018). By contrast, the entities at issue here are charged with considering the medical research in certain designated areas in order to issue guidelines or recommendations about best practices in preventive medicine, a far more discrete and limited task.

decision of the PTAB. But that would be the same result here should the Court hold that the Preventive Services Provision unconstitutionally prevents the review of a principal officer (which it does not do): The Secretary would, under that holding, be required to review those decisions in every instance before they take effect. True, the Secretary has already done so here, so no further process would be necessary on remand in this case, but the remedy itself would be in the same as *Arthrex*. Plaintiffs do not articulate any basis to distinguish this case from *Arthrex* on the question of remedy or explain why the Court would “not have the power” to order that the Secretary must have authority to review his subordinates’ work. Pls.’ Reply at 22.

Nor is it relevant that “Plaintiffs have not asked for this remedy.” *Id.* The Supreme Court’s remedy in *Arthrex* was not that requested by the petitioner, but rather the remedy the Court determined was appropriate for the constitutional violation it found. *See* 141 S. Ct at 1978, 1986 (holding that “[d]ecisions by APJs must be subject to review by the Director” who “Congress vested . . . with the ‘powers and duties’ of the PTO” even though “*Arthrex* ask[d] [the Court] to hold the entire regime of inter partes review unconstitutional” and the statutory regime passed by Congress had given “neither the Secretary nor the Director . . . the authority to review [the APJs’] decisions”). And in *Guedes*, the plaintiffs sought to invalidate a rule that would regulate bump stocks as “machine guns” by arguing, *inter alia*, that the Acting Attorney General who issued the rule was unconstitutionally appointed. But rather than invalidate the rule, the Court found that the subsequent Attorney General, who was undisputedly confirmed by the Senate after being nominated by the President, independently ratified the rule. The *Guedes* plaintiffs assuredly did not “ask[] for this remedy,” Pls.’ Reply at 22, but the court nonetheless found that they were not entitled to relief, because “a properly appointed official’s ratification of an allegedly improper official’s prior action . . . resolves the claim on the merits by ‘remedy[ing] [the] defect’ (if any) from the initial appointment.” *Guedes*, 920 F.3d at 13 (citing cases).⁸ Ultimately, Plaintiffs’

⁸ The cases cited by Plaintiffs provide them no help, either. Their quotation from *Steel Co. v. Citizens for a Better Environment*, 523 U.S. 83, 107 (1998), states no more than the uncontroversial proposition that a plaintiff has no Article III standing to bring a claim for relief that will not redress their injury. It says nothing about the scope of a court’s authority to issue a given ruling once it

argument is no more than an expression of disagreement with the caselaw establishing that ratification is a remedy for putative Appointments Clause violations. Notwithstanding that disagreement, the Secretary's January 21, 2022 ratification of all current guidelines subject to the Preventive Services Provision is sufficient in and of itself to resolve Plaintiffs' constitutional claims in Defendants' favor.

B. The Preventive Services Provision's Coverage Requirements Are Constitutional Even Absent Explicit Secretarial Ratification

Defendants previously demonstrated the constitutionality of the Preventive Services Provision even absent the Secretary's ratification of the recommendations and guidelines encompassed by it. *See* Defs.' Br at 35-45. Plaintiffs fail to refute Defendants' arguments. In their Reply, they fail to address altogether key statutory authority and binding precedent cited by Defendants and advance arguments that rely on demonstrably false premises. For these independent reasons, their constitutional claims must also fail.

1. As Inferior Officers, the HRSA Administrator and CDC Director's Issuance of the Coverage Requirements Is Consistent with the Appointments Clause

Defendants previously established that the CDC Director and HRSA Administrator are duly appointed inferior officers of the United States, acting under the direction and supervision of the Secretary and subject to removal by the Secretary, such that they constitutionally have the authority to accept and support, respectively, the recommendations and guidelines at issue in the Preventive Services Provision. *See* Defs.' Br. at 36-39. Plaintiffs' arguments to the contrary are inconsistent with the text of the Preventive Services Provision, other statutes passed by Congress, and binding authority that Plaintiffs ignore.

has been established that a case is properly before it. Similarly, the citation to the dissenting portion of Judge Oldham's partial dissent in *Collins v. Mnuchin*, 938 F.3d 553, 611 (5th Cir. 2019), provides no help: It addresses a proposed remedial path rejected by the *en banc* court in the Fifth Circuit and which—Plaintiffs fail to mention—the Supreme Court subsequently rejected as “neither logical nor supported by precedent.” *Collins v. Yellen*, 141 S. Ct. 1761, 1787 (2021).

The CDC Director, Who Is Directed and Supervised by the Secretary, Directs and Supervises ACIP. Plaintiffs do not challenge the CDC Director’s appointment or dispute that the Secretary has the authority to direct, supervise, and remove the CDC Director. Instead, they contend that the Preventive Services Provision gives ACIP unilateral authority to determine relevant preventive services without the CDC Director’s oversight. This is not so. As Plaintiffs acknowledge, the Preventive Services Provision states that only “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” be covered. 42 U.S.C. § 300gg-13(a)(2) (emphasis added). Plaintiffs do not seriously dispute that such recommendations *only* take “effect” if they are (1) “reviewed by the CDC Director,” (2) “adopted” by the CDC Director, and (3) “published as official CDC/HHS recommendations in the Morbidity and Mortality Weekly Report.” APP 148; *see* 45 C.F.R. § 147.130(a)(1)(ii) (“a recommendation or guideline of [ACIP] is considered issued on the date on which it is adopted by the CDC Director”).⁹ Thus, there is no textual support in the Preventive Services Provision for Plaintiffs’ assertion that it transforms ACIP from an advisory committee within the Public Health Service to an unsupervised independent agency with unilateral authority.

Plaintiffs next contend that ACIP members are principal officers because their work takes effect without the “direction and supervision of a principal officer.” Pls.’ Reply at 24. But as already explained, Plaintiffs do not dispute the Secretary’s authority to direct, supervise, and dismiss the CDC Director, and the CDC Director supervises ACIP’s work and can decline its recommendations—and has in fact done so. *See* Defs.’ Br. at 38 n. 26 (noting the CDC Director

⁹ Plaintiffs assert that the “ACIP charter merely says that ‘Recommendations made by the ACIP are reviewed by the CDC Director’” without providing the CDC Director any ability to do anything upon that review. Pls.’ Reply at 24. Plaintiffs’ reading makes little sense—they do not explain why an official would be empowered to “review” guidelines without being empowered to approve them or even what that would mean. But the Charter itself demonstrates the falsity of this reading in any event; the Charter’s express text also requires that the CDC Director “adopt” ACIP’s recommendations on review for them to take effect. APP 148.

declined to follow ACIP’s recommendation with respect to COVID booster shots with respect to certain populations). Plaintiffs do not acknowledge or respond to this example, despite inviting it in their opening brief. Nor do they acknowledge 42 U.S.C. § 202, which provides the Secretary with the authority to “supervis[e] and direct[.]” the entire Public Health Service, of which the CDC and ACIP are a part. *See* APP 148; 42 U.S.C. § 217a.

Further, Plaintiffs also do not, and cannot, dispute that even without the intermediary step of the CDC Director, ACIP members are appointed by the Secretary pursuant to statute, “for the purpose of advising him in connection with any of his functions”—again making clear that ACIP members act at the Secretary’s pleasure and under his direction and supervision. 42 U.S.C. § 217a(a). In the end, Plaintiffs rest their argument entirely on the assertion that the Preventive Services Provision silently transformed ACIP from an advisory committee into an entity empowered to act unilaterally without oversight despite the background of numerous laws making clear that it is under the Secretary’s direction and control. *But see supra* Part II.A. Such a complete overhaul of HHS’s lines of authority and the status of an advisory committee that had been in existence for nearly 50 years is far too big an elephant to fit in the nonexistent mousehole in which Plaintiffs try to force it.¹⁰ *Cyan, Inc.*, 138 S. Ct. at 1071-72.

The HRSA Administrator Is Constitutionally Appointed and Is Directed and Supervised by the Secretary. Plaintiffs make similar and equally unsupported arguments about the HRSA Administrator. Plaintiffs note that an “inferior officer” is one whose “*work* is ‘directed and supervised’ by principal officers.” Pls.’ Reply at 26. True enough. They fail to note, however, that the Secretary has express statutory authority to “supervis[e] and direct[.]” the agencies within

¹⁰ Plaintiffs talk in circles by contending that Defendants “fail to identify any federal statute that vests [ACIP members’] appointment in the Secretary,” Pls.’ Reply at 25, and simultaneously asserting that Defendants “cannot rely on” 42 U.S.C. § 217a, the statute pursuant to which ACIP members are appointed, because that statute permits appointments “only to . . . advisory councils . . . for the purpose of advising him,” Pls.’ Reply at 25. The Secretary’s clear, statutory authority over the Public Health Service, including ACIP in general, and clear, statutory authority to appoint its members *to advise him*, in particular, demonstrate that Plaintiffs’ reading of the Preventive Services Provision to *preclude* the Secretary from exercising control over ACIP is incorrect.

the Public Health Service, including HRSA. 42 U.S.C. § 202. Indeed, Plaintiffs fail to even cite Section 202 in their briefing.

Plaintiffs likewise claim that Reorganization Plan No. 3 of 1966 does not authorize the Secretary to appoint the HRSA Administrator. But Plaintiffs fail to address *Willy v. Administrative Review Board*, 423 F.3d 483 (5th Cir. 2005), in which the Fifth Circuit held that a substantively identical Reorganization Plan, coupled with 5 U.S.C. § 301, “vests the Secretary with ample authority to . . . appoint [inferior officers] and delegate final decision-making authority to them.” *Id.* at 491-492. Plaintiffs do not even *acknowledge* the Fifth Circuit’s binding decision in *Willy*, let alone distinguish it. They cannot, and it governs here.

Similarly, as with respect to ACIP, Plaintiffs simply assert, without support in the statutory text, that the Preventive Services Provision grants HRSA unilateral authority to act without oversight, notwithstanding the ample authority establishing the Secretary’s power to “direct and supervise” agencies in the Public Health Service like HRSA. *See, e.g.*, 42 U.S.C. § 202; Reorganization Plan No. 3 of 1966 § 1, 5 U.S.C. app. 1. But the Preventive Services Provision does not speak to how HRSA is, or is not, overseen within the Department of Health and Human Services in any way. It provides only that certain preventive services will be covered if they appear in “comprehensive guidelines *supported by* the Health Resources and Services Administration.” 42 U.S.C. § 300gg-13(a)(3) & (a)(4). This language hardly can be read to vest unreviewable discretion in the HRSA Administrator, who it does not even mention, let alone to implicitly repeal the Secretary’s statutory authority under 42 U.S.C. § 202 and Reorganization Plan No. 3 of 1966. *See supra* Part II.A.

Plaintiffs seek to buttress their contention by quoting language out of context from the Supreme Court’s decision in *Little Sisters of the Poor Saints Peter and Paul Homes v. Pennsylvania*, 140 S. Ct. 2367 (2020), which refers to HRSA’s authority under the Preventive Services Provision. Pls.’ Reply at 20. But that language does not purport to suggest that HRSA has authority *independent from the rest of HHS*, nor can it be read to support such a notion. Indeed,

that decision reviews nearly a decade of regulations *issued at the Department level*¹¹ regarding the Preventive Services Provision without questioning that authority, and ultimately upholds regulations issued by the Department and signed by the Secretary in which the Department *directs* that

Guidelines issued [pursuant to the Preventive Services Provision] by the Health Resources and Services Administration *must not provide for or support* the requirement of coverage or payments for contraceptive services with respect to a group health plan established or maintained by an objecting organization, or health insurance coverage offered or arranged by an objecting organization, to the extent of the objections specified below. Thus the Health Resources and Service Administration *will* exempt from any guidelines' requirements that relate to the provision of contraceptive services

45 C.F.R. § 147.132(a)(1), quoted in Religious Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act, 83 FR 57536, 57590 (Nov. 15, 2018) (emphasis added); *see Little Sisters*, 140 S. Ct. at 2372-2379 (discussing history of Department's regulation of HRSA's administration of guidelines under Preventive Services Provision); *id.* at 2386 ("We hold today that *the Departments* had the statutory authority to craft that exemption [from coverage under HRSA's guidelines], as well as the contemporaneously issued moral exemption." (emphasis added)). This language—and the Supreme Court's decision upholding it—cannot be squared with Plaintiffs' assertion that HRSA is not subject to the Secretary's supervision and direction.

2. Plaintiffs' Claims Regarding the PSTF Must Fail Because the PSTF Is Either an Independent Body Not Subject to the Appointments and Vesting Clauses or It Is Subject to the Secretary's Control

In Plaintiffs' opening brief, they relied on a 2007 OLC Opinion to support their contention that members of the PSTF are principal officers. Pls.' Br. 12-18. Defendants demonstrated in response that the PSTF did not satisfy the criteria established by that OLC Opinion, the criteria set

¹¹ The Department of Health & Human Services issued those regulations jointly with the Departments of Labor and the Treasury.

forth in the Fifth Circuit’s binding *en banc* decision in *Riley v. St. Luke’s Episcopal Hospital*, 252 F.3d 749, 757 (5th Cir. 2001), or any of the Supreme Court Appointments Clause cases cited by either party in their opening two briefs. Defs.’ Br. 42-45.

In their Reply, Plaintiffs retrench to the test articulated by the Supreme Court in *Lucia*. But as Defendants previously demonstrated, *Lucia*’s test does not apply, because—like all the tests discussed in the caselaw—it is based on, and applies to, those who hold government positions and exercise government authority, which PSTF members plainly do not do. PSTF members are volunteer doctors who are assisted by a government agency to make scientific recommendations about the contemporary standard of care in preventive medicine. *See* APP 063; 42 U.S.C. § 299b-4(a)(1). That is all.

This certainly does not qualify as “exercise[ing] significant authority pursuant to the laws of the United States.” *Lucia*, 138 S. Ct. at 2051 (quoting *Buckley v. Valeo*, 424 U.S. 1, 126 (1976)). True, the PSTF’s recommendations may be used for important purposes, including, as Congress has decided, being incorporated within certain insurance coverage. But PSTF members themselves are not tasked with considering what is appropriate about insurance at all, nor are they tasked with making discretionary decisions about insurance; they are tasked only with “[r]eview[ing] the scientific evidence related to the effectiveness, appropriateness, and cost-effectiveness of clinical preventive services for the purpose of developing recommendations for the health care community, and updating previous clinical preventive recommendations[.]” 42 U.S.C.A. § 299b-4(a)(1). They thus do not have “authority” over insurance coverage, and the fact that *others*—those who actually have the authority to regulate the insurance market—have decided to use the PSTF’s work (in which the PSTF engages based on a separate statutory mandate for entirely separate purposes) to establish certain insurance coverages cannot be bootstrapped into a basis for asserting that *the PSTF* has that authority.

Even if the Court were to find that the PSTF is a government “office” that is exercising government authority, however, it would not help Plaintiffs. For if it is, either the avoidance canon or *Arthrex* provides that the remedy is to permit the Secretary to “direct and supervise” the PSTF

as part of the Public Health Service. *See supra* Part II.A. The Court could permit this in one of two ways. First, the Court could construe the provision in the statute creating the PSTF that provides that the PSTF’s recommendations “shall be independent, and to the extent practicable, not subject to political pressure,” 42 U.S.C. § 299b-4(a)(6), as *permitting* the Secretary’s direction and supervision in the context of the Preventive Service Provision’s coverage, consistent with the Secretary’s power over the Public Health Service in 42 U.S.C. § 202 and the canon requiring that courts construe statutes in a manner that does not create serious constitutional questions. The Preventive Services Provision, in other words, would be a circumstance where it is not “practicable” in light of the constitutional concerns raised by Plaintiffs to preclude the Secretary’s review of the PSTF’s recommendations. Alternatively, the Court could conclude that subsection (a)(6) of Section 299b-4 is unconstitutional in the context of the Preventive Services Provision and sever it. *See* Defs.’ Br. at 46-47; *see also* *Arthrex*, 140 S. Ct. at 1986; *Seila Law LLC v. Consumer Fin. Prot. Bureau*, 140 S. Ct 2183, 2209 (2020) (“[W]hen confronting a constitutional flaw in a statute, we try to limit the solution to the problem, severing any problematic portions while leaving the remainder intact.”); *id.* at 2210-11. Under either construction, the Secretary is empowered to direct and supervise the PSTF, and his ratification would be consistent with that power and would resolve any putative constitutional infirmity with the PSTF members’ appointments or vesting of authority.

Plaintiffs’ only argument in response not already addressed above with respect to the other entities mentioned in the Preventive Services Provision is the contention that affording the Secretary the authority to direct and supervise the PSTF “does nothing to cure the President’s lack of removal powers over the Task Force members.” Pls’ Reply at 34. But—unlike *Seila Law* and *Myers*, cited by Plaintiffs—*there is no removal restriction with respect to PSTF members*, and Plaintiffs point to none. *Cf. Seila Law*, 140 S. Ct. at 2193 (invalidating statutory restriction on removal of CFPB Director under which, during the Director’s five year term, “the President may remove the Director from office only for ‘inefficiency, neglect of duty, or malfeasance in office.’” (quoting 12 U.S.C. §§ 5491(c)(1), (3))); *Myers* 272 U.S. 52, 107 (1926) (invalidating

removal requirement of Senate consent in statute providing that postmasters “may be removed by the President *by and with the advice and consent of the Senate*” (emphasis added)); *cf.* Defs.’ Br. at 4 (“PSTF members do not have any specific tenure protections and are thus removable at will.”). Because there is no removal restriction on PSTF members, Plaintiffs’ cases are inapposite and their argument is simply based on a false premise for which they provide no support.

III. THE PREVENTIVE SERVICES PROVISION DOES NOT VIOLATE NONDELEGATION PRECEDENTS

In their opening brief, Defendants demonstrated that each subsection of the Preventive Services Provision confers not just an “intelligible principle” to which the bodies administering the provisions must conform, but significant, clear standards far beyond the “not demanding” requirements of the nondelegation doctrine. *Big Time Vapes, Inc. v. Food & Drug Admin.*, 963 F.3d 436, 441 (5th Cir. 2020); *see* Defs.’ Br. 48-54. Each subsection is limited to defining specific preventive care services that should be covered by health plans without cost sharing, defines the specific category of preventive services at issue, identifies the body that is responsible in the first instance for recommending the relevant services, and identifies the specific category of preventive services addressed by each respective body in that subsection. *See* 42 U.S.C. § 300gg-13(a)(1)-(4); *Big Time Vapes*, 963 F. 3d at 441 (quoting *Am. Power & Light Co. v. SEC*, 329 U.S. 90, 105 (1946)) (“It is constitutionally sufficient if Congress clearly delineates the general policy, the public agency which is to apply it, and the boundaries of th[e] delegated authority.”).

In the fewer than three pages devoted to this argument in Plaintiffs’ Reply, Plaintiffs concede that the cases cited by Defendants regarding other statutory delegations satisfy the “intelligible principle” requirement and simply state that the Preventive Services Provision “has nothing of this sort to provide guidance to the agency.” Pls.’ Reply at 37. But that conclusory assertion does not bear scrutiny when comparing the actual text of the Preventive Services Provision with the previously upheld delegations. *Cf., e.g.*, 42 U.S.C. § 300gg-13(a)(4) (limiting agency’s discretion to identifying “with respect to women . . . additional preventive care and screenings [that do not have in effect an “A” or “B” rating in the current recommendations of the

Preventive Services Task Force]”) with *Nat’l Broad. Co. v. United States*, 319 U.S. 190, 225-26 (1943) (authorizing regulation of broadcast licensing as “public interest, convenience and necessity requires”) and *Yakus v. United States*, 321 U.S. 414, 420 (1944) (authorizing establishment of “fair and equitable” commodities prices).

Plaintiffs also contend that 42 U.S.C. § 299b-4—the statute that authorizes the scope of the PSTF’s work and cabins its discretion—cannot be read to inform the putative delegation in 42 U.S.C. § 300gg-13(a)(1). This contention is not supportable. Section 299b-4 provides *inter alia* that the PSTF must “[r]eview the scientific evidence related to the effectiveness, appropriateness, and cost-effectiveness of clinical preventive services” and “consider clinical preventive best practices recommendations” from various government and non-government groups when developing its recommendations. *Id.* § 299b-4(a)(1). This statute expressly constrains the PSTF’s discretion in establishing the recommendations at issue in subsection (a)(1) of the Preventive Services Provision. Plaintiffs offer no support for the illogical conclusion that this statute must be ignored in considering the scope of the putative “delegation.” Indeed, because 42 U.S.C. § 299b-4 establishes the bounds of the PSTF’s discretion by law, the Preventive Services Provision would have to expressly expand PSTF’s authority beyond the scope of 299b-4 for the PSTF to act outside its requirements in connection with the Preventive Services Provision. *See, e.g., Maine Cmty. Health Options*, 140 S. Ct. at 1323. But the Preventive Services Provision does not purport to do so. *See* 42 U.S.C. § 300gg-13(a)(1).¹²

Finally, while Plaintiffs claim that the Supreme Court’s opinion in *Little Sisters* “makes

¹² For this reason, the Fifth Circuit’s recent divided decision in *Jarkesy v. SEC*, ___ F.4th ___, 2022 WL 1563613 (5th Cir. May 18, 2023) also provides no support to Plaintiffs. There, the Court found that the statute at issue gave “no guidance whatever” on the critical question of when the SEC could bring enforcement actions within the agency or federal court, as “[e]ven the SEC agrees that Congress has given it exclusive authority and absolute discretion” over that question. *Id.* at *11. There is no analogue to the present case, where Congress expressly delimited the scope of the entities’ authority. Nor, as noted above and in Defendants’ Brief, are there any removal restrictions on PSTF members, ACIP members, or the HRSA Administrator, so the related concern expressed in *Jarkesy* about the removal restrictions on SEC ALJs has no bearing on this case, either. *See supra* Part II.B; *see also* Defs.’ Br. at 4-5.

clear that the [nondelegation] doctrine remains judicially enforceable,” Pls.’ Reply at 35, they offer no response to the Fifth Circuit’s clear, binding, and repeated admonition that lower courts are to apply existing precedent and “not . . . read tea leaves to predict where it might end up.” *Big Time Vapes*, 963 F.3d at 447 (quoting *United States v. Mechum*, 950 F.3d 257, 265 (5th Cir. 2020)). Plaintiffs’ nondelegation claim is no more than a naked request for the Court to flout this rule. The Court should decline Plaintiffs’ invitation.

IV. PLAINTIFFS FAIL TO ESTABLISH A VIOLATION OF THE RELIGIOUS FREEDOM RESTORATION ACT

As demonstrated above, Plaintiffs cannot establish a RFRA violation because they have no standing, and to the extent the Court finds that one religious objector Plaintiff has standing, the other religious objectors who have not established that they have standing are not entitled to relief on this claim. *See supra* Part I.B.

Plaintiffs also cannot expand the scope of their RFRA claim beyond the claim asserted in their FAC, which is limited to the claim that enforcement of the PrEP mandate against Plaintiffs violates RFRA. *See* FAC ¶¶ 108-111. Plaintiffs’ belated contention, raised for the first time in their summary judgment briefing, that coverage requirements for the HPV vaccine and for screenings and counseling for STDs and drug use also violate RFRA contravenes the basic premise of notice pleading.

It is axiomatic that a “[p]laintiff cannot amend [its] complaint by merely . . . filing a motion for summary judgment[.]” *Sloan ex rel. Juergens v. Urban Title Servs., Inc.*, 652 F. Supp. 2d 51, 62 (D.D.C. 2009); *see Solferini as Tr. of Corradi S.p.A. v. Corradi USA, Inc.*, No. 4:18-CV-00293, 2020 WL 1511315, at *6 (E.D. Tex. Mar. 30, 2020), *affirmed*, No. 20-40645, 2021 WL 3619905 (5th Cir. Aug. 13, 2021) (“A party may not raise a claim in its motion for summary judgment that was not asserted in the party’s complaint”); *see also Fisher v. Metro Life Ins. Co.*, 895 F.2d 1073, 1078 (5th Cir. 1990) (a claim not “raised in [the Plaintiff’s] . . . complaint . . . was not properly before the court”); *Jackson v. Gautreaux*, 3 F.4th 182, 189 (5th Cir. 2021) (new theory first asserted in summary judgment “is precisely the sort of the sort of surprise switcheroo that our

precedents forbid”).

Here, Plaintiffs never sought to timely amend their complaint to expand the scope of their RFRA claim, and have not sought leave to do so even now, as required by the Federal Rules. *See* Fed. R. Civ. P. 15(a)(1); *cf. Jackson*, 3 F.4th at 189 (“Plaintiffs’ counsel never moved to amend under Rule 15. Their failure to do so forfeited the issue and prevented the district court from considering the merits of their summary-judgment argument.”). But more than that, Plaintiffs did the opposite—their RFRA claim in their original complaint had a broader scope, but when Plaintiffs amended their complaint in response to Defendants’ motion to dismiss, they affirmatively chose to narrow their RFRA claim to encompass only PrEP, abandoning any further contentions. *Compare* Compl. ¶¶ 114-125, ECF No. 1 *with* FAC ¶¶ 108-111. This change enabled Plaintiffs to avoid a ruling on their broader claims in response to Defendants’ motion to dismiss and avoid discovery on the claims they abandoned. In these circumstances, in particular, Plaintiffs’ efforts to circumvent pleading rules and belatedly assert abandoned claims is highly prejudicial and should not be countenanced.

Plaintiffs attempt to avoid this conclusion by arguing that *Fisher* and *Jackson* involve plaintiffs who were raising new claims in opposition to a motion for summary judgment, rather than in support of a plaintiff’s own motion for summary judgment. Pls.’ Reply at 7-8. But this ignores *Solferini* and other caselaw which hold the same in the exact same circumstances as the instant case: cross-motions for summary judgment in which the plaintiff’s own motion is at issue. *See, e.g., Sloan ex rel. Juergens*, 652 F. Supp.2d at 62. Plaintiffs’ proposed distinction is also immaterial to the purpose of the rule, which is to protect against the unfair surprise engendered by the assertion of new claims after the close of discovery.¹³

¹³ Plaintiffs’ attempt to justify the distinction—that a defendant has an adequate opportunity to respond if a plaintiff raises a new theory in his or her own motion but not if the plaintiff does so in response to defendant’s motion—makes little sense. In either circumstance, the defendant has an opportunity to respond in briefing—whether in an opposition brief in the former circumstance or a reply brief in the latter. What the defendant does not have the opportunity to do in either situation is to test the new claim in discovery.

As to the PrEP-related RFRA claim Plaintiffs actually brought, as set forth in Defendants' opening brief, Plaintiffs fail to create a genuine issue of material fact either that RFRA applies in this case or that the elements of RFRA are satisfied. *See* Defs.' Br. at 54-60. First, Plaintiffs claim that *Hobby Lobby* holds that they need only express a sincere "complicity" based objection to assert the claim and need show no more for RFRA to apply. But *Hobby Lobby* does not speak to the situation here, where Plaintiffs claim they are complicit by taking an action that they do not in fact take or by virtue of an action's having an effect that it does not in fact have. *See* 573 U.S. at 724 (RFRA claim cannot be defeated by claim "that [plaintiffs' religious] beliefs are flawed"). Here, Defendants do not challenge Plaintiffs' religious beliefs. Rather, Plaintiffs have made *empirical* claims that they do not support with evidence—that coverage of PrEP drugs "encourages" various behaviors and that health insurance companies "use[] [Plaintiffs'] premiums to pay for coverage of PrEP drugs." *See* Defs.' Br. at 55 (citing Def's Appendix). These are not claims about Plaintiffs' *beliefs*, but about concrete effects of actions in the outside world. And they are unsupported. Plaintiffs offer no evidence whatsoever on the effect the availability of PrEP medications, costless or otherwise, has on the behaviors Plaintiffs condemn, and they concede they cannot identify any impact at all on their premiums from the coverage of PrEP drugs. *Id.* Indeed, the status of John Kelley, Kelley Orthodontics, and Joel Starnes lays bare the lack of support for their claims—they concededly don't participate in the health insurance market *at all*, so the alleged burdens of the PrEP coverage requirement simply have no effect on them. *See* Defs.' Br. at 24-26; *supra* Part I.B. Similarly, the Maxwells made no showing that they would have obtained a plan that does not cover PrEP absent the Preventive Services Provision and concededly never made any effort to do so prior to that provision taking effect, despite widespread coverage of those medications in Texas even before the coverage requirement took effect. *See* Defs.' Br. at 22. Finally, in contrast to the plaintiffs in *Hobby Lobby*, whose circumstances were sufficient to demonstrate (at least to a sufficient degree to meet the standard for a preliminary injunction) that they *would* be forced to pay for objectionable forms of contraception if required to cover it under their plans, Braidwood has offered no evidence, despite being asked for such evidence in

discovery, that it has any expectation beyond pure speculation that it will *ever* have to underwrite a PrEP prescription. *See* Defs.’ Br. at 23; *supra* Part I.B. Plaintiffs cannot make out a RFRA claim based on complicity that they sincerely believe would be caused by actions they are not taking or being forced to undertake.

Plaintiffs also do not dispute that preventing the spread of HIV, a potentially fatal, infectious disease, is a compelling government interest. Pls.’ Reply at 39. They contend, however, that the government must show that the PrEP coverage requirement “with no religious exemptions for anyone—is a policy of such overriding importance that it can tolerate no exceptions for religious exemptions for religious objectors.” *Id.* But the question is not whether the government has a compelling interest in allowing *no* religious exceptions to *anyone*, it is whether the government has a compelling interest in not allowing *these* Plaintiffs a religious exemption. *See* 42 U.S.C. § 2000bb-1(b). And to the extent these Plaintiffs can establish standing (*but see* Part I.B), the government has shown it has a compelling interest in protecting any specific person associated with Plaintiffs’ insurance payments that is eligible for and seeking PrEP medications—and anyone that this person could potentially infect—from a fatal infectious disease.

Finally, Plaintiffs argue they did not waive their proposed less restrictive means when they failed to assert it in discovery, supporting their argument only by restating RFRA’s standard and claiming they have no obligation to “produce evidence demonstrating that their proposed alternative will be less burdensome to their religious freedom.” Pls.’ Reply at 40. That misses the point entirely. Plaintiffs had a duty to respond completely and accurately to Defendants’ interrogatories and to supplement their responses if their answers changed. *See* Fed. R. Civ. P. 26(e)(1), 33(b)(3). Plaintiffs were not asked to “produce evidence demonstrating that their proposed alternative will be less burdensome to their religious freedom”; they were asked to identify *all* means they contended would be less restrictive than the PrEP coverage requirement that would be adequate to further the government’s interest in preventing the transmission of the HIV virus, and they did not refuse to answer the interrogatory. *See* Defs’ Br. at 59 (citing Defs.’ Appendix). Yet Plaintiffs did not offer the answer they subsequently asserted at summary

judgment, nor at any time prior to summary judgment did they supplement their responses. They thus forfeited their opportunity to offer their late-asserted less restrictive means. *See* Fed. R. Civ. P. 37(c)(1). While Plaintiffs are correct that the government must show “that it lacks other means of achieving its desired goal without imposing a substantial burden on the exercise of religion by *the objecting parties in [this case]*,” the government cannot be expected to meet that burden when Plaintiffs fail to satisfy their discovery obligations on the issue and cannot even proffer a sworn statement that the newly-asserted putative less restrictive means *would* in fact be less burdensome on them. *Hobby Lobby*, 573 U.S. at 728 (emphasis added).

CONCLUSION

For the reasons set forth above, Plaintiffs’ motion for summary judgment (ECF No. 44) should be denied, Defendants’ cross-motion to for summary judgment (ECF No. 62) should be granted, and judgment should be entered in favor of Defendants on Plaintiffs’ remaining claims.

Respectfully submitted,

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Certificate of Service

On May 26, 2022, I electronically submitted the foregoing document with the clerk of court for the U.S. District Court, Northern District of Texas, using the electronic case filing system of the court. I hereby certify that I have served all parties who have appeared in the case electronically or by another manner authorized by Federal Rule of Civil Procedure 5(b)(2).

/s/ Christopher M. Lynch
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