IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF INDIANA

IRISH 4 REPRODUCTIVE HEALTH *et al.*,

Plaintiffs,

v.

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES *et al.*,

Defendants.

Case No. 3:18-cv-0491-PPS-JEM

REPLY MEMORANDUM IN SUPPORT OF FEDERAL DEFENDANTS' MOTION TO DISMISS THE AMENDED COMPLAINT

INTRODUCTION

As set forth in Federal Defendants' Motion to Dismiss, ECF No. 58 (MTD), Plaintiffs' challenges to the Rules and Settlement Agreement should be dismissed. The Settlement Agreement is an appropriate exercise of the Agencies' discretion to make enforcement decisions, and the Rules are a substantively proper accommodation of the substantial religious and moral objections that some entities have to providing or facilitating coverage for certain contraceptives.

ARGUMENT

I. The Court Should Dismiss Many of Plaintiffs' Claims for Threshold Reasons.

A. Plaintiffs' APA Challenges to the Settlement Agreement May Not Proceed.

1. Alternative Remedies Exist.

Plaintiffs do not dispute that they have raised one claim against the Settlement Agreement under the APA (Count I), and a separate claim on a common law theory (Count II). Yet Plaintiffs now maintain that these claims are "intertwined," and therefore this Court should overlook the statutory prohibition against APA claims where alternative remedies exist. Pls.' Opp'n Defs.' MTD (Opp'n) at 24, ECF No. 61. No such special rule exists.[1] Whether Plaintiffs will need relief regarding both the Settlement Agreement and Rules, Opp'n at 24 n.15, is irrelevant because Federal Defendants only argue that Plaintiffs' APA claims challenging the Settlement Agreement should be dismissed due to the availability of alternative remedies—Plaintiffs' non-APA claims regarding the Settlement Agreement and APA claims concerning the Rules are barred not because of alternative remedies but for other reasons. As to the individual plaintiffs' potential ERISA claims, Plaintiffs simply assert without support that the Settlement Agreement and Rules would

[1] Contrary to Plaintiffs' suggestion, Opp'n at 25 n.17, whether Federal Defendants would be necessary parties to any such non-APA claim is of no moment in determining whether the APA claims can proceed.

bar any recovery. Not so—the Settlement Agreement merely memorializes the government's agreement not to take enforcement action; it does not affect the underlying law or prohibit the individual plaintiffs from raising any valid claims under that law.[2] And Plaintiffs' separate challenges to the Rules must rise or fall on their own merits.

2. The Decision to Settle Litigation Is Committed to Agency Discretion.[3]

Plaintiffs do not dispute that *Heckler v. Chaney* holds that an agency's decision to not take enforcement action is presumptively committed to the agency's "absolute discretion" and "general[ly] unsuitab[le] for judicial review." 470 U.S. 821, 831 n.4 (1985). Plaintiffs also do not dispute that numerous courts have concluded that the decision to *settle* is likewise un-reviewable under the APA. MTD at 19. Instead, Plaintiffs argue that a narrow exception applies, claiming that the Settlement Agreement "is so extreme as to amount to an abdication of [the Agencies'] statutory responsibilities." Opp'n at 18 (quoting *Heckler*, 470 U.S. at 833). But the Settlement Agreement is far from the vast and generalized policy that Plaintiffs claim it is. The Settlement Agreement comprises a specific enforcement decision to resolve the claims of specific litigants in a discrete number of lawsuits. It does not bind the Agencies as to entities that are not parties to the Settlement Agreement. Thus, the Agencies have not abdicated their ability to enforce the contraceptive mandate against any other entities. Even as to the entities that are parties to the Settlement Agreement, the Agreement addresses only enforcement actions brought by the

[2] Plaintiffs also argue that plaintiffs on the student health plan may not be able to bring an ERISA claim, Opp'n at 24 n.16, but of course Notre Dame is under no obligation to provide a student health plan at all. *See, e.g.*, Religious Exemption & Accommodations for Coverage of Certain Preventative Services Under the ACA (Religious Exemption Rule), 83 Fed. Reg. 57,565. (Nov. 15, 2018).

[3] Contrary to Plaintiffs' suggestion, Opp'n at 17 n.10, Federal Defendants recognize that the Seventh Circuit has treated the § 701(a)(2) determination as a merits determination, and thus requested dismissal pursuant to both Federal Rule of Civil Procedure 12(b)(1) and 12(b)(6). MTD.

Agencies, not others. The Settlement Agreement is nothing more than the standard "single-shot" decision that Plaintiffs accept is within the Agencies' discretion. Opp'n at 19. The fact that the Settlement Agreement is of continuing effect is of no moment—in a case, like this one, where the behavior comprising the subject of the enforcement decision may continue, an agreement not to bring enforcement action *at this time only* would be of little worth.

Although Plaintiffs suggest that settlement agreements are not permitted to have any effect on non-parties to the settlement, *see, e.g.*, Opp'n at 21 ("Settlement Agreements that . . . Infringe the Rights of Third Parties are Subject to Judicial Review"), they identify no authority for that proposition, and, indeed, such a rule would be implausible, as many settlement agreements will have some downstream effects on others (for example, the prototypical non-enforcement agreement might be less desirable for competitors of the potential enforcement target). Plaintiffs do cite cases indicating that the government may not *violate the law* when it settles cases, but this proposition finds no application here—Plaintiffs do not allege that the Agencies violated a law in making a discretionary choice about how to prioritize their enforcement resources.[4] In any event, as noted above, the Settlement Agreement only addresses enforcement actions brought by the Agencies; it does not prevent others from any efforts to enforce their purported rights.

Once Plaintiffs have accepted, as they must, that *Heckler* stands for the proposition that an agency can decide not to take enforcement action against a particular entity with respect to a particular application of a law, they cannot distinguish this case merely because the Settlement

[4] Plaintiffs find no support in the cases they cite. For example, *Executive Business Media, Inc., v. U.S. Department of Defense*, which is not binding on this Court, addressed a settlement agreement that bound the government to violate a separate regulation requiring competitive bidding. 3 F.3d 759 (4th Cir. 1993). Here, the Settlement Agreement simply states that the government will not take enforcement action against the signatories stemming from their failure to provide or facilitate coverage for contraceptives to which they object on religious grounds.

Agreement dealt with multiple litigants (all but one of whom Plaintiffs do not even claim standing to address). As their arguments, *infra* II.A, attempting to interpret internal DOJ guidance make clear, Plaintiffs' aggressive position seeks nothing less than the power to control the terms on which DOJ settles litigation against the United States.

B. Plaintiffs' Contract Claim Concerning the Settlement Agreement Fails Because Plaintiffs Are Not in Privity with the Government.

Plaintiffs' common law challenge to the Settlement Agreement faces an additional hurdle: "[a] plaintiff must be in privity with the United States to have standing to sue the sovereign on a contract claim." *Sullivan v. United States*, 625 F.3d 1378, 1379-80 (Fed. Cir. 2010) (per curiam) (citing *Anderson v. United States*, 344 F.3d 1343, 1351 (Fed. Cir. 2003)). "Not only is privity a fundamental requirement of contract law, but it is particularly important in cases involving government contracts because the 'government consents to be sued only by those with whom it has privity of contract.'" *Id.* (quoting *Erickson Air Crane Co. of Wash. v. United States*, 731 F.2d 810, 813 (Fed. Cir. 1984)). While there are limited exceptions to this doctrine, none applies here. *Haddon Hous. Assocs., LLC v. United States*, 99 Fed. Cl. 311, 322 n.23 (2011), *aff'd in part, rev'd in part sub nom. Haddon Hous. Assocs., Ltd. P'ship v. United States*, 711 F.3d 1330 (Fed. Cir. 2013) (discussing exceptions for third-party beneficiaries to contracts, shareholders of contractors, and subcontractors). Here, Plaintiffs are not parties to the Settlement Agreement, nor do they fit within any exemptions that would permit them to raise a contract claim against the government.

C. Plaintiffs Lack Standing to Challenge the Final Rules.

Plaintiffs have not shown that they have standing to challenge the Final Rules, because Notre Dame's decision not to provide certain contraceptive coverage stems from the Settlement Agreement, not the Rules. Notre Dame's argument that it *could* have relied on both, Opp'n at 14, does not negate the fact that the university's President invoked only the Settlement Agreement in

announcing the university's decision to cease providing contraceptive coverage. *See* MTD at 21 (citing Notre Dame President's Letter).

Moreover, Plaintiffs cannot claim that they are injured by both the Final Rules and the Settlement Agreement when the Rules are currently enjoined. It is axiomatic that "a plaintiff must demonstrate standing separately for each form of relief sought." *Friends of the Earth, Inc. v. Laidlaw Envtl. Servs.*, 528 U.S. 167, 185 (2000). Plaintiffs claim that "[t]he fact that an injury is caused by two simultaneous harms cannot defeat standing," but cite cases where multiple sources actually caused the injury. Opp'n at 14-15. Here, Plaintiffs' alleged injury is *only* caused by the Settlement Agreement. This Court should dismiss Plaintiffs' claims against the Rules, because any relief as to the Rules would fail to redress Plaintiffs' injuries. *See, e.g.*, *Delta Const. Co. v. EPA*, 783 F.3d 1291, 1297 (D.C. Cir. 2015) (rejecting "the idea that an injury is redressable for standing purposes so long as a favorable decision would remove one of its multiple regulatory causes, even if the decision would fail to actually redress the injury").

II. The Amended Complaint Fails to State a Claim.

A. The Settlement Agreement Is Not Void for Illegality.

Plaintiffs assert in a conclusory fashion that the Settlement Agreement violates the ACA and the Constitution. Opp'n at 43. Not so. For the reasons stated *infra* at II.C, II.D, the Rules are in accord with the ACA and the Constitution, and those same reasons largely apply to the Settlement Agreement. In addition, it is unclear how the Settlement Agreement could violate the ACA, when the Attorney General's settlement authority and the Agencies' enforcement discretion are not cabined to a particular statutory scheme. It is also unclear how the Settlement Agreement—which necessarily relates to specific plaintiffs rather than groups or classes—could violate equal protection principles or the Establishment Clause. And, of course, many settlement agreements could indirectly affect third-parties, but it is clear that the Settlement Agreement does not violate

the standard set forth in Plaintiffs' cases by purporting to settle or dispose of any of Plaintiffs' claims (as this action illustrates) or imposing "duties or obligations" on third parties. Opp'n at 44.

Plaintiffs also stubbornly insist that the Settlement Agreement violates Supreme Court orders while failing to engage with the Federal Defendants' argument that the Supreme Court in *Zubik* merely instructed the Courts of Appeals to allow the parties the *opportunity* to find a solution that would satisfy all concerns raised at that time—and the Agencies diligently attempted but were unable to find such a solution. *Zubick* did not require the Agencies to continue to impose a substantial burden on employers with sincere religious objections to the contraceptive mandate in perpetuity. And, although Plaintiffs argue that no options beyond Notre Dame's health plan exist that would allow access to contraceptives, Opp'n at 45, they offer no support for this assertion, which, in any event, is wrong. *See* Religious Exemption Rule, 83 Fed. Reg. 57,551 (discussing Title X and other options for obtaining contraceptive coverage).

Plaintiffs also boldly request that this Court deem the Settlement Agreement void and unenforceable because, in their estimation, it is contrary to internal DOJ guidance. Opp'n at 45-47. As an initial matter, this Court should disregard this claim because it is not raised in Plaintiffs' Amended Complaint. *See* Am. Compl. at ¶ 186, ECF No. 43 (alleging that the Settlement Agreement violates several sources of law, not including any DOJ internal guidance). In addition, neither DOJ nor the Attorney General is a party to this case, and it is unclear on what theory Plaintiffs believe the defendant Agencies or their heads have violated internal DOJ guidance.

Furthermore, unlike the cases on which Plaintiffs rely, which involved contracts that allegedly violated various statutes, DOJ's internal guidance does not carry the force of law, and therefore a contract cannot be voided for allegedly failing to comply with it. *See Ctr. for Food Safety v. Salazar*, 898 F. Supp. 2d 130, 153 (D.D.C. 2012) ("[W]hile agency rules that establish

binding norms or agency actions that occasion legal consequences [ ] are subject to review, general statements of [agency] policy are unreviewable." (internal quotation marks and citations omitted)). And in any event, the internal guidance on which Plaintiffs rely is consistent with the Settlement Agreement. That guidance exudes deference to the Attorney General and makes clear that the Attorney General will have the "flexibility and discretion" to "grant[] exceptions" to the guidance in order "to respond to the realities of a particular case."

Plaintiffs' newfound challenge to the unremarkable decision to settle a case through a non-enforcement agreement (which would be worth little if it did not extend to ongoing conduct) reveals the extreme nature of Plaintiffs' position, which would subject all settlement agreements entered into by the United States to judicial review, contrary to DOJ's broad discretion to resolve litigation against the United States. *See* 28 U.S.C. § 516; 28 U.S.C. §§ 517-19.

B. The Final Rules Are Procedurally Proper.

1. The Agencies Engaged in Notice-And-Comment Prior to Promulgating the Final Rules.

Plaintiffs argue that the issuance of interim final rules prior to notice and comment infected the Final Rules with procedural error, notwithstanding that the Final Rules were issued *after* the notice and a full opportunity for comment required by APA § 553. Plaintiffs' argument rests almost entirely on out-of-circuit case law and dubious reasoning. They relegate to a footnote the Seventh Circuit's most closely analogous case, which upheld a final rule because the agency had shown itself "willing to consider, fully and objectively, all comments in the post-promulgation period" and because the absence of an opportunity to comment caused plaintiffs no harm. *U.S.*

Steel Corp. v. EPA, 605 F.2d 283, 291 (7th Cir. 1979).[5] Plaintiffs cannot dispute that they had ample opportunity to comment before the Final Rules issued, and thus any error is harmless.

The cases Plaintiffs cite to support their position that post-promulgation notice and comment procedures cannot cure the failure to provide pre-promulgation notice and comment are all ones in which Plaintiffs challenged the validity *of IFRs*, not of the final rules that came after notice and comment.[6] *See* Opp'n at 40-41 (citing *N.J. Dep't of Envtl. Prot. v. EPA*, 626 F.2d 1038 (D.C. Cir 1980); *Nat. Res. Def. Council v. EPA*, 683 F.2d 752 (3d Cir. 1982); *Steel Corp. v. EPA*, 595 F.2d 207 (5th Cir. 1979); *Air Transp. Ass'n v. Dep't of Transp.*, 900 F.2d 369 (D.C. Cir. 1990); *Advocates for Highway & Auto Safety v. Fed. Highway Admin.*, 28 F.3d 1288 (D.C. Cir. 1994)). They conveniently ignore those cases in which courts have found that a final rule is valid notwithstanding a procedural defect with the interim final rule. *See* MTD at 26 n.9 (collecting cases). They also ignore the numerous cases that have found that the proper remedy for an agency's failure to follow notice-and-comment procedures is the exact remedy plaintiffs have already received, that is, an opportunity to comment. *See id.* (citations omitted).

Plaintiffs rely heavily on a vacated out-of-circuit case to argue that this court should presume that the agencies did *not* maintain an open mind when they assessed comments. *See* Opp'n at 41-42 (citing *Air Transport*, 900 F.2d at 379-80). Numerous other cases do not follow

[5] That *Steel Corp*. resulted from an interpretation of a provision of the Clean Air Act that narrowed the scope of the court's review changes nothing about its applicability—as here, the agency largely affirmed the provisions of an interim final rule when it finalized it, and the Court upheld the rule because the agency had fully considered post-promulgation comments. *Id.* at 285.

[6] Only one of these cases, *NRDC v. EPA*, 683 F.2d 752, 768 (3d Cir. 1982), actually invalidated a final rule issued after notice and comment. In *NRDC*, the plaintiffs challenged only the IFR. Because the IFR delayed certain amendments to other rules, the remedy for the procedural defect in the IFR was to make the amendments effective as of that date. The court thus had to declare the final rule "ineffective" as well to put plaintiffs in the position they would have occupied but for the invalid IFR. *Id.* at 767-68.

that case's lead, however. *See e.g.*, *Salman Ranch, Ltd. v. Comm'r*, 647 F.3d 929, 940 (10th Cir. 2011) (holding that although the regulation at issue was issued in response to litigation and did not undergo notice and comment, "[n]either factor alters our conclusion," and the argument that the rules were infected with procedural error was moot); *see also Grapevine Imps., Ltd. v. United States*, 636 F.3d 1368, 1380-81 (Fed. Cir. 2011); *United States v. Johnson*, 632 F.3d 912 (5th Cir. 2011). Plaintiffs' assertion flies in the face of the understanding that "a presumption of regularity attaches to the actions of Government agencies," *U.S. Postal Serv. v. Gregory*, 534 U.S. 1, 10 (2001), and does not comport with the approach to assessing post-promulgation comments that has been suggested by this circuit, *see Beard v. Comm'r*, 633 F.3d 616, 623 (7th Cir. 2011) (where a temporary regulation issued without notice and comment was "replaced by a nearly identical final regulation, issued after a notice and comment period" the agency would have been entitled to *Chevron* deference), *cert. granted, judgment vacated*, 566 U.S. 971 (2012).

In this case, however, it is clear that the Agencies *did* maintain an open mind in reviewing the comments they received before issuing the Final Rules. *See* MTD at 27-28. Once again, Plaintiffs appear to be conflating procedure with substance—they contend that the Agencies must not have had an open mind because the Final Rules do not reflect Plaintiffs' policy priorities. The Rules describe in great detail their consideration of the more than 110,000 comments. *See* Religious Exemption Rule, 83 Fed. Reg. at 57,540; Moral Exemption & Accommodations for Coverage of Certain Preventative Services Under the ACA, 83 Fed. Reg. 57,592, 57,596 (November 15, 2018) (Moral Exemption Rule). Demonstrating their careful consideration of public comments, the agencies made numerous responsive changes—albeit not ones that amount to the about-face Plaintiffs would prefer. *See* Religious Exemption Rule, 83 Fed. Reg. at 57,556-73; Moral Exemption Rule, 83 Fed. Reg. at 57,613-26.

Plaintiff's other arguments are both incorrect and irrelevant. They argue first that the Settlement Agreement shows that the Agencies did not maintain an open mind with respect to the Final Rules. In actuality, the Agencies decision to settle ongoing litigation was an exercise of their enforcement discretion, which is entirely separate from the rulemaking—the Settlement Agreement applies only to those entities that signed it, and no other parties. *See* Compl., Ex. A, Settlement Agreement, ECF No. 1-1. Thus the Agreement does not "foreclose any possibility of meaningful regulatory changes," let alone amount to an "attempt[] to preempt Congress." *See* Opp'n at 42. Second, the fact that the Government solicited comments on the EBSA Form 700 shows that the Agencies *did* maintain an open mind, not that they did not. *See* Opp'n at 42.

2. Even if Any Procedural Impropriety in the IFRs Could Infect the Final Rules, the IFRs Were Procedurally Proper.

Plaintiffs assert that the agencies were required to go through notice and comment before issuing the IFRs, and that this defect renders the Final Rules unlawful. They note that modifications of the APA's notice and comment requirements must be express. *See* Opp'n at 39. But an agency may bypass those requirements where a subsequent statute "expresses a Congressional intent to depart from normal APA procedures." *Lake Carriers Ass'n v. EPA*, 652 F.3d 1, 6 (D.C. Cir. 2011). Here, there is such a statute. The Agencies may issue "any interim final rules as the Secretar[ies] determine[] are appropriate" in this area, which permits such a departure from the APA. 26 U.S.C. § 9833; 29 U.S.C. § 1191c; 42 U.S.C. § 300gg-92. Plaintiffs' contrary reading would render the express language of the provision entirely superfluous. *See Williams v. Taylor*, 529 U.S. 362, 404 (2000) (explaining that courts "must give effect, if possible, to every clause and word of a statute" (citation omitted)); *United States v. Gray*, 780 F.3d 458, 466 (1st Cir. 2015). Just as the Agencies correctly relied on this authority to issue interim final rules in 2010, 2011, and 2014, they permissibly relied on that same authority to issue these Rules.

C. The Final Rules Are Neither Contrary to Law nor Arbitrary and Capricious.

Although Plaintiffs ask this Court to rubberstamp the non-binding opinions of other federal courts, they have failed to state a claim that the Rules violate the APA.

1. The Final Rules Are Authorized by the ACA.

As previously explained, the Rules are authorized by the ACA's delegation of authority to HRSA (a component of HHS). *See* 42 U.S.C. § 300gg-13(a)(4) (requiring that certain health plans and health insurance issuers cover "with respect to women" such "additional preventive care and screenings . . . as provided for in comprehensive guidelines supported by the [HRSA]"). Plaintiffs' contrary interpretation of the ACA suffers from a glaring error—if it were correct, it would doom not only the Rules, but also the prior exemption for churches and their integrated auxiliaries, and changes to the accommodation.[7] Although Plaintiffs attempt to distinguish this exemption as "rooted in the provisions of the Internal Revenue Code," Opp'n at 28 n.20, it is § 300gg-13(a) that authorizes the exemption for churches and their integrated auxiliaries, not the Internal Revenue Code. Indeed, the Internal Revenue Code provisions Plaintiffs cite, 26 U.S.C. § 6033(a)(1), (a)(3)(A)(i) & (iii), are wholly unrelated to the provision of contraceptive coverage. Although the Agencies borrowed the definition of a "religious employer" from § 6033 when exercising their authority under 42 U.S.C. § 300gg-13(a) to provide the exemption for churches and their integrated auxiliaries, nothing in § 6033 serves as an independent source of authority for the government to create exemptions. The cases cited by Plaintiffs, Opp'n at 26 (citing *Nw. Envtl. Advocs. v. EPA*, 537 F.3d 1006, 1021 (9th Cir. 2008) and *NRDC v. Costle*, 568 F.2d 1369, 1377 (D.C. Cir. 1977)),

[7] The Settlement Agreement, unlike the Rules, need not be authorized by the ACA because the authority to settle civil litigation against the United States arises from a separate statute. And, for the same reasons discussed *supra* at II.A, it does not violate the ACA for the Agencies to enter into a particular non-enforcement settlement agreement—such enforcement discretion was part of the background milieu against which the ACA was enacted.

stand for the proposition that an agency may not act *ultra vires*, but shed no light on the situation here, where Congress has delegated the agency authority to implement regulations.

Also, Plaintiffs misinterpret the word "shall" in the ACA. Opp'n at 26-27. The term imposes a mandatory obligation *on covered plans* to cover the identified preventive services, but it does not limit HRSA's authority (that is, HHS's) to decide both what preventive services must be covered and by what categories of regulated entities. Any contrary conclusion would mean that the Agencies likewise lacked (and continue to lack) the statutory authority to create the exemption for churches and their integrated auxiliaries. Plaintiffs also give insufficient weight to the statutory text stating that the preventive-services requirement applies only "as provided for" and "supported by" HRSA's guidelines, suggesting that "as provided for" indicated that the guidelines would be forthcoming. Opp'n at 27. That distinction does not negate the fact that what, and to what extent, those guidelines provide for and support particular coverage by particular entities is left to HHS's discretion by Congress. Moreover, Plaintiffs' position is already accounted for by the omission of the word "the" in § 300gg-13(a)(4). At a minimum, the statute is ambiguous when read as a whole, and the Agencies' construction is a reasonable one entitled to deference.

Plaintiffs also suggest that Congress's inclusion of the exemption for grandfathered plans suggests that it disfavored other exemptions. Opp'n at 28. But "[t]he force of any negative implication . . . depends on context" and that presumption can only apply when "circumstances support[ ] a sensible inference that the term left out must have been meant to be excluded." *NLRB v. Sw. Gen., Inc.*, 137 S. Ct. 929, 940 (2017) (citations and quotation marks omitted). In *Johnson*, the case cited by Plaintiffs, the Supreme Court was interpreting a single paragraph containing express exemptions, and that context may indeed have reasonably suggested that Congress did not intend other exemptions. Opp'n at 28 (quoting *United States v. Johnson*, 529 U.S. 53 (2000)). No

such implication is warranted, however, with respect to the ACA's preventive-services provision, when Congress was well aware that it had delegated authority relating to the scope of the provision to HRSA, and when Congress had declined to require that contraceptive coverage be included in HRSA's guidelines at all. Indeed, the exemption for grandfathered plans is an umbrella provision of the ACA that is not tied to § 300gg-13(a)(4), and thus provides no insight into HRSA's discretion under that provision.

Plaintiffs also incorrectly seek support from a proposed, but not enacted, conscience amendment to the ACA. Opp'n at 28. Congress's failure to adopt a proposal is a "particularly dangerous ground on which to rest an interpretation" of a statute. *Cent. Bank of Denver, N.A. v. First Inter. Bank of Denver, N.A.*, 511 U.S. 164, 187 (1994). Although Plaintiffs suggest that accommodating religious and moral liberty is against the intent of the ACA, Opp'n at 28-29, in fact, the provision of conscience exemptions is in keeping with the highest ideals of our nation.

2. RFRA Justifies the Expanded Religious Exemption.

Plaintiffs' RFRA arguments also fail—not least because they do not explain how RFRA could authorize (and indeed require) the church exemption but not the Rules.

As an initial matter, Plaintiffs wrongly suggest that the accommodation does not impose a substantial burden on religious exercise. Some employers "have a sincere religious belief that their participation in the accommodation process makes them morally and spiritually complicit" in providing contraceptive coverage, because their "self-certification" triggers "the provision of objectionable coverage through their group health plans." *Sharpe Holdings v. HHS*, 801 F.3d 942 (8th Cir. 2015), *granting cert. and vacating judgment*, --- S.Ct.---, 2016 WL 2842448 (May 16, 2016) (mem.). Just as in *Hobby Lobby*, these employers are put to the untenable choice of either complying with an accommodation process that violates their sincerely held religious beliefs or paying devastating financial penalties. 573 U.S. 682, 719-20. Thus the contraceptive mandate,

even with its accommodation process, imposed the same substantial burden on employers like Notre Dame that the Supreme Court identified in *Hobby Lobby*.

Hobby Lobby establishes that a court's "narrow function . . . in this context is to determine whether the line drawn reflects an honest conviction," as opposed to "tell[ing] the plaintiffs that their beliefs are flawed." 573 U.S. at 724 (cleaned up). That some courts have described RFRA's substantial-burden inquiry as an objective test also does not license courts to second-guess the sincerity of an objector's religious beliefs. *See id.* at 726 (concluding that the mandate imposed a substantial burden on plaintiffs' religious exercise by forcing them to pay an "enormous sum of money"); *Sharpe*, 801 F.3d at 938 (explaining that once a court determines that a religious belief is burdened, "substantiality is measured by the severity of the penalties for noncompliance" (quoting *University of Notre Dame v. Burwell*, 786 F.3d 606, 628 n.1 (7th Cir. 2015) (Flaum, J., dissenting), *cert. granted*, 136 S. Ct. 2007 (2016) (mem.))); *Priests for Life v. HHS*, 808 F.3d 1, 16-21 (D.C. Cir. 2015) (Kavanaugh, J., dissenting from the denial of rehearing en banc).

In remedying a substantial burden, the Agencies also have discretion to create a regulatory exemption that may be broader than strictly necessary to eliminate the substantial burden. *See, e.g.*, *Ricciv. DiStefano*, 557 U.S. 557, 585 (2009) (holding that an entity faced with potentially conflicting legal obligations should be afforded some leeway in resolving that conflict); *Walker v. Beard*, 789 F.3d 1125, 1136-37 (9th Cir. 2015) (denying a religious exemption under RLUIPA, which employs the same substantial burden and compelling interest test as RFRA, from prison rules requiring racially integrated cells given "an objectively strong legal basis" for believing that doing so would violate the Equal Protection Clause). Indeed, even the *California* decision, extensively cited by Plaintiffs, recognized that there is "some space for legislative action neither compelled by the Free Exercise Clause nor prohibited by the Establishment Clause." Order

Granting Pls.' Mot. Prelim. Inj. at 34, *California v. HHS*, No. 17-cv-5783, ECF No. 234 (N.D. Cal. Jan. 13, 2019) (quoting *Cutter v. Wilkinson*, 544 U.S. 709, 719 (2005)).

Plaintiffs nevertheless argue that RFRA permits agencies to provide exemptions only to the extent required by an adverse judicial ruling. Opp'n at 32. But this assertion is at odds with RFRA's plain language, which applies to "the implementation of" "all Federal law," 42 U.S.C. § 2000bb-3(a), and provides that "Government shall not substantially burden a person's exercise of religion" unless strict scrutiny is satisfied, *id.* § 2000bb-1(a), (b). RFRA thus permits, and in some cases requires, agencies to create exemptions (including through regulations) to alleviate substantial burdens on the exercise of religion that would otherwise result from the implementation of federal law. Plaintiffs' contrary understanding would lead to perverse results: Here, for example, absent any court order, the Agencies would not initially have been able to create the accommodation (to which Plaintiffs do not object), and instead the courts would have granted an exemption (to which Plaintiffs *do* object) when objecting employers inevitably invoked RFRA as "a claim or defense" against enforcement of the mandate, 42 U.S.C. § 2000bb-1(c).

Finally, Plaintiffs wrongly assert that the Rules unduly burden the rights of third parties. As an initial matter, the Agencies reasonably concluded that application of the mandate to objecting entities neither serves a compelling interest nor is narrowly tailored to any such interest for multiple reasons, including that (1) Congress did not mandate coverage of contraception; (2) the preventive-services requirement exempts "grandfathered plans"; (3) the prior rules exempted churches and their related auxiliaries, and also effectively exempted entities that participated in self-insured church plans; (4) multiple federal, state, and local programs provide free or subsidized contraceptives; and (5) many entities object to only some contraceptives. *See* Religious Exemption Rule, 83 Fed. Reg. at 57,546-48. That conclusion precludes any finding that

the religious exemption exceeds the Agencies' authority under RFRA on the ground that it allegedly unduly burdens the interests of third parties. *Cf. Benning v. Georgia*, 391 F.3d 1299, 1312-13 (11th Cir. 2004) (holding that RLUIPA's religious exemption does not facially place an undue burden on third parties because RLUIPA allows States to satisfy compelling interests). Furthermore, as the Agencies also reasonably concluded, the burden the mandate places on some employers with religious objections is greater than previously thought, and outweighs the burden on women who might lose contraceptive coverage through their employers or schools (but have options for obtaining it elsewhere). *See* Religious Exemption Rule, 83 Fed. Reg. at 57,546-48.

Furthermore, calling the *loss* of compelled contraceptive coverage a government burden rests on the "incorrect presumption" that "the government has an obligation to force private parties to benefit [ ] third parties and that the third parties have a right to those benefits." *Id.* at 57,549. Before the contraceptive-coverage mandate, women had no entitlement to contraceptive coverage without cost sharing through their health plans. It does not "burden" affected women that the same agencies that created and enforce the mandate also created a limited exemption to accommodate sincere religious objections, because they are no worse off than before the agencies first chose to act. *Cf. Corp. of the Pres. Bishop of the Church of Jesus Christ of Latter-day Saints v. Amos*, 483 U.S. 327, 330-38 & n.15 (1987) (holding that Title VII's religious exemption permitting religious discrimination in employment was consistent with the Establishment Clause despite allowing the employer to terminate a third party because "it was the Church . . . , and not the Government, who put him to the choice of changing his religious practices or losing his job"). And again, the contrary conclusion would mean that the church exemption is not authorized by RFRA.

3. The Final Rules Are Reviewed Only for Reasonableness, Which They Easily Surpass.

Contrary to Plaintiffs' assertions, Opp'n at 34-38, the Agencies met and exceeded the lenient standard for explaining their position and change of position in the Rules.[8] In deciding an arbitrary-and-capricious claim, the question for the Court is whether the agency's decision "was the product of reasoned decisionmaking." *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 52 (1983). This standard is "highly deferential," and the agency's decision is upheld "so long as the [its] path may be reasonably discerned." *Boutte v. Duncan*, 348 F. App'x 151, 154 (7th Cir. 2009) (citation and quotation marks omitted). The same standard applies where, as here, the government's action reflects a change in policy. *See FCC v. Fox Television Stations*, 556 U.S. 502, 514-15 (2009). An agency that changes policy need not demonstrate "that the reasons for the new policy are better than the reasons for the old one," but only that "the new policy is permissible under the statute, that there are good reasons for it, and that the agency believes it to be better." *Id.* at 515.

The Agencies fully satisfied those obligations in issuing the Rules. After reviewing a litany of competing comments and scientific studies regarding the efficacy and health benefits of contraceptives, *see* Religious Exemption Rule, 83 Fed. Reg. at 57,552-55, the Agencies explained that "significantly more uncertainty and ambiguity exists on these issues than the Departments previously acknowledged when we declined to extend the exemption to certain objecting organizations and individuals," *id.* at 57,555. The Agencies' view of the medical evidence is accorded deference because it falls within HHS's expertise, and cannot be deemed arbitrary and capricious given the highly deferential character of that standard. *See Zero Zone, Inc. v. Dep't of*

[8] Plaintiffs' argument that the Settlement Agreement disregarded internal DOJ guidance, Opp'n at 37-38, is addressed *supra* at II.A.

Energy, 832 F.3d 654, 668 (7th Cir. 2016) ("[W]e give great deference to an agency's predictive judgments about areas that are within the agency's field of discretion and expertise. . . . [W]hen reviewing an agency's scientific and technical determinations, a reviewing court must generally be at its most deferential." (citations and quotation marks omitted)). The Agencies also addressed any reliance interests that may have arisen, concluding that "it is not clear that merely expanding exemptions as done in these rules will have a significant effect on contraceptive use," given that "[t]here is conflicting evidence regarding whether the [m]andate alone, as distinct from birth control access more generally, has caused increased contraceptive use, reduced unintended pregnancies, or eliminated workplace disparities, where all other women's preventive services were covered without cost sharing." Religious Exemption Rule, 83 Fed. Reg. at 57,556. Moreover, the Agencies explained at length why the religious and moral objections to providing contraceptive coverage—and to utilizing the accommodation—are more substantial than previously acknowledged. *See id*. at 57,542-48; Moral Exemption Rule, 83 Fed. Reg. 57,592, 57,596-602. And the fact that the Agencies decided not to eliminate the contraceptive-coverage mandate altogether further demonstrates that the Agencies did not ignore factors they had considered in the past and amply satisfied their obligation to provide a reasoned explanation for the change in policy.

Plaintiffs' arguments to the contrary are unconvincing. The Agencies did more than simply state that there was substantial uncertainty, *contra* Opp'n at 36, by "explain[ing] the evidence which [was] available, and . . . offer[ing] a rational connection between the facts found and the choice made," which is precisely what the court in *State Farm* required, 463 U.S. at 52. As the Supreme Court recognized, "an agency may also revoke a standard on the basis of serious uncertainties if supported by the record and reasonably explained. . . . It is not infrequent that the

available data does not settle a regulatory issue and the agency must then exercise its judgment in moving from the facts and probabilities on the record to a policy conclusion." *Id.* at 51-52.

Plaintiffs now tacitly accept that the Agencies need not construe the comments as a democratic contest and choose the most popular option, but they suggest that the Agencies ignored the content of the comments they received. Opp'n at 36 n.25. Not so. The Agencies simply did not *agree* with those comments, but they did engage with them by explaining their disagreement in the Rules. It is, of course, well within an agency's discretion to recognize disagreement and chart a different course. Plaintiffs also suggest, without explanation, that it was "spurious" of the Agencies to examine the evidence on the effectiveness of contraceptive access in decreasing the incidence of unintended pregnancies, Opp'n at 36 n.26, yet of course such examination is precisely what an agency should undertake. And, contrary to Plaintiffs' assertion that the Agencies "provide no rationale" explaining why "the pre-existing accommodation substantially burdens religious exercise such that RFRA authorizes a broader exemption," Opp'n at 37, the Rules do explain the Agencies' position, which is based on the position of commenters and the Agencies that complying with the accommodation "was inconsistent with [the] religious observation or practice" of some entities. Religious Exemption Rule, 83 Fed. Reg. 57,546.

D. Plaintiffs Fail to State Cognizable Constitutional Claims.

1. Plaintiffs Have Not Stated a Valid Establishment Clause Claim.

Federal Defendants' opening brief demonstrated that Plaintiffs fail to state a valid Establishment Clause claim. MTD at 39-43. As the Supreme Court has repeatedly held, "there is room for play in the joints between the Free Exercise and Establishment Clauses, allowing the government to accommodate religion beyond free exercise requirements, without offense to the Establishment Clause." *Cutter v. Wilkinson*, 544 U.S. 709, 713 (2005) (citation and internal punctuation omitted). The Rules and Settlement Agreement serve the legitimate secular purpose

of alleviating significant governmental interference with the exercise of religion, while the Moral Exemption Rule serves the legitimate secular purpose of respecting moral conscience on sensitive issues in the healthcare space. Additionally, the Religious Exemption Rule and Settlement Agreement neither promote nor subsidize any religious belief; rather, they allow those with objections to contraception based on religious beliefs to practice those beliefs as they would in the absence of state-imposed regulations, achieving a more complete separation of church and state.

i. The Rules Do Not Unduly Burden Any Third Parties.

Plaintiffs incorrectly contend that the Rules and Settlement Agreement are inconsistent with the Establishment Clause because they unduly burden third parties, including Plaintiffs. Opp'n at 48-50. This argument fails for the reasons previously set forth in the discussion of RFRA. *See supra* II.C.2. Plaintiffs' attempt to distinguish *Amos*—and the Supreme Court's later decision in *Hosanna-Tabor Evangelical Lutheran Church & School v. EEOC*, 565 U.S. 171 (2012)—is not persuasive. Opp'n at 49 n.33. Contrary to Plaintiffs' assertion, *Amos* broadly addressed the government's authority to alleviate governmental interference with religious organizations' ability to "define and carry out their religious missions," 483 U.S. at 335.

Plaintiffs also incorrectly suggest that the Religious Exemption Rule is an "absolute and unqualified" exception. Opp'n at 48 (citing *Estate of Thornton v. Caldor*, 472 U.S. 703, 710 (1985)). The statute at issue in *Caldor* did not lift any governmental burden on religion, but instead intruded on private relationships by imposing on employers an "absolute duty" to allow employees to be excused from work on the Sabbath day of the employee's choice. *Id*. at 709. Here, by contrast, the government has simply lifted a burden that it itself imposed, *see Amos*, 483 U.S. at 338, and, moreover, has done so only after determining that the burden is not narrowly tailored to achieve any compelling interest. The lifting of a *government-imposed* burden on religious exercise

is permitted under the accommodation doctrine referenced in *Amos*. *See Tex. Monthly, Inc. v. Bullock*, 489 U.S. 1, 18 n.8 (1989) (plurality opinion).[9]

ii. The Rules and Settlement Agreement Do Not Promote Religion.

Federal Defendants' opening brief explained that there is no indication in the Rules or Settlement Agreement of any intention to promote any particular faith or to advance religion in general. Rather, the Rules and Settlement Agreement seek to alleviate certain substantial burdens on religious and moral beliefs. Plaintiffs contend that a circuit split had developed as to whether the accommodation imposed a substantial burden on objecting employers, Opp'n at 50, but those appellate cases are no longer good law, having been vacated in *Zubik*, and, in any event, federal agencies possess an independent obligation to comply with RFRA.

Additionally, Plaintiffs do not dispute that Notre Dame's religious beliefs are sincerely held. Thus, Plaintiffs cannot rely on hypothetical allegations that an unknown employer or school, at some unknown time, might claim the exemption without a sincerely-held religious belief. Opp'n at 51. Moreover, Plaintiffs cite no authority that such an allegation would state an Establishment Clause claim. In any event, Plaintiffs are simply incorrect that the Rules contain no oversight mechanisms aimed at preventing insincere assertions of religious belief. As the Agencies explained, "the Mandate is enforceable through various [statutory] mechanisms" and "[e]ntities

[9] Plaintiffs also misinterpret Free Exercise jurisprudence. Opp'n at 49. Contrary to Plaintiffs' view, the Supreme Court in *United States v. Lee*, 455 U.S. 252, 260 (1982) denied an Amish employer an exemption from social security taxes because "the 'tax system could not function" if denominations could object based on taxes being spent "in a manner that violates their religious belief,'"—not because the request burdened third parties. *Gonzales v. O Centro Espirita Beneficente Uniao do Vegetal*, 546 U.S. 418, 435 (2006) (quoting *Lee*, 455 U.S. at 258). Similarly, the Sunday closing law in *Braunfeld v. Brown*, 366 U.S. 599, 605 (1961) could be constitutionally applied to Jewish business owners in large part because of the "strong state interest in providing one uniform day of rest for all workers," which an exemption would render "unworkable." *Sherbert v. Verner*, 374 U.S. 398, 408 (1963). No such important governmental interests in administrability are present here. *Cf.* Religious Exemption Rule, 83 Fed. Reg. 57,559 & n.56.

that insincerely or otherwise improperly operate as if they are exempt would do so at the risk of enforcement and accountability under such mechanisms." Religious Exemption Rule, 83 Fed. Reg. at 57,558; Moral Exemption Rule, 83 Fed. Reg. at 57,615.

iii. The Existence of the Moral Exemption Underscores the Fact That the Rules and Settlement Agreement Do Not Establish Religion.

As previously explained, the fact that the Rules apply to entities and individuals with secular, non-religious moral beliefs regarding contraception confirms the Rules' secular purpose. Plaintiffs cite no authority for their novel proposition that the mere fact that the Religious Exemption Rule may apply to publicly-traded companies but the Moral Exemption Rule does not, Opp'n at 52, violates the Establishment Clause. The Agencies explained in the moral IFR that "the combined lack of any lawsuits challenging the Mandate by for-profit entities with non-religious moral convictions, and of any lawsuits by any kind of publicly traded entity" had led them "to not extend the expanded exemption in these interim final rules to publicly traded entities, but rather to invite public comment on whether to do so." Moral Exemptions and Accommodations for Coverage of Certain Preventative Services Under the ACA, 82 Fed. Reg. 47,838, 47,851 (Oct. 13, 2017). After considering comments, and without any impermissible religious purpose, the Agencies reasonably chose not to include publicly-traded entities in the moral exemption.

Finally, Plaintiffs' bold argument that the moral exemption itself violates the Establishment Clause, Opp'n at 52-53, rests on flawed logic. Accepting Plaintiffs' argument would require the Court to agree with the following syllogism: (1) The moral exemption applies to convictions that are deeply and sincerely held. (2) Courts have recognized that such moral beliefs can play a role in a nonreligious person's life that is akin to a religion. (3) Therefore, relieving a government-imposed burden on deeply-held moral beliefs violates the Establishment Clause. But the conclusion does not follow from the stated premises; moreover, Plaintiffs cite no case in which a

court found an Establishment Clause violation based on an attempt to relieve burdens on non-religious moral beliefs and the government is not aware of any.[10]

2. Plaintiffs Fail to State Valid Substantive Due Process or Equal Protection Claims.

Plaintiffs fail to state a valid substantive due process claim. Refusing to subsidize—or to require employers to subsidize—contraceptives does not infringe on any protected liberty interest. As explained in Defendants' opening brief, while the Supreme Court has recognized a fundamental right to privacy that encompasses certain decisions about contraceptive use, it has plainly rejected the contention that refusing to fund the exercise of a liberty interest represents an infringement of that interest. *See* MTD at 44-45 (collecting cases). Here, neither the Rules nor the Settlement Agreement prohibit the use of any contraceptives or penalize women for their use. Rather, the Rules merely relieve those with sincere religious and moral objections from the obligation to subsidize or facilitate the subsidization of contraceptives to which they object.

Plaintiffs' contrary contention relies heavily on *Carey*, in which the Supreme Court invalidated a state law directly prohibiting the distribution of contraceptives except by licensed pharmacists. *Carey v. Pop. Servs. Int'l*, 431 U.S. 678 (1977). That reliance is misplaced because the Rules do not prohibit the distribution of contraceptives by anyone. "There is a basic difference between direct state interference with a protected activity and state encouragement of an alternative activity consonant with legislative policy." *Maher v. Roe*, 432 U.S. 464, 475 (1977). The Agencies are under no constitutional obligation to fund contraception (or to force employers or

[10] *Kaufman v. McCaughtry*, 419 F.3d 678 (7th Cir. 2005), does not assist Plaintiffs. In that case, citing *Amos*, the court explained that "in certain circumstances the government may make special accommodations for religious practices that are not extended to nonreligious practices without violating the Establishment Clause," *id*. at 684, but did not address whether an exemption for nonreligious moral practices would violate the Establishment Clause. In any event, the special circumstances justifying the Rules and Settlement Agreement fall within *Amos*'s safe harbor.

schools to fund or facilitate the provision of contraception), and *Harris v. McRae*, decided after *Carey*, made clear that "[a] refusal to fund protected activity, without more, cannot be equated with the imposition of a 'penalty' on that activity." 448 U.S. 297, 317 n.19 (1980); *see also Pl. Parent. of Ind. v. Comm'r of Ind. State Dep't Health*, 699 F.3d 962, 988 (7th Cir. 2012) ("It is settled law that the government's refusal to subsidize abortion does not impermissibly burden a woman's right to obtain an abortion. . . . [thus] Indiana's ban on other forms of public subsidy for abortion providers cannot be an unconstitutional condition that *indirectly* violates the right.").

Nor can Plaintiffs distinguish cases such as *McRae*. Opp'n at 55. Plaintiffs ignore the fact that the exemptions *lift* a government-imposed burden on private entities and individuals. Moreover, Plaintiffs selectively quote *McRae*, omitting the case's recognition that "although government may not place obstacles in the path of a woman's exercise of her freedom of choice, it need not remove those not of its own creation," and "[i]ndigency falls in the latter category." 448 U.S. at 316. Consequently, "[i]t cannot be that because government may not prohibit the use of contraceptives, . . . government, therefore, has an affirmative constitutional obligation to ensure that all persons have the financial resources to obtain contraceptives," as Plaintiffs allege here. *Id.* at 318. Like the subsidization limits in cases like *McRae* and *Rust*, the Rules "do not impinge on the [due process] liberty" protected by the Fifth Amendment.

Finally, Plaintiffs fail to state an equal protection claim. MTD at 44-48. Neither the Rules nor the Settlement Agreement discriminate on the basis of sex, facially or otherwise. Because they do not draw any sex-based distinctions, they are subject only to rational basis review, which they satisfy (as they would intermediate scrutiny, if applicable) because they relate to the important government interest in accommodating sincerely-held religious beliefs and moral convictions.

Notably, Plaintiffs fail to cite any authority suggesting that declining to subsidize contraception (or to force employers or schools to subsidize contraception) constitutes a sex-based equal protection violation. *Caban v. Mohammed*, 441 U.S. 380 (1979), involved a distinction between unwed mothers and unwed fathers in state domestic-relations law, not subsidization. Moreover, neither *International Union v. Johnson Controls*, 499 U.S. 187 (1991), nor the EEOC decision cited by Plaintiffs even involved alleged constitutional violations; instead, they were exclusively concerned with statutory claims (Title VII) not present here. That distinction matters because unlike Title VII, "[t]he equal protection component of the Fifth Amendment prohibits only purposeful discrimination," not disparate impact. *McRae*, 448 U.S. at 323 n.26 (citing *Washington v. Davis*, 446 U.S. 229 (1976)). And distilled to its essence, Plaintiffs' contention is that despite the lack of any sex-based distinction in the Rules or Settlement Agreement, they disparately affect women, but that contention does not state a cognizable equal protection claim on the basis of sex.

Moreover, the Rules do not infringe any fundamental right because, as explained above, the right to privacy that includes decisions about contraceptive use is not infringed by a lack of subsidization of contraceptives. *See McRae*, 448 U.S. at 316. Plaintiffs' contrary argument, Opp'n at 57, simply rehashes their substantive due process claim, which fails as discussed above. And having failed to allege a sex-based equal protection claim *or* a claim of infringement of a fundamental right, Plaintiffs' invocation of jurisprudence governing the intersection of such claims is misdirected. Opp'n at 57-58. Accordingly, rational basis review applies and, as previously explained, MTD at 46-47, the Rules and Settlement Agreement easily satisfy that standard.

CONCLUSION

Federal Defendants therefore respectfully request that the Court dismiss this action for lack of subject matter jurisdiction and failure to state a claim on which relief can be granted.

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Respectfully submitted,

JOSEPH H. HUNT
Assistant Attorney General

JENNIFER D. RICKETTS
Director, Federal Programs Branch

MICHELLE R. BENNETT
Assistant Director, Federal Programs Branch

/s/ Rebecca M. Kopplin
REBECCA M. KOPPLIN
Trial Attorney (California Bar No. 313970)
JUSTIN M. SANDBERG
Senior Trial Counsel
MICHAEL GERARDI
Trial Attorney
CHRISTOPHER R. HEALY
Trial Attorney
DANIEL RIESS
Trial Attorney
United States Department of Justice
Civil Division, Federal Programs Branch
1100 L Street, NW
Washington, D.C. 20001
Telephone: (202) 514-3953
Facsimile: (202) 616-8470
Email: Rebecca.M.Kopplin@usdoj.gov

Counsel for Federal Defendants