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IN THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

THE STATE OF CALIFORNIA; THE STATE OF CONNECTICUT; THE STATE OF DELAWARE; THE DISTRICT OF COLUMBIA; THE STATE OF HAWAII; THE STATE OF ILLINOIS; THE STATE OF MARYLAND; THE STATE OF MINNESOTA, BY AND THROUGH ITS DEPARTMENT OF HUMAN SERVICES; THE STATE OF NEW YORK; THE STATE OF NORTH CAROLINA; THE STATE OF RHODE ISLAND; THE STATE OF VERMONT; THE COMMONWEALTH OF VIRGINIA; THE STATE OF WASHINGTON,

Plaintiffs,

THE STATE OF OREGON,

Plaintiff-Intervenor,

THE STATE OF COLORADO; THE STATE OF MICHIGAN; THE STATE OF NEVADA,

Proposed-Plaintiffs-Intervenors,

v.

ALEX M. AZAR, II, IN HIS OFFICIAL CAPACITY AS SECRETARY OF THE U.S.

4:17-cv-05783-HSG

STATES' OPPOSITION TO DEFENDANTS' AND INTERVENORS' MOTIONS TO DISMISS AND MOTIONS FOR SUMMARY JUDGMENT; STATES' REPLY IN SUPPORT OF STATES' MOTION FOR SUMMARY JUDGMENT

Date: September 5, 2019
Time: 2:00 p.m.
Dept: 2, 4th Floor
Judge: The Honorable Haywood S. Gilliam, Jr.

Action Filed: October 6, 2017

DEPARTMENT OF HEALTH & HUMAN SERVICES; U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES; R. ALEXANDER ACOSTA, IN HIS OFFICIAL CAPACITY AS SECRETARY OF THE U.S. DEPARTMENT OF LABOR; U.S. DEPARTMENT OF LABOR; STEVEN MNUCHIN, IN HIS OFFICIAL CAPACITY AS SECRETARY OF THE U.S. DEPARTMENT OF THE TREASURY; U.S. DEPARTMENT OF THE TREASURY; DOES 1-100,

Defendants,

and,

THE LITTLE SISTERS OF THE POOR, JEANNE JUGAN RESIDENCE; MARCH FOR LIFE EDUCATION AND DEFENSE FUND,

Defendant-Intervenors.

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INTRODUCTION

Women's access to contraceptive care and the corresponding decision about whether and when to use it are fundamental to her freedom and equality. Before the Patient Protection and Affordable Care Act (ACA), more than half of all American women delayed or avoided care due to costs. With the passage of the Women's Health Amendment to the ACA, women have guaranteed "no cost" coverage of all Food and Drug Administration (FDA)-approved contraceptive methods, sterilization, and contraceptive counseling (contraceptive coverage). Since 2012, over 62 million women have benefited from this law, including millions of women in the Plaintiff States.

Defendants' Exemption Rules, if implemented, would steal away the benefits provided by the Women's Health Amendment by allowing nearly any employer, university, or insurer to exempt itself from the contraceptive coverage mandate. These Rules will have short- and long-term consequences for women—and, by extension, for their States. Women will be denied full and equal access to healthcare benefits, and will face financial and logistical obstacles as they struggle to obtain necessary healthcare. As the Defendants explained before the Rules were proposed, "the medical evidence prompting the contraceptive coverage requirement showed that even minor obstacles to obtaining contraception led to more unplanned and risky pregnancies, with attendant adverse effects on women and their families." Resp. Br., *Zubik v. Burwell*, 2016 WL 537623, at *74-75 (Feb. 10, 2016).

The Exemption Rules must be set aside because they violate not only the ACA, but the federal Constitution, as well. As the Supreme Court instructed, this Court should "ensur[e] that women covered by [religious employers'] health plans receive full and equal health coverage, including contraceptive coverage," while protecting the religious beliefs of employers by granting the States' motion and setting aside the Rules. *Zubik v. Burwell*, 136 S. Ct. 1557, 1559-60 (2016). Here, the Court should follow this instruction and set aside the Exemption Rules.

ARGUMENT

I. THE STATES HAVE STANDING

Defendants half-heartedly argue that the States lack standing to challenge the Exemption

Rules.[1] As this Court and the Ninth Circuit have already concluded, however, the States have standing because the Rules will inflict economic injury on them. *California v. Azar*, 351 F. Supp. 3d 1267, 1281-82 (N.D. Cal. 2019); *California v. Azar*, 911 F.3d 558, 571 (9th Cir. 2018) (concluding that the Rules "will first lead to women losing employer-sponsored contraceptive coverage, which will then result in economic harm to the states").

Defendants have conceded that the Ninth Circuit's decision on this point is "controlling." Defs.' Br. (Dkt. No. 30) at 49, Ninth Circuit (No. 19-15072). And the "law of the case doctrine generally precludes reconsideration of 'an issue that has already been decided by the same court, or a higher court in the identical case.'" *Rocky Mountain Farmers Union v. Corey*, 913 F.3d 940, 951 (9th Cir. 2019).

Despite its concession in the Ninth Circuit, and without offering any analysis of the Ninth Circuit's substantive decision on standing, Defendants now suggest in a footnote that the Ninth Circuit decision is not actually controlling because it was rendered at the preliminary injunction stage. Defs. Opp'n at 13 n.6; *see also* Sisters Opp'n at 13. This, however, does not affect the standing inquiry. The Supreme Court has explained that when a preliminary injunction is sought, a plaintiff's burden to demonstrate standing "will normally be no less than that required on a motion for summary judgment." *Lujan v. Nat'l Wildlife Fed'n*, 497 U.S. 871, 907 n.8 (1990). Accordingly, to establish standing for a preliminary injunction and for a motion for summary judgment, a plaintiff cannot "rest on such 'mere allegations,' [as would be appropriate at the pleading stage] 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 v. Defenders of Wildlife*, 504 U.S. 555, 561 (1992). Both this Court and the Ninth Circuit relied not on mere allegations, but on the affidavits setting forth the specific facts as to how the States will be harmed as a result of the Exemption Rules. *California*, 911 F.3d at 572-73 (explaining that the "declarations submitted by the states" demonstrate the states' standing); *California*, 351 F. Supp. 3d at 1282-83. And there is nothing to suggest that the Ninth Circuit's standing analysis was

[1] The States' opposition refers to the Exemption Rules, but to the extent the Court considers the legality of the interim final rules (IFRs), the arguments herein apply to the IFRs as well.

cabined by the preliminary injunction stage of the case. *See also Massachusetts v. U.S. Dep't of Health & Human Servs.*, 923 F.3d 209, 222-228 (1st Cir. 2019) (holding that Massachusetts demonstrated Article III standing to challenge the Exemption Rules at the summary judgment stage).[2]

March for Life seeks to distinguish the Ninth Circuit's holding based on the procedural cause of action that formed the basis for the States' first preliminary injunction. March Opp'n at 12. Such an argument, however, misreads and improperly narrows the Court's opinion. The Court explained that "the record supports the [States'] [] theory" that "the IFRs expanded the number of employers categorically exempt from the ACA's contraceptive coverage requirements, and [the] state will incur significant costs as a result of their resident's reduced access to contraceptive coverage" because "women who lose coverage will seek contraceptive care through state-run programs or programs that the states are responsible for reimbursing." *California*, 911 F.3d at 571. The Court rejected Defendants' argument that there was a "speculative chain of events," and instead explained that "[j]ust because a causal chain links the states to the harm does not foreclose standing." *Id*. at 571-72. By further holding that "[t]here is no requirement that the economic harm be of a certain magnitude," the Court also rejected Defendants' argument that the magnitude of the harm was insufficient. *Id*. at 572; s*ee also Massachusetts*, 923 F.3d at 221-228 (concluding that the State's procedural Administrative Procedure Act (APA) challenge was moot, but nevertheless holding the State had standing to proceed on its substantive claims). As these holdings demonstrate, the Court did not limit its analysis to a procedural injury framework.

[2] Intervenors also assert that the States lack standing because they have not "identif[ied]" an employer that will utilize the Exemption Rules or a woman who will lose coverage. Sisters Opp'n at 13; March Opp'n at 15. Defendants and Intervenors vigorously pressed this same argument in the Ninth Circuit, and the Ninth Circuit squarely rejected it. *California*, 911 F.3d at 572 ("Appellants fault the states for failing to identify a specific woman likely to lose coverage. Such identification is not necessary to establish standing"); Defs.' Br., 2018 WL 1831303, at *25-41 (9th Cir. Apr. 9, 2018); Sisters' Br., 2018 WL 1831304, at *27-38 (9th Cir. Apr. 9, 2018); March Br., 2018 WL 1831305, at *10-49 (9th Cir. Apr. 9, 2018). Moreover, Sisters themselves moved to intervene on the grounds that it intends to use the Exemption Rules in California. Dkt. No. 38 at 1; *see also Pennsylvania v. United States*, No. 17-3752, Oral Arg. at 27:06-28:00 (3d Cir. May 21, 2019) (Counsel for Sisters explaining how Intervenors would utilize the Exemption Rules), available at https://www.ca3.uscourts.gov/oral-argument-recordings.

Moreover, the States continue to assert procedural injuries and continue to challenge the IFRs. *See infra* at 56-59.

Despite the Ninth Circuit's decision, Intervenors argue that the States lack standing because they have purportedly failed to show any injury. Sisters Opp'n at 13; March Opp'n at 14-15. To demonstrate an "injury in fact," the States must show an invasion of a legally protected interest that is concrete and particularized, and harm that is actual or imminent, not conjectural or hypothetical. *Spokeo, Inc. v. Robins*, 136 S. Ct. 1540, 1548 (2016). Here, as explained more fully below, the States have demonstrated that the Rules will damage the States' fiscs: (1) "through increased reliance on state-funded family-planning programs," (2) "through the state-borne costs of unintended pregnancies," and (3) through the negative affects on "women's educational attainment and ability to participate in the labor force, affecting their contributions as taxpayers." *California*, 351 F. Supp. 3d at 1281 (States demonstrated standing on the first two theories); *California*, 911 F.3d at 571 (the "record supports the first theory" and thus not reaching the alternative standing theories); *Clinton v. New York*, 524 U.S. 417, 432-33 (1998); *Alfred L. Snapp & Son, Inc. v. Puerto Rico, ex rel. Barez*, 458 U.S. 592, 601-602 (1982).

First, the States' declarations confirm that the States will bear increased costs of providing contraceptive services to eligible residents who lose coverage as a result of the Rules. Cantwell Decl. ¶ 16-18; Nelson Decl. ¶ 20; Rattay Decl. ¶ 8; Tosh Decl. ¶¶ 31-33; Maisen Decl. ¶ 11; Nguyen Decl. ¶¶ 15-17; Skinner Decl. ¶¶ 21-24; Meyers Decl. ¶ 21; Tomiyasu Decl. ¶ 3; Lightner Decl. ¶¶ 11-14; Tobias Decl. ¶ 4; Ganim Decl. ¶ 6; Gallagher Decl. ¶¶ 18-19; Zerzan-Thul Decl. ¶¶ 9-10; Harris Decl. ¶ 11; Rimberg Decl. ¶ 7; Charest Decl. ¶ 8; Welch Decl. ¶ 10. This is especially true for States like Virginia and Minnesota (and proposed-intervenor Michigan), where there are no contraceptive equity laws requiring insurance plans to cover contraception. Whorley Decl. ¶ 8; Zimmerman Decl. ¶ 4; Charest Decl. ¶ 5.[3]

[3] Even for those states with contraceptive laws, several state laws are not as comprehensive as the contraceptive mandate, and consequently the Rules will cause women in those states to lose coverage. For instance, North Carolina's contraceptive equity law does not require that all FDA-approved methods of contraceptives be covered and does not require no-cost coverage. N.C. Gen. Stat. § 58-3-178; *see also, e.g.*, Wash Rev. Code § 284-43-5150 (does not prohibit cost

The harm is real; even by Defendants' conservative estimates, tens of thousands of women will be affected by the Rules. 83 Fed. Reg. 57536, 57551 n.26 (Nov. 15, 2018). Of this number, more than two in five are residents of the Plaintiff States.[4] Moreover, given that the numerous employers involved in the *Zubik* litigation are likely to avail themselves of the new Rules—as Defendants predict—Defendants appear to have significantly underestimated the Rules' impact on women and the States.[5] *See* Werberg Decl. ¶¶ 5-8; Chance Decl. ¶¶ 7, 15-19, 20-23, Exhs. A-C; *Massachusetts*, 923 F.3d at 223-225 (holding the State had standing based, in part, on Defendants' estimates, including estimates on which entities would utilize the Exemption Rules).[6]

Second, women who lose no-cost contraceptive coverage are more likely to become pregnant, and the States will suffer financial harm as a result of these unintended and often high-risk pregnancies. Kost Decl. ¶¶ 15-18, 24, 28, 38-43; Lawrence Decl. ¶ 9; Grossman Decl. ¶¶ 8-9; Ikemoto Decl. ¶ 5; Jones Decl. ¶ 15; Tosh Decl. ¶ 33; Nelson Decl. ¶ 30; Rattay Decl. ¶¶ 6, 8; Lytle-Barnaby Decl. ¶ 28; Nguyen Decl. ¶ 22; Peterson Decl. ¶ 5; Lightner Decl. ¶ 15; Ganim Decl. ¶ 6; Rimberg Decl. ¶¶ 7-9. For example, long-acting contraceptives such as intrauterine devices (IUDs) are the most effective but have the highest up-front costs. Kost Decl. ¶ 25. Women who lose their contraceptive access are more likely to use an ineffective or less effective

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sharing); Del. Code. Ann. Tit. 18, §§ 3342A, 3559 (same). Additionally, state insurance regulators do not have authority to enforce contraceptive equity laws to self-insured plans, which are regulated by the U.S. Department of Labor, Employee Benefits Security Administration. Jones Decl. ¶ 12; Taylor Decl. ¶ 13; Navarro Decl. ¶ 11; Peterson Decl. ¶ 3; Lightner Decl. ¶ 4; Ganim Decl. ¶ 5; Gobeille Decl. ¶ 3; Kreidler Decl. ¶¶ 12-14.

[4] *See* 2010 Census Briefs, *Age and Sex Composition: 2010*, at 4, 7 (issued May 2011), *available at* https://www.census.gov/prod/cen2010/briefs/c2010br-03.pdf.

[5] This impact extends to providing services for state residents who work for out-of-state employers and students at state universities who have out-of-state insurance. Pomales Decl. ¶ 9; Johnson Decl. ¶ 3; Childs-Roshak Decl. ¶ 16.

[6] Intervenor March for Life alleges that the States' harm is self-inflicted (March Opp'n at 15-17), yet the Ninth Circuit rejected this argument. *California*, 911 F.3d at 573-74. Moreover, Defendants explicitly rely on the "multiple Federal, State, and local programs that provide free or subsidized contraceptives for low-income women" to fill the coverage gap created by the Rules. 82 Fed. Reg. 47792, 47803 (Oct. 13, 2017); 83 Fed. Reg. at 57546, 57548, 57574, 57576 (relying on "federal, state, or local governmental programs"); Rabinovitz Decl. ¶¶ 9-12; Cantwell Decl. ¶ 18 (explaining that all Title X clinics screen patients for California's Family PACT program). In any event, leaving women without any coverage would rob Peter to pay Paul; the States would still bear responsibility for covering the costs associated with the even greater rise in unintended pregnancies that would result.

method, or will fail to use any method at all, leading to unintended pregnancies. Hollier Decl. ¶ 6; Wilson Decl. ¶ 5; Nelson Decl. ¶ 30. Whether these pregnancies end in miscarriage or abortion or result in live birth, the States will share the costs imposed by these medical procedures, both during and after pregnancy. Kost ¶ 54; Tosh Decl. ¶ 33; Rattay Decl. ¶¶ 5, 8; Zimmerman Decl. ¶ 5; Novais Decl. ¶ 3; Wilson Decl. ¶ 5; Maisen Decl. ¶ 11.

Third, the outcomes described above cost the States not only in the short-term, but in the long-term. The States are burdened with the social and economic repercussions flowing from lost opportunities for affected women to succeed in the classroom, participate in the workforce, and contribute as taxpayers. Kost Decl. ¶ 45; Lawrence Decl. ¶ 5; Arensmeyer Decl. ¶ 4; Nelson Decl. ¶ 31; Bates Decl. ¶¶ 3, 6; Meyers Decl. ¶ 26; Childs-Roshak Decl. ¶ 27; Gobeille Decl. ¶ 6; Dutton Decl. ¶ 20. These lifelong consequences for women and their families are severe and inflict lasting harm upon the States. *See California*, 911 F.3d at 1283 n.10.

Additionally, the States have "standing to seek judicial review of governmental action that affects the performance of [their] duties." *Cent. Delta Water Agency v. United States*, 306 F.3d 938, 950-51 (9th Cir. 2002). Here, the Rules directly affect the ability of state agencies to carry out their duties. For instance, as the California Department of Fair Employment and Housing (DFEH) explained, the Rules will "impact the analysis that DFEH must engage in to carry-out its required responsibility under the law," when confronted with claims about gender-based workplace classifications filed in response to women losing coverage. Kish Decl. ¶¶ 12-14; *see also* Jones Decl. ¶¶ 23-24 (explaining that the California Department of Insurance has had to field additional consumer complaints and calls in response to the Rules); Kreidler Decl. ¶ 17.

Lastly, the Intervenors challenge the States' standing to bring constitutional claims. March Opp'n at 18; Sisters Opp'n at 12. However, the APA provides the States with a vehicle to raise their constitutional arguments. 5 U.S.C. § 706(2)(B). Because the States have standing to sue under the APA, they do not need to demonstrate an alternative basis for standing to bring constitutional challenges. *See Scanwell Labs., Inc. v. Shaffer*, 424 F.2d 859, 865-66, 872-73 (D.C. Cir. 1970) (adversely affected party has standing under the APA "regardless of a lack of legal right" under provision to be enforced); *Seeger v. U.S. Dep't of Def.*, 306 F. Supp. 3d 265,

276, 279-80 (D. D.C. 2018) (applying *Scanwell Labs.*). Indeed, Intervenors point to no case for the proposition that a different analytical framework for standing applies for plaintiffs asserting constitutional causes of action in the context of APA claims. Sisters Opp'n at 12.[7]

II. THE EXEMPTION RULES ARE CONTRARY TO LAW

The Exemption Rules must be held "unlawful and set aside" because they are "not in accordance with the law" and are "in excess of statutory jurisdiction." 5 U.S.C. §§ 706(2)(A), 706(2)(C). Specifically, the Rules are contrary to the Women's Health Amendment. Further, the Religious Exemption Rule is neither required nor permitted by the Religious Freedom Restoration Act (RFRA), and the Moral Exemption Rule is not authorized by any Congressional act. The Rules also create unreasonable barriers to healthcare and impede timely access to care, and violate the ACA's nondiscrimination provision.

A. The Exemption Rules Are Contrary to the Women's Health Amendment

The Exemption Rules are contrary to the plain text of the Women's Health Amendment, which specifies that women's preventive services "shall" be provided. 42 U.S.C. § 300gg-13(a)(4). Nothing in the Women's Health Amendment explicitly or implicitly permits Defendants to exempt employers from the statutory requirement. Nor does the existence of the church exemption, a narrow exemption for houses of worship that is not at issue in this case, render these Rules lawful. And Defendants' reliance on *Chevron* is misplaced given the text of the Women's Health Amendment.

[7] Moreover, with regard to an Establishment Clause claim, the Supreme Court has consistently held that legislation constituting a governmental endorsement of religion inflicts cognizable injury per se. *McCreary Cnty., Ky. v. Am Civil Liberties Union of Ky.*, 545 U.S. 844, 870 (2005). Plaintiffs have standing "in a wide variety of Establishment Clause cases." *Catholic League for Religious & Civil Rights v. City & Cnty. of San Francisco*, 624 F.3d 1043, 1049-50 (9th Cir. 2010) (en banc) (collecting cases); *see also Washington v. Trump*, 847 F. 3d 1151, 1160 n.4 (9th Cir. 2017) (State asserting Establishment Clause claim); *Hawai'i v. Trump*, 241 F. Supp. 1119, 1131 n.9 (D. Haw. 2017) (same). The very purpose of the Establishment Clause is to "protect[] States, and by extension their citizens, from the imposition of an established religion by the Federal Government." *Zelman v. Simmons-Harris*, 536 U.S. 639, 677 (2002) (Thomas, J., concurring); *Separation of Church & State Comm. v. City of Eugene*, 93 F. 3d 617, 621 (9th Cir. 1996) (O'Scannlain, J., concurring) ("[C]oncerns about federalism … motivated ratification of the Establishment Clause.").

1. The Exemption Rules Are Contrary to the Plain Language and Legislative History of the Women's Health Amendment

As this Court concluded, the contraceptive mandate is "in fact a statutory mandate." *California*, 351 F. Supp. 3d at 1285. This statutory command was recognized by the Supreme Court when it explained that the "ACA requires an employer's group health plan or group-health-insurance coverage to furnish 'preventive care and screenings' for women." *Burwell v. Hobby Lobby Stores, Inc.*, 573 U.S. 682, 697 (2014). The limited authority delegated to Health Resources and Services Administration (HRSA) was to determine "what types of preventive care must be covered." *Id*. As the Supreme Court explained, "Congress itself . . . did not specify *what types* of preventive care must be covered. Instead, Congress authorized [HRSA], a component of HHS, to make *that* important and sensitive decision." *Id.* (emphasis added); *see also Catholic Health Care System v. Burwell*, 796 F.3d 207, 210 (2d Cir. 2015) ("The ACA does not specify *what types* of preventive care must be covered for female plan participants. Instead, Congress left *that issue* to be determined" by HRSA) (emphasis added). Defendants seek to expand this narrow delegation of authority into the ability to exempt any and all employers from the statutory mandate. The text and legislative history of the statutory scheme forecloses that result, and Defendants' arguments to the contrary are unavailing.

Defendants assert that because HRSA's guidelines regarding preventive services did not exist at the time of the ACA, Congress granted HRSA "broad discretionary authority" to promulgate any and all regulations. Defs. Opp'n at 14. While it is true that the HRSA guidelines were not in existence at the time the ACA was enacted, that does not somehow suggest that Congress *silently* granted HRSA broad authority to re-define the regulated entities, when Congress itself has already answered the question of who must provide preventive services at no cost: "group health plan[s]" and "health insurance issuer[s]." 42 U.S.C. § 300gg-13(a). Nothing suggests that Congress, sub silentio, authorized HRSA to override Congress's explicit determination as to what entities are subject to the preventive services mandate. Moreover, Defendants' atextual reading of the statute would mean that the language of the mandate (*Id*.) has different meanings in different subsections. Under Defendants' reading, regulated entities for

purposes of all other subsections of the mandate are those defined by the statute (group health plans and issuers), but for purposes of the Women's Health Amendment (42 U.S.C. § 300gg-13(a)(4)), the regulated entities are only the subset of plans and issuers selected by HRSA. *See Pennsylvania v. Azar*, 351 F. Supp. 3d 791, 820 (E.D. Pa. 2019) (explaining that Defendants' statutory interpretation is at odds with § 300gg-13(a)); *see also Whitman v. Am. Trucking Assoc.*, 531 U.S. 457, 468 (2001) (It is a basic principle that Congress "does not alter the fundamental details of a regulatory scheme in vague terms or ancillary provisions—it does not, one might say, hide elephants in mouseholes"). Defendants cite no legal authority or canon of statutory construction to arrive at such an interpretation. And such an interpretation is nonsensical, as there is nothing about the need to develop guidelines regarding specific preventative care and screenings for women that would be relevant to the scope of the entities required to actually provide such care.

The fact that Congress did not explicitly use the word "contraceptives" or the phrase "birth control" in the statute does not change the clear language limiting the scope of the authority that Congress explicitly delegated to HRSA. Defs. Opp'n at 14; Sisters Opp'n at 15. There is no dispute that since the enactment of the Women's Health Amendment, HRSA has always concluded that covered preventive services include contraceptives. This is no surprise given that the federal government itself concluded that improved access to contraception is among the ten great public health achievements of the twentieth century. Ex. 57 (D10 00207323); *see also Priests for Life v. U.S. Dep't of Health & Human Servs.*, 808 F.3d 1, 22-23 (D.C. Cir. 2015) (Kavanaugh, J., dissenting from the denial of rehearing en banc) ("It is commonly accepted that reducing the number of unintended pregnancies would further women's health, advance women's personal and professional opportunities, . . . and help break a cycle of poverty that persists when women who cannot afford or obtain contraception become pregnant unintentionally at a young age."). The regulated entities, as defined by Congress, are bound by this statutory mandate to provide the preventive services included in HRSA's guidelines. Defendants cannot, in the guise of preparing guidelines requiring contraceptive coverage, alter Congress's direction that health plans and issuers "shall" provide that coverage.

Similarly, Defendants claim that because Congress omitted the words "evidence-based" or "evidence-informed" from the Women's Health Amendment, the Court should read into this omission a "positive grant of [delegated] authority" to HRSA "to exempt anyone [it] wish[es] from the contraceptive mandate." Defs. Opp'n at 15; *California*, 351 F. Supp. 3d at 1285. That interpretation goes beyond what such an omission can bear. *See MCI Telecommunications Corp. v. Am. Tel. & Tel. Co.*, 512 U.S. 218 (1994) (concluding the FCC did not have authority to exempt certain carriers from requirement that all carriers "shall" file tariffs with the FCC, despite a provision allowing the FCC to "modify any requirement"). Congress did not, silently, grant Defendants unfettered authority to create sweeping exemptions from the statute's unqualified mandate that coverage "shall" include preventive services.

Additional statutory text within the ACA confirms that Congress considered what statutory exemptions might be appropriate under the Act because (a) Congress exempted grandfathered plans from the contraceptive mandate, and (b) Congress granted specific religious exemptions to other ACA statutory mandates (aid-in-dying legislation). Defendants concede that the exemption for grandfathered plans is "significant" but assert that this explicit Congressional exemption somehow impliedly translates to greater authority for the Defendants to craft *their own* exemptions. Defs. Opp'n at 16. To the contrary, where Congress creates exceptions in the statute, "additional exceptions are not to be implied." *Hillman v. Maretta*, 569 U.S. 483, 496 (2013). There is no authority—and Defendants cite none—for the notion that because Congress creates specific exceptions, federal agencies have equal authority to carve out their own, additional exceptions to the statute.

Similarly, Defendants argue that "*Congress* has long recognized the need for protecting objections of conscience in the area of health care." Defs. Opp'n at 19. But Congress *did* consider such objections in promulgating the ACA and created such exemptions in aid-in-dying provisions (42 U.S.C. § 18113); Congress did not create an exemption for the preventive services mandate. Defendants fail altogether to address this point, and again, do not cite any authority for their argument that where Congress can—and does—create "conscience exemptions," that express action by Congress silently also grants agencies the authority to carve out their own,

additional conscience exceptions from Congressional mandates.[8] Precisely the opposite is true under the law. *Syed v. M-I, LLC*, 853 F.3d 492, 501 (9th Cir. 2017) (concluding that "in light of Congress's express grant" of an exclusion, "the familiar judicial maxim *expressio unius est exclusio alterius* counsels against finding additional, implied exceptions").

Defendants are also incorrect that their Exemption Rules comport with the purpose of the Women's Health Amendment. Defs. Opp'n at 18; *California v. Block*, 663 F.2d 855, 860 (9th Cir. 1981) (the Court's "primary task when testing the statutory authority of a challenged regulation must always be to determine the intent of Congress"); *Syed*, 853 F.3d at 501 ("'an implied exception to an express statute is justifiable only when it comports with the basic purpose of the statute'"). Congress enacted the Women's Health Amendment to promote access to affordable women's healthcare. Specifically, the Women's Health Amendment sought to ensure that "women of America [ ] have the same access to preventive care and screening services as the women of Congress." 155 Cong. Rec. S12026 (Dec. 1, 2009) (Sen. Mikulski). At that time, federal health plans covered contraception. Ex. 9 (D4 000406). More broadly, the Women's Health Amendment was enacted to reduce gender disparities, eliminate charging women more for healthcare than men, improve women's preventative care services and screening, and improve women's access to family planning. *See, e.g.*, 155 Cong. Rec. S12030 (Dec. 1, 2009) (Sen. Dodd). As Defendants acknowledge, "Congress, by amending the Affordable Care Act during the Senate debate to ensure that recommended preventive services for women are covered adequately . . . recognized that women have unique healthcare needs and burdens [and] [s]uch needs include contraceptive services." 77 Fed. Reg. 8725, 8727 (Feb. 15, 2012). Thus, Defendants' purported authority to create exemptions does not comport with the basic purpose of

[8] Defendants' reliance on *Rodriguez v. United States*, 480 U.S. 522, 525-26 (1987) (per curiam), is similarly misplaced. *Rodriguez* dealt with the scope of judicial authority in criminal sentencing matters. That is far afield from the issue here which is whether Defendants had the power to create exceptions to a statutory mandate. *La. Pub. Serv. Comm'n v. FCC*, 476 U.S. 355, 374 (1986) ("an agency literally has no power to act . . . unless and until Congress confers power upon it"); *City & County of San Francisco v. Sessions*, 372 F. Supp. 3d 928, 943 (N.D. Cal. 2019) (same); *City of Los Angeles v. Sessions*, 293 F. Supp. 3d 1087, 1095 (C.D. Cal. 2018) (same).

the statute; "to the contrary," it frustrates Congress's goal of ensuring women have full and equal access to healthcare. *Syed*, 853 F.3d at 501-02.[9]

Subsequent acts of Congress confirm their intent, such that adopting Defendants' interpretation would be tantamount to "giv[ing] a reading to [an] Act that Congress considered and rejected." *Pacific Gas & Elec. Co. v. State Energy Res. Conservation & Dev. Comm'n*, 461 U.S. 190, 220 (1983); *see also Aaron v. Sec. & Exch. Comm'n*, 446 U.S. 680, 694 n.11 (1980) (finding "further support for [the Court's] interpretation" based on "the fact that Congress was expressly informed" on the issue on two occasions "and on each occasion Congress left" the issue undistributed). As this Court recognized, in 2012, the Senate was presented with "the so-called conscience amendment, which would have enabled any employer or insurance provider to deny coverage based on its asserted 'religious beliefs or moral convictions.'" *California*, 351 F. Supp. 3d at 1286 (citing *Hobby Lobby*, 573 U.S. at 744 (Ginsburg, J. dissenting)). While Defendants seek to diminish the relevance of this failed amendment (Defs. Opp'n at 17), it is directly applicable to the analysis here as its supporters conceded that the ACA was "the first time the Federal Government had passed a healthcare law that didn't include" language that would authorize exemptions for religious beliefs or moral convictions. 158 Cong. Rec. S1116 (Feb. 29, 2012) (Sen. Blunt). Further, those supporting the amendment made repeated reference to the Women's Health Amendment, which they further admitted does "not allow purchasers, plan sponsors, and other stakeholders with religious or moral objections to specific items or services to decline providing or obtaining coverage of such items." *Id*. at S539 (Feb. 9, 2012). In rejecting the amendment, "Congress left health care decisions—including the choice among contraceptive methods—in the hands of women, with the aid of their health care providers." *Hobby Lobby*, 573 U.S. at 744 (Ginsburg, J. dissenting).

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[9] Defendants are also incorrect to characterize the Women's Health Amendment as serving only "marginal advances." Defs. Opp'n at 18. Since the contraceptive-coverage requirement took effect, more than 62 million women nationwide have benefited. Ex. 49 (D10 00207142), Ex. 49 (D10 00207145-46), Ex. 28 (D10 00195105), Ex. 64 (D10 00208988), Ex. 24 (D9 668958-59), Ex. 63 (D10 00208945). The cost reductions have been significant, with estimates ranging from $483 million to $1.4 billion in savings related to just one form of contraception (the pill) in one year alone. As noted below, access to contraception advances a compelling government interest as several courts, including a majority of the Supreme Court have concluded.

2. The Existence of the Church Exemption—an Exemption Not at Issue in this Litigation—Does Not Render These Broad Exemptions Lawful

Defendants rely on the existence of the "church exemption" to support their position that the Women's Health Amendment authorizes the broad Exemption Rules here. Defs. Opp'n at 14-16 & n.8; *see also* Sisters Opp'n at 14. As explained in the States' Motion at 8-9, in 2011, Defendants exempted houses of worship from the contraceptive mandate, with the understanding that line-level employees of these entities share their employer's religious objection to contraception. 76 Fed. Reg. 46621, 46623 (Aug. 3, 2011). This "church exemption" imported a long-standing and narrowly tailored category of employers defined in the Internal Revenue Code. *Hobby Lobby*, 573 U.S. at 698 (citing 26 U.S.C. § 6033(a)(3)(A)). Defendants recognized that a broader exemption would sweep in employers "more likely to employ individuals who have no religious objection to the use of contraceptive services," and thereby risk "subject[ing] [such] employees to the religious views of [their] employer." 77 Fed. Reg. at 8728. To date, no one has challenged the "church exemption" or Defendants' authority to implement it. Defendants' argument that the "church exemption" authorizes these broader exemptions is without merit.

As this Court already recognized, "the legality of that exemption is not before the Court." *California*, 351 F. Supp. 3d at 1286. And even if it were, whatever authority Defendants might have had to create the church exemption, does not emanate from the Women's Health Amendment. In enacting the exemption, the regulation does not itself reference the Women's Health Amendment. *See* 76 Fed. Reg. at 46625 (The Departments "provide HRSA the discretion to exempt" houses of worship); *id*. at 46624 (same); *id*. at 46623 (same). Thus, by Defendants' own account, the Women's Health Amendment did not grant HRSA the authority to create the church exemption.

This is not to say that the church exemption (or accommodation) is necessarily unlawful: as noted above, that question is not at issue here. It does, however, mean that any authority to promulgate the church exemption is separate from the Women's Health Amendment. *See also* 80 Fed. Reg. 41318, 41325 (July 14, 2015) (recognizing the longstanding governmental recognition of particular sphere of autonomy for houses of worship, such as special treatment in the Internal

Revenue Code); *Zubik* Resp. Br., 2016 WL 537623, at *28, 67-69 (discussing basis for the church exemption); *Geneva Coll. v. Sec'y U.S. Dep't of Health & Human Servs.*, 778 F.3d 422, 443 (3d Cir. 2015) (same), *vacated sub. nom. Zubik*, 136 S. Ct. at 1561; *Little Sisters of the Poor Home for the Ages, Denver, Colo. v. Burwell*, 794 F.3d 1151, 1202 (10th Cir. 2015) (same), *vacated sub. nom. Zubik*, 136 S. Ct. at 1561. Therefore Defendants' effort to characterize the church exemption as an exception to the Women's Health Amendment—and thereby to justify the Exemption Rules—is erroneous.[10]

3. *Chevron* Deference Is Not Warranted

Defendants ask this Court to defer to HRSA's interpretation of the Women's Health Amendment using the analytical framework adopted in *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 842-43 (1984). Defs. Opp'n at 16. But no deference is warranted in this case. *Chevron* cautions that the first step in determining whether an agency's interpretation of the law is entitled to deference is to consider "'whether Congress has directly spoken to the precise question at issue.'" *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 132 (2000); *cf. Baldwin v. United States*, 921 F.3d 836, 842 (9th Cir. 2019) (finding *Chevron* step one satisfied where the statute was "conspicuously silent" on the issue presented). Here, as discussed above, Congress *has* spoken on the issue of *who* must cover preventive services, and therefore, "the inquiry is at an end; the court must give effect to the unambiguously expressed intent of Congress." *Brown & Williamson*, 529 U.S. at 132. In *Brown & Williamson*, the Court explained that no *Chevron* deference would be afforded to the agency based on the Court's review of the plain text of the specific statute, contextual indications, subsequent acts of Congress, and "common sense." *Id*. at 133.

"With these principles in mind," it is clear that Defendants are not entitled to deference. *Id*. Congress itself spoke directly as to which entities were subject to the "preventive services"

[10] As the federal government previously argued, "[i]t would be perverse and profoundly at odds with our Nation's traditions to hold" "that the provision of an exemption for houses of worship" "effectively mandate[es], through RFRA, the extension of the same exemption" "to all religious objectors, a result that could extinguish the statutory rights of millions of people." *Zubik* Resp. Br., 2016 WL 537623, at *68; *see also Zubik*, Oral Arg. at 30 (now-current Solicitor General Noel Francisco: "I am not suggesting that whenever you give an exemption to churches, that exemption has to apply to all other religious organizations").

mandate, and explicitly defined HRSA's limited authority. Similarly, for the same reason, Defendants would not be entitled to any deference if they promulgated a regulation allowing cost sharing for certain preventive services because Congress already foreclosed that possibility when it said that plans and issuers "shall not impose any cost sharing requirements." § 300gg-13(a).

B. The Religious Exemption Rule Is Not Required by RFRA[11]

Congress enacted RFRA "to restore the compelling interest test" after the Supreme Court eliminated it in *Employment Division v. Smith*, 494 U.S. 872 (1990). 42 U.S.C. § 2000bb. RFRA provides that the federal government cannot substantially burden a person's exercise of religion. 42 U.S.C. § 2000bb-1(a). Where federal action is a substantial burden on a person's exercise of religion, RFRA requires that action to be in furtherance of a compelling government interest and the least restrictive means of furthering that compelling government interest. 42 U.S.C. § 2000bb-1(b). Defendants assert that the Religious Exemption Rule is required by RFRA. Given the availability of the current accommodation process, Defendants are incorrect. *See also* States' Mot. at 9-10.

Under the existing accommodation, a nonprofit employer certifies its religious objection to the federal government or to the insurer, and the insurer becomes responsible for providing separate contraceptive coverage for female beneficiaries. 45 C.F.R. § 147.131(c)(2). Upon notification, the government works with the insurer to guarantee that women receive coverage. This process ensures a seamless, automatic mechanism for female employees and dependents to receive contraceptives to which they are statutorily entitled outside of their employer-sponsored health plan. 45 C.F.R. § 147.131.

Defendants assert that the Exemption Rules are required because the existing accommodation violates RFRA. This is erroneous inasmuch as the accommodation: (1) does not substantially burden the exercise of religion because it allows religious objectors to opt out of providing, paying for, referring, contracting, or arranging for contraceptive coverage; (2) furthers the compelling governmental interest in ensuring that women have full and equal access to

[11] RFRA does not apply to the Moral Exemption Rule because RFRA does not extend to moral convictions.

preventive care, including contraceptives, and (3) is the least restrictive means of achieving that compelling government interest. *See* States' Mot. at 21-34.

1. The Accommodation Does Not Substantially Burden the Exercise of Religion

Defendants and Sisters offer three arguments for why the accommodation, in their view, substantially burdens the exercise of religion. First, they claim that the accommodation imposes a substantial burden as a matter of law because to conclude otherwise would be to impermissibly question the beliefs of religious employers. Defs. Opp'n at 23; Sisters Opp'n at 26. Second, they assert that the financial penalty imposed on employers who decline to provide contraceptive coverage or avail themselves of the accommodation constitutes a substantial burden. Defs. Opp'n at 24; Sisters Opp'n at 25-26. Third, they argue that even under the accommodation, the objecting employer's insurer or third party administrator (TPA)[12] uses the employer's "plan" or "contracts" to provide separate contraceptive coverage, and that this alleged "use" of the plan itself imposes a substantial burden. Defs. Opp'n at 25; Sisters Opp'n at 26. All of these contentions are incorrect, and each is addressed in turn.

a. Whether the accommodation substantially burdens the exercise of religion is a legal question for the courts to decide

Defendants and Sisters continue to conflate the *factual* question of whether a religious belief is sincerely held (which is not in dispute here) with the *legal* question of whether a governmental action substantially burdens a person's exercise of religion. *See* Defs. Opp'n at 23; Sisters Opp'n at 26. It is simply untrue to suggest that the States are questioning the sincerity or correctness of religious employers' beliefs. Rather, the point is that—as a matter of law—the way that the accommodation operates does not substantially burden the exercise of religion. That is a quintessentially legal question that courts must decide in all RFRA cases. *See Guam v. Guerrero*, 290 F.3d 1210, 1222 n.20 (9th Cir. 2002) (whether a governmental action "substantially burdens one's religion is a legal question for courts to decide."); *see also Geneva Coll.*, 778 F.3d at 436 ("We may consider the nature of the action required of the appellees, the

[12] A third-party administrator (TPA) is an entity that processes insurance claims or handles certain aspects of employee benefit plans.

connection between that action and the appellees' beliefs, and the extent to which that action interferes with or otherwise affects the appellees' exercise of religion—all without delving into the appellees' beliefs").

Defendants and Sisters' contention, in effect, is that courts must completely defer to litigants on the substantial burden question. But that position cannot be reconciled with the text, legislative history, or case law interpreting RFRA. Their argument would erase the statutory requirement that only *substantial* burdens must pass strict scrutiny. *United States v. Menasche*, 348 U.S. 528, 538-39 (1955) (It is the duty of the Court "to give effect, if possible, to every clause and word of a statute"). By its plain terms, RFRA "accommodates religion" but it does not "wholly exempt religion from the reach of the law." *Little Sisters of the Poor*, 794 F.3d at 1172 (accommodation "may be more burdensome than the [religious objectors] would prefer, and may sometimes subordinate their interests to other policies not of their choosing"); *Priests for Life v. U.S. Dep't of Health & Human Servs.*, 772 F.3d 229, 257-267 (D.C. Cir. 2014) ("In our cosmopolitan nation with its people of diverse convictions, freedom of religious exercise is protected yet not absolute."), *vacated sub. nom. Zubik*, 136 S. Ct. at 1561; *United States v. Lee*, 455 U.S. 252, 257 (1982) ("[n]ot all burdens on religion are unconstitutional"). As the Supreme Court explained, "activities of individuals, even when religiously based, are often subject to regulation" by the government in its exercise of its "undoubted power to promote health, safety, and general welfare." *Wisconsin v. Yoder*, 406 U.S. 205, 220 (1972). RFRA confirms this by providing that only "substantial" burdens must pass strict scrutiny.

The legislative history of RFRA provides a further basis for rejecting Defendants' proffered statutory interpretation. *Abramski v. United States*, 573 U.S. 169, 179 (2014) (court must interpret relevant words of a statute not in a vacuum, but with reference to the statutory history). As the Supreme Court explained, "the word 'substantially' was inserted [into RFRA] pursuant to a clarifying amendment offered by Senators Kennedy and Hatch. In proposing the amendment, Senator Kennedy stated that RFRA, in accord with the Court's pre-*Smith* case law, 'does not require the Government to justify every action that has some effect on religious exercise.'" *Hobby Lobby*, 573 U.S. at 758 (citing 139 Cong. Rec. 26,180 (Oct. 26, 1993)); *see also Priests*

for Life, 772 F.3d at 248 (recognizing the import of the same legislative history); *see also* S. Rep. No. 103-111 (1993) (courts should look to pre-*Smith* cases to interpret "whether the exercise of religion has been substantially burdened"). Congress did not intend for every conceivable burden—no matter how slight—to be justified using a strict scrutiny standard.

Beyond the statutory text and legislative history, an extensive body of case law has developed in the quarter century since RFRA's passage. And it is telling that neither Defendants nor Intervenors have cited a single case, with the arguable exception of *Sharpe Holdings, Inc. v. U.S. Dep't of Health & Human Servs.*, 801 F.3d 927 (8th Cir. 2015) (addressed below), where a court has concluded that a substantial burden on the exercise of religion existed solely because a litigant sincerely believed that it was so. On the contrary, courts have consistently required litigants to demonstrate both the existence of sincerely held religious beliefs, *and* that the governmental action substantially burdened the exercise of those religious beliefs. *See Holt v. Hobbs*, 135 S. Ct. 853, 862 (2015) ("In addition to showing that the relevant exercise of religion is grounded in a sincerely held religious belief, petitioner bore the burden of proving that the Department's grooming policy substantially burdened that exercise of religion."); *Catholic Health Care Sys.*, 796 F.3d at 218 ("the fact that a RFRA plaintiff *considers* a regulatory burden substantial does not make it a substantial burden. Were it otherwise, no burden would be insubstantial").

If sincerely held religious beliefs, by themselves, established a substantial burden as a matter of law, there would be a broad range of governmental and third party conduct that religious adherents could effectively preclude. For example, in *Zubik*, the Baptist Joint Committee for Religious Liberty pointed out that if employers could prevent their insurers from providing separate contraceptive coverage to their employees, "others might say that they cannot do business with any insurer that provides contraception to anyone."[13] As Defendants previously

[13] *See* Baptist Joint Committee for Religious Liberty as Amicus Curiae in Support of Respondents Br., 2016 WL 692850, at *2 (Feb. 17, 2016); *see also* Ninth Circuit Oral Arg. at 13:25-14:46; 29:56-30:23, available at https://www.ca9.uscourts.gov/media/view_video.php?pk_vid=0000015818 (asking whether employers could refuse to provide any physician-based healthcare, or to cover blood transfusions, based on sincerely held religious beliefs).

explained, the religious claims here "assert a right not only to be relieved from the obligation to provide contraceptive coverage themselves, but also to prevent the government from arranging for third parties to fill the resulting gap." *Zubik* Resp. Br., 2016 WL 537623, at *5. The concept of substantial burden is not so far-reaching that it permits private individuals and entities to dictate how the government conducts its affairs with third parties. *See, e.g.*, *Bowen v. Roy*, 476 U.S. 693, 699 (1986) ("The Free Exercise Clause simply cannot be understood to require the Government to conduct its own internal affairs in ways that comport with the religious beliefs of particular citizens.").

b. The financial penalty is irrelevant if the accommodation does not impose a substantial burden

Defendants and Intervenors assert that the financial penalty for not complying with the accommodation substantially burdens the exercise of religion. *See* Defs. Opp'n at 24; Sisters Opp'n at 25; *see* 26 U.S.C. § 4980D(a)-(b) ($100/day tax for non-compliance with the ACA). But if option A (complying with the accommodation process) does not impose a substantial burden, then it is irrelevant if option B (a financial penalty in the alternative) does so. In other words, if complying with the accommodation does not substantially burden the exercise of religion, that is the end of the matter. *Hobby Lobby* itself proves this point. In that case, the Court concluded that complying with the contraceptive mandate or paying the fine substantially burdened the exercise of religion. *Hobby Lobby*, 573 U.S. at 726. But the Court also concluded that complying with the accommodation or paying the fine did *not* substantially burden the exercise of religion in that case. *Id*. at 731 (holding that the accommodation "does not impinge on the plaintiffs' religious belief that providing insurance coverage for the contraceptives at issue here violates their religion"). Yet the monetary fine was identical in both cases. If the financial penalty alone substantially burdened the exercise of religion, the Court could not have reached the result that it did. *Id.*; *see also Catholic Health Care Sys.*, 796 F.3d at 221 (explaining that "this argument is a non sequitur. An objectively insubstantial burden does not become substantial simply because a RFRA plaintiff faces substantial burdens in the alternative"); *Eternal Word Television Network, Inc. v. Sec'y of U.S. Dep't of Health & Human Servs.*, 818 F.3d 1122, 1146

(11th Cir. 2016) (this "view is flawed because any burden (even an objectively insubstantial one) becomes a substantial burden if the penalty is heavy enough"), *vacated* 2016 WL 11503064 (11th Cir. May 31, 2016).

In *Sharpe*, the Eighth Circuit erred by focusing solely on the monetary penalties without considering whether plaintiff's compliance with the accommodation was a substantial burden. The Court simply held that as long as plaintiff's beliefs that complying with the accommodation violated its religion were sincerely held, then participating in the accommodation "is a burden too heavy to bear." 801 F.3d at 937, 941. That holding, however, departs from longstanding RFRA precedent requiring the Court "to examine the acts [plaintiff] must perform—not the effect of the act—to see if it burdens substantially the [plaintiff's] religious exercise." *Geneva Coll.*, 778 F.3d at 440; *Little Sisters of the Poor*, 794 F.3d at 1177 (court must "consider how the law or policy being challenged actually operates and affects religious exercise"); *Navajo Nation v. U.S. Forest Serv.*, 535 F.3d 1058, 1068 (9th Cir. 2008) (en banc); *see also Zubik*, 136 S. Ct. at 1561 (Sotomayor, J., concurring) (explaining that *Sharpe* improperly "ignored" the Court's prior instructions that it expressed no view on the merits, and wrongly interpreted those decisions as signals of where the Court stands).

c. The accommodation does not use the employer's health plan to provide contraceptive coverage

Defendants and Sisters argue that the accommodation substantially burdens the exercise of religion because the objecting employer's insurer or TPA uses the employer's "own contracts" or "plan" to provide the separate contraceptive coverage. Defs. Opp'n at 25; Sisters Opp'n at 26. Defendants' argument is factually incorrect. Under the accommodation, the employer's group health plan—the "contract" between the employer and his insurer—does not provide, pay for, or contract for contraceptive coverage. 45 C.F.R. § 147.131(d)-(e). By law, the insurer "must *expressly exclude* contraceptive coverage from the group health insurance coverage provided in connection with the group health plan and provide *separate* payments for any contraceptive services required to be covered." 45 C.F.R. § 147.131(d)(2)(i) (emphases added). Defendants'

and Intervenors' argument is directly refuted by the plain language of the accommodation regulation. They do not—and cannot—provide any evidence to the contrary.

Nor does the separate contraceptive coverage utilize any "plan infrastructure" associated with the employer's group health plan in any way, including the plan's "network." Sisters Opp'n at 26-28; *see* Borzi Decl. ¶ 16. An "insurance coverage network" is a set of doctors, hospitals, and other providers with which an insurer carrier or TPA has pre-negotiated payment rates. The accommodation ensures that female employees and covered dependents receive contraceptive services from healthcare providers in their existing "insurance coverage networks"—i.e., from their regular doctor. Borzi Decl. ¶ 16. And because those providers already have relationships with the women's insurers and TPAs, they also have the "coverage administration infrastructure" to verify the women's coverage for benefits and bill the insurers and TPAs for contraceptive services. *Id*. But the "networks" and "infrastructure" through which the insurers or TPAs provide contraceptive coverage are not owned or controlled by objecting employers—they are relationships among third-party insurers, TPAs, and healthcare providers. *Id.*; *cf. Catholic Health Care Sys.*, 796 F.3d at 224 (RFRA does not give objector "a blanket religious veto over the government's interactions with others"); *E. Texas Baptist Univ. v. Burwell*, 793 F.3d 449, 461 (5th Cir. 2015) ("The acts that violate [plaintiffs'] faith are the acts of the government, insurers, and [TPAs], but RFRA does not entitle them to block third parties from engaging in conduct with which they disagree"), *vacated sub. nom. Zubik*, 136 S. Ct. at 1561; *Little Sisters of the Poor*, 794 F.3d at 1193 (religious objector "cannot hamstring government efforts to ensure" that women "receive the coverage to which they are entitled under the ACA"); *Geneva Coll.*, 778 F.3d at 441 ("RFRA does not permit person to impose restraints on another's actions because action is religiously abhorrent.").

The result is no different for self-funded plans. When a TPA administering a group health plan receives notification that an eligible employer opts out of providing coverage, the accommodation requires the TPA to arrange for separate contraceptive coverage. *See* Borzi Decl. ¶ 19 (citing 26 C.F.R. § 54.9815–2713AT(b)(2); 29 C.F.R. § 2590.715–2713A(b)(2)); *see also* Volk Decl. Ex. 1 (information on the accommodation sent by a TPA to a plan participant, stating

that the employer does not "contract, arrange, pay, or refer for contraceptive coverage."). The TPA's obligations are enforceable under the Employee Retirement Income Security Act (ERISA). *Id*. (citing 78 Fed. Reg. 39870, 39879-80 (July 2, 2013)). But the fact that ERISA provides the legal authority to require the TPA to provide separate contraceptive coverage does not mean that the separate contraceptive coverage is part of the employer's group health plan coverage. Borzi Decl. ¶ 20. The employer's group health plan coverage remains completely separate from the TPA-provided contraceptive coverage. *Id*. ¶ 19.

Notably, the manner in which the accommodation functions "is typical of religious objection accommodations that shift responsibility to non-objecting entities only after an objector declines to perform a task on religious grounds." *Little Sisters of the Poor*, 794 F.3d at 1183. Quite often, "an affirmative opt out" is required "before another person is required to step in and assume responsibility." *Id*. at n.31 (comparing Utah laws that allow county clerks to opt out of issuing same sex marriage licenses but ensuring that another clerk is able and willing to step in, and pharmacies being allowed to opt out of providing contraceptives so long as they refer patients to other providers, among other examples). The accommodation is consistent with such practices.

Sisters urge this Court to reach a different conclusion based on purported concessions made by the federal defendants in *Zubik* that for self-insured plans, the accommodation uses the employer's health plan. Sisters Opp'n at 27-28. But the federal defendants in *Zubik* squarely rejected the notion that the separate contraceptive coverage was part of the "same plan" or used employers' "plan infrastructure." For example, the federal government stated that "[i]n all cases, the regulations mandate strict separation between the contraceptive coverage provided by an insurer or TPA and other coverage provided on behalf of the employer." *Zubik* Resp. Br., 2016 WL 537623, at *18. Separate payments for that contraceptive coverage "occur entirely outside the employers' plans." *Zubik* Resp. Supplemental Reply Br., 2016 WL 1593410, at *2. "Nor does the government, in fact, provide contraceptive coverage using any 'plan infrastructure' belonging to petitioners." *Zubik* Resp. Br., 2016 WL 537623, at *38. The government acknowledged that if an objecting employer has a self-insured plan subject to ERISA, "the [Defendants'] authority to require the TPA to provide contraceptive coverage derives from

ERISA," and thus "the coverage provided by the TPA is, as a formal ERISA matter, part of the same plan as the coverage provided by the employer." *Id*. But the fact that ERISA provides the legal authority for the government to require the TPA to provide separate contraceptive coverage does not mean that the separate contraceptive coverage is part of the *employer's* group health plan coverage—it is not.[14] *Id.*; *see also* Borzi Decl. ¶ 20; Volk Decl. Ex. 1 (information sent to plan participant that "contraceptive benefits are paid for" by the TPA), Ex. 2 ("Contraceptives Card" provided to plan participant noting that the TPA "will provide separate payments for [] contraceptive services").

Moreover, an "ERISA plan is not a tangible thing. It is simply a set of rules that defines the rights of a beneficiary." Borzi Decl. ¶ 21. In any event, as Defendants previously argued, objecting entities "could avoid any objectionable features of the regulations applicable to such plans by switching to insured plans." *Zubik* Resp. Br., 2016 WL 537623, at *39 n.16. Neither Defendants nor objecting entities have "suggested that the alternative of switching to an insured plan would constitute a substantial burden." *Id*.

2. The Accommodation Furthers a Compelling Government Interest in Providing Women with Full and Equal Access to Preventive Care

If the Court reaches the question whether the accommodation furthers a compelling government interest—the second prong in the RFRA analysis—it should conclude that it does because maintaining women's seamless access to contraceptives is a compelling government interest. As discussed previously, the text, structure, purpose, and legislative history of the Women's Health Amendment demonstrate that Congress viewed women's full and equal access to preventive healthcare—including contraceptive services—as a compelling government interest. *See supra* at 8-13. A majority of Justices on the Supreme Court have endorsed this conclusion, which was also the position of the federal government until recently. *See Hobby Lobby*, 573 U.S.

[14] Solicitor General Verilli's "one fair understanding" comment at oral argument—responding to an ambiguous question about "one insurance package"—does not fatally undermine these statements either. During the same oral argument, General Verrilli also said that separate contraceptive coverage "isn't through that [employer] plan. It's in parallel to that plan." *See* Oral Arg., at 66:16-21, https://www.supremecourt.gov/oral_arguments/argument_transcripts/2015/14-1418_j4ek.pdf; *see also id.* at 77:2-12.

at 761 (Ginsburg, J., dissenting); *id*. at 739 (Kennedy, J., concurring); *see also Priests for Life*, 808 F.3d at 15 (Kavanaugh, J., dissenting from the denial of rehearing en banc) ("*Hobby Lobby* strongly suggests that the Government has a compelling interest in facilitating access to contraception for the employees of these religious organizations."); *Zubik* Resp. Br., 2016 WL 537623 at *58 ("Contraceptive coverage also furthers the compelling interest in ensuring that women have *equal* health coverage."); *see also* 78 Fed. Reg. at 39887 (the contraceptive coverage requirement furthers the government's compelling interest "in safeguarding public health by expanding access to and utilization of recommended preventive services for women" and "assuring that women have equal access to health care services"). Several courts of appeals have correctly reached the same conclusion. *See Univ. of Notre Dame v. Burwell*, 786 F.3d 606, 624 (7th Cir. 2015), *vacated*, 136 S. Ct. 2007 (2016); *Eternal Word*, 818 F.3d at 1151; *Priests for Life*, 772 F.3d at 257-267.

a. The compelling interest in full and equal access to contraception applies with equal force to the female employees of organizations holding religious beliefs

Defendants seek to reframe the interest at stake, by asserting that there is "no compelling government interest in forcing employers with religious objections to provide contraceptive coverage." Defs. Opp'n at 25. As discussed previously, the accommodation expressly *excludes* objecting employers from the provision of contraceptive coverage. But setting aside Defendants' factually erroneous premise, the compelling interest in ensuring access to contraception applies with equal force to the female employees of organizations holding religious beliefs. The Eleventh Circuit found that applying the accommodation to the religious employers in that case furthered the government's compelling interest because "the accommodation ensures that the plaintiffs' female plan participants and beneficiaries—who may or may not share the same religious beliefs as their employer—have access to contraception without cost sharing or additional administrative burdens as the ACA requires." *Eternal Word*, 818 F.3d at 1155. As the Court noted, "poor health outcomes related to unintended or poorly timed pregnancies apply to the plaintiffs' female plan participants or beneficiaries and their children just as they do to the general population." *Id.*; *see also Kaemmerling v. Lappin*, 553 F.3d 669, 683 (D.C. Cir. 2008) (the compelling interests served

by the DNA Act were not diminished when applied to first time, non-violent felons such as the plaintiff). In other words, none of the important benefits associated with access to contraceptives are diminished by the status of the *employer* for whom female employees (and female dependents of male employees) happen to work.

Preventing gender discrimination independently qualifies as a compelling government interest as well. *See Roberts v. United States Jaycees*, 468 U.S. 609, 626 (1984) ("Assuring women equal access to such goods, privileges, and advantages clearly furthers compelling state interests."). Defendants concede that up to 126,400 women will lose contraceptive coverage under the Religious Exemption Rule. 83 Fed. Reg. at 57551 n.26, 57578. Those women will be forced to pay out of pocket for preventive care like contraception, or seek less costly, less effective alternatives due to high costs. Ex. 57 (D10 00207393-00207404). Congress sought to remedy that longstanding inequity when it passed the Women's Health Amendment. *See, e.g.*, States' Mot. at 19. Remediating such longstanding and deeply entrenched gender discrimination and preventing it from reoccurring are compelling interests in their own right that applies with equal force.

Defendants and Sisters further argue that there is no compelling government interest in providing "seamless" contraceptive coverage. Defs. Opp'n at 26; Sisters Opp'n at 29. But they offer no alternative that would further the interests at stake "equally well." *Hobby Lobby*, 573 U.S. at 731. There is no dispute that the Religious Exemption Rule will cause—at a minimum—tens of thousands of women to lose their existing coverage. Even assuming that they qualify to receive contraceptive coverage elsewhere, those women would need to "take steps to learn about, and to sign up for, a new health benefit." *Eternal Word*, 818 F.3d at 1160. That would reimpose the very barriers to contraceptive access that Congress sought to eradicate, and would be less effective at preventing the harms that Congress sought to remedy. *See, e.g.*, States' Mot. at 4. "Seamlessness" is therefore an integral part of furthering Congress's goal of ensuring that women have broad and comprehensive access to affordable contraceptives. As Defendants concluded, every added burden or barrier increases the likelihood that some women will experience an unintended pregnancy, which in turn increases the health risks to those women and their children.

Zubik Resp. Br., 2016 WL 537623, at *57. There is a compelling interest in maintaining contraceptive access for tens of millions of women at risk of experiencing an unintended pregnancy in the most effective way possible. *See* 83 Fed. Reg. at 57579 (estimating that in 2017, "49 million women under 65 years of age received primary health insurance coverage from private sector, third party employment-based, non-grandfathered plans.").[15]

b. The exceptions to the contraceptive mandate do not undermine the compelling interest at stake

Defendants and Intervenors also claim that because there are exceptions to the contraceptive mandate (for houses of worship and grandfathered plans), the interest at stake cannot be "compelling." Defs. Opp'n at 26; Sisters Opp'n at 29. But as discussed previously, those exceptions are narrowly drawn (the "church" exemption) or were transitional measures (grandfathered plans) designed to ease the transition to ACA-compliant plans. States' Mot. at 28-29. Moreover, nearly all laws contain exceptions, including the tax code, the draft, and Title VII prohibitions on employment discrimination. *Zubik* Resp. Br., 2016 WL 537623, at *27. Yet there is little dispute that these laws further compelling interests. Defendants provide no authority for the notion that any exceptions to a generally applicable law necessarily doom any claim that the underlying interest is compelling. The exceptions to the mandate do not undermine the compelling interest that those requirements further.

Defendants also argue that there cannot be a compelling interest where the government "has not asserted such an interest." Defs. Opp'n at 27. As a preliminary matter, Defendants overlook the fact that until recently, their formal position was that the accommodation "furthers a compelling interest in securing for women the full and equal health coverage the Affordable Care

[15] As explained herein at 31-32, RFRA requires that the compelling interest test be "satisfied through application of the challenged law 'to the person'—the particular claimant whose sincere exercise of religion is being substantially burdened." *Hobby Lobby*, 573 U.S. at 726. Instead of the case-by-case adjudication that RFRA contemplates, the Rule allows any employer to self-exempt without the Government's knowledge, and without any individualized consideration of what that employer's religious beliefs are, whether they are sincerely held, whether they are substantially burdened by utilizing the accommodation, and whether there is a compelling interest in applying the accommodation to that specific employer. The Court cannot even assess whether there is a compelling interest in exempting a particular employer from complying with the accommodation because the Religious Exemption Rule automatically exempts nearly any employer who wishes to be exempt.

Act provides. . . ." *Zubik* Resp. Br., 2016 WL 537623, at *54-55. In any event, the Women's Health Amendment was adopted by Congress—not the federal agencies before this Court. It is the statutory text and Congress's stated aims that form the basis for determining whether the contraceptive mandate serves a compelling government interest. *See, e.g.*, *Priests for Life*, 772 F.3d at 263 ("When Congress added the Women's Health Amendment to the ACA, which requires group health plans to include preventive healthcare services for women without cost sharing, it did so precisely to end 'the punitive practices of the private insurance companies in their gender discrimination'" (citing 155 Cong. Rec. 28,842 (Dec. 1, 2009) (Sen. Mikulski)). This Court should determine the compelling interest question by looking to the text, structure, purpose, and legislative history behind the Women's Health Amendment. The recently-adopted litigation position of Defendants should have no bearing on that analysis.

c. Courts must take third party harm into account when considering exemptions under RFRA

Defendants claim that this Court can ignore the third-party harm that will occur if the Religious Exemption Rule goes into effect. Defs. Opp'n at 28 ("RFRA contains no separate limitation on avoiding exemptions that may affect third parties."). That is incorrect as a matter of law; even the Little Sisters acknowledge that "[p]er *Hobby Lobby*, the burdens on third parties are properly considered under the compelling interest test. . . ." Sisters Opp'n at 31. *Hobby Lobby* directly refutes the notion that third party harm is irrelevant under RFRA. The Court explained that "[i]t is *certainly true* that in applying RFRA, 'courts must take adequate account of the burdens a requested accommodation may impose on nonbeneficiaries.'" *Hobby Lobby*, 573 U.S. at 730 n.37) (emphasis added). The Court also emphasized that "we *certainly* do not hold or suggest that 'RFRA demands accommodation of a for-profit corporation's religious beliefs no matter the impact that accommodation may have on . . . thousands of women employed by Hobby Lobby.'" *Id.* at 693 (emphasis added).

Defendants suggest that because the Court in *Hobby Lobby* was relying on cases that pre-date RFRA, this part of the Court's opinion has less force. Defs. Opp'n at 28 n.12 (citing *Estate of Thornton v. Caldor, Inc.*, 472 U.S. 703 (1985)). But that merely underscores the Supreme

Court's consistent practice of evaluating third-party harm over decades of Free Exercise, Establishment Clause, *and* RFRA jurisprudence. The Court has traditionally ruled in favor of religious adherents when the effects of the religious accommodation on third parties (if any) were limited and borne by the government or society as a whole. *See, e.g.*, *Sherbert v. Verner*, 374 U.S. 398, 400 (1963) (holding that South Carolina could not deny unemployment benefits to a claimant who was discharged for refusing to work on the Sabbath); *Yoder*, 406 U.S. at 231, 234 (Wisconsin could not compel Amish parents to comply with the compulsory school-attendance law when the parents and children wished to be exempt in accordance with their religious beliefs). As noted, Congress enacted RFRA "to restore the compelling interest test established" in *Sherbert* and *Yoder*. 42 U.S.C. § 2000bb.

Conversely, the Court has rejected religious accommodations or exemptions when discrete groups of citizens are singled out to bear the costs of another's religious exercise. For example, the Court rejected religious claims that would "impose the employer's religious faith on the employees." *Lee*, 455 U.S. at 261 (refusing to exempt Amish employer and his employees from social security taxes). The Court similarly invalidated accommodations which "would require the imposition of significant burdens on other employees." *Caldor*, 472 U.S. at 710 (invalidating Connecticut statute which gave Sabbath observers an absolute and unqualified right not to work on their chosen day of Sabbath). In a similar vein, the Court struck down a Texas statute exempting only religious periodicals from sales and use taxes (in part) because it "burdens nonbeneficiaries markedly" (i.e., non-religious periodicals). *Texas Monthly, Inc. v. Bullock*, 489 U.S. 1, 15 (1989) (plurality op.). In all of these instances, third parties would carry the burden of another's religious exercise, and that fact played an important role in the ultimate outcome.

Here, the Religious Exemption Rule requires no less than tens of thousands of women to lose contraceptive coverage because of their employers' religious views about contraceptives. That heavy impact on third parties sets this case apart from both traditional Free Exercise Clause cases and every other contraceptive mandate case that has come before the Supreme Court. The common thread in *Hobby Lobby, Wheaton College*, and *Zubik* was the Supreme Court's insistence that no woman would lose access to the full range of FDA-approved contraceptives

because of the accommodation—a result that is no longer the case under the Religious Exemption Rule. *See Hobby Lobby*, 573 U.S. at 693 ("under that accommodation, these women would still be entitled to all FDA-approved contraceptives without cost sharing"); *Wheaton Coll. v. Burwell*, 134 S. Ct. 2806, 2807 (2014) ("Nothing in this interim order affects the ability of the applicant's employees and students to obtain, without cost, the full range of FDA approved contraceptives"); *Zubik*, 136 S. Ct. at 1560-61 ("Nothing in this opinion . . . is to affect the ability of the Government to ensure that women covered by petitioners' health plans 'obtain, without cost, the full range of FDA approved contraceptives.'").

3. The Accommodation Is the Least Restrictive Means of Furthering the Government's Compelling Government Interest

As a final matter, the accommodation meets the "least restrictive means" prong of RFRA because there is no other alternative means of providing full and equal access to healthcare that would work "equally well." *Hobby Lobby*, 573 U.S. at 731; *see also Sherbert*, 374 U.S. at 409 (rejecting alternatives that would be "unworkable"); *Kaemmerling*, 553 F.3d at 684 (rejecting alternative methods of identification that would be "less effective"). In fact, as Defendants admit, they could not develop another approach that would ensure women affected by the rules received full and equal healthcare coverage. 83 Fed. Reg. 57592, 57604 (Nov. 15, 2018); *see also* States' Mot. at 14, 31-32.

Defendants do not respond to any of these arguments. Instead, they claim that because the contraceptive mandate does not further a compelling government interest, "the least-restrictive-means analysis is not relevant." Defs. Opp'n at 32 n.14. Defendants have thus waived any argument that the accommodation is *not* the least restrictive means of furthering the compelling interests at stake, including their suggestion that women take additional steps—outside of their employer-sponsored coverage—and seek out contraceptive coverage through the federal Title X family planning clinics. 83 Fed. Reg. at 57548, 57551; 83 Fed. Reg. at 57605, 57608. The Intervenors essentially concede that Title X, a safety-net program designed for low-income patients, is not "a perfect substitute," but argue that *any* available alternative is sufficient to demonstrate that the mandate and accommodation are not the least restrictive means of ensuring

access to contraceptives. Sisters Opp'n at 31.[16] But the standard is whether an alternative serves the "stated interests equally well." *Hobby Lobby*, 573 U.S. at 731; *see also Eternal Word*, 818 F.3d at 1158-60 (evaluating several contraceptive coverage proposals and concluding that "these proposals are not less restrictive alternatives because they would not serve the government's interests 'equally well.'").

In sum, the Religious Exemption Rule is not required by RFRA.

C. The Religious Exemption Rule Is Not Permitted by RFRA

Defendants assert that even if the Religious Exemption Rule is not required under RFRA, RFRA permits the agencies to promulgate the Rule. This broad interpretation of RFRA suffers from several fatal defects, including that (1) it is contrary to the plain language of RFRA, (2) it would violate the nondelegation doctrine, and (3) it would allow the agencies to pick religious winners and losers. To the extent RFRA grants agencies some authority, that authority must be cabined to only those situations where authorized to do so by RFRA, namely where there is a "substantial burden." And that authority is further limited by Defendants' obligation to abide by and harmonize with other statutes and to obey the limitations imposed by the Establishment Clause.

1. RFRA Does Not Give Agencies Unchecked Leeway to Create Exemptions to Statutory Mandates

Defendants claim that under RFRA all federal agencies have unlimited authority and unchecked "leeway" to craft any religious exemptions to any Congressional mandate, without

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[16] As the record demonstrates, the Title X program is ill-equipped to replicate or replace the seamless contraceptive-coverage requirement. *See* States' Mot. at 14 (citing Ex. 57 (D10 00207405-08), Ex. 44 (D10 00207048-49), Ex. 44 (D10 00207048) ("[A] recent study published in the American Journal of Public Health confirms that reductions in funding for Title X limit the number of patients Title X-funded providers are able to serve, concluding that Congress would have to increase federal funding for Title X by over $450 million to adequately address the existing need for publicly funded family planning services."), Ex. 28 (D10 00195115-18), Ex. 30 (D10 00195141-42), Ex. 64 (D10 00208990-94), Ex. 60 (D10 00207662-66), Ex. 55 (D10 00207247-52), Ex. 57 (D10 00207405-06) ("With its current resources, Title X is only able to serve one-fifth of the nationwide need for publicly funded contraceptive care."), Ex. 82 (D12 00651932-33) (Congressional leaders noting current efforts to undermine and dismantle Title X), Ex. 57 (D10 00207347), Ex. 74 (D11 00373535-39)).

regard to the third party harms that might result, without regard to the purpose of the underlying statute, and with limited judicial oversight. Such an interpretation of RFRA fails for several reasons.

First, RFRA itself contemplates individualized exemptions that would require a legal determination as to whether the government-imposed action is a substantial burden on the individual claimant. 42 U.S.C. § 2000bb-1(a) (discussing "a person's exercise of religion"); *Id*. at (b) (same); *Id*. at (c) (providing judicial relief for "a person"). Congress expressly provided that the "purpose of this chapter" is to (1) "restore the compelling interest test as set forth in *Sherbert v. Verner*, 374 U.S. 398 (1963) and *Wisconsin v. Yoder*, 406 U.S. 205 (1972) and to guarantee its application in all cases where free exercise *is substantially burdened*," and (2) "to provide a claim or defense to persons whose religious exercise *is substantially burdened*." 42 U.S.C. § 2000bb; *Molzof v. United States*, 502 U.S. 301, 307 (2012) (when Congress employs a term of art, "'it presumably knows and adopts the cluster of ideas that were attached to each borrowed word in the body of learning from which it was taken'"); *Sekhar v. United States*, 570 U.S. 729, 733 (2013) ("'if a word is obviously transplanted from another legal source, whether the common law or other legislation, it brings the old soil with it'"). These "cardinal rule[s] of statutory construction" apply with even more force here where Congress cited two Supreme Court cases and explained its legal purpose in enacting RFRA. *Molzof*, 502 U.S. at 301. And, under that established precedent, to determine whether there has been a substantial burden necessarily requires an individualized, legal determination as to whether that person holds a sincerely held religious belief and whether the government's action constitutes a "substantial burden."

Nothing in the plain language of the statute suggests that Congress granted federal agencies the sweeping authority that they now claim to have under RFRA. To the contrary, Congress expressly provided the purpose of RFRA and while it includes judicial relief to individuals—it does not grant any further relief to a person aggrieved or additional, separate authority to the agencies. 42 U.S.C. § 2000bb. Tellingly, Defendants cite no authority that supports their expansive exclusionary interpretation.

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Defendants contend that the States' interpretation of RFRA will force agencies to "await a lawsuit." Defs. Opp'n at 29. This argument is a red herring, unsupported by evidentiary support. "In construing the provisions of a statute, [the court] first analyze[s] its language to determine whether its meaning is plain." *In re HP Inkjet Printer Litigation*, 716 F.3d 1173, 1180 (9th Cir. 2013). The inquiry "begins with the statutory text, and ends there as well if the text is unambiguous." *Id*. Here, the plain language of RFRA requires a determination as to whether a government action constitutes a "substantial burden," which, as explained, is a legal determination for the courts. If there is a substantial burden, the government must "demonstrate,"—which is defined as "meet[ing] the burdens of going forward with the evidence and of persuasion" (§§ 2000bb-2(3))—its action is in furtherance of a compelling government interest and is the least restrictive means. Finally, RFRA provides a specific form of relief for a person who believes that the government violated this statute: judicial relief. §§ 2000bb-1, 2. This overwhelming textual evidence shows that, far from granting Defendants the unconstrained authority that they seek, RFRA simply, "restore[s] the compelling interest test" and "provide[s] a claim or defense to a person." § 2000bb(b). Defendants may find it cumbersome to undertake an individualized analysis, but it is not for the Court to rewrite RFRA's stated purpose or expressly provided form of relief. *Puerto Rico v. Franklin California TaxFree Trust*, 136 S. Ct. 1938, 1949 (2016) ("[O]ur constitutional structure does not permit this Court to 'rewrite the statutes that Congress has enacted,'" even if that means that the aggrieved parties "have to wait for possible congressional action to avert the consequences").[17]

Second, Defendants' argument that RFRA permits the agencies to promulgate broad exemptions to any statute runs afoul of the nondelegation doctrine. Legislative power is vested in

[17] Furthermore, Defendants fail to show that Congress "intended to delegate … decision[s]" of far-reaching "economic and political significance to an agency" in a "cryptic … fashion." *Brown & Williamson*, 529 U.S. at 160 (Congress did not implicitly delegate to the FDA authority to regulate tobacco, "an industry constituting a significant portion of the American economy"); *see also, e.g., Whitman*, 531 U.S. at 468 (Congress did not implicitly give EPA authority to consider costs in setting air-quality standards, which "are the engine that drives nearly all of Title I of the [Clean Air Act]"); *Gonzales v. Oregon*, 546 U.S. 243, 267 (2006) (Congress did not implicitly give the Attorney General "broad and unusual" authority to determine whether physician-assisted suicide is a "legitimate medical purpose" for a drug prescription).

Congress, and that authority may not be delegated to another branch or entity with "unfettered discretion to make whatever laws" it sees fit. *A.L.A. Scherer Poultry Corp. v. United States*, 295 U.S. 495, 537-38 (1935); *Mistretta v. United States*, 488 U.S. 361, 371-72 (1989) ("'Congress generally cannot delegate its legislative power to another Branch.'"); *see also* States' Mot. at 20. This is so because "[i]n the framework of our Constitution, the President's power to see that the laws are faithfully executed refutes the idea that he is to be a lawmaker." *Youngstown Sheet & Tube Co. v. Sawyer*, 343 U.S. 579, 587 (1952); *Mistretta*, 488 U.S. at 371 (nondelegation doctrine is "rooted in the principle of separation of powers" (citing U.S. Const., Art. 1, § 1)). Therefore, agencies may only act to the extent Congress has articulated an "intelligible principle" to which the agencies are "directed to conform." *J.W. Hampton, Jr., & Co. v. United States*, 276 U.S. 394, 409 (1928). To demonstrate that they are acting within their authority, agencies must demonstrate, among other things, that Congress "clearly delineate[d] the general policy" they are acting under "and the boundaries of this [asserted] delegated authority." *Mistretta*, 488 U.S. at 372-73; *Loving v. United States*, 517 U.S. 748, 772 (1996).

Here, Defendants' argument is that under RFRA they have open-ended discretion to waive otherwise applicable laws and that they can utilize this discretion with "leeway" such that it is essentially unreviewable by the Court. Defs. Opp'n at 28-31. Stated differently, Defendants claim that under RFRA (1) the agencies can determine whether a federal statute imposes a "substantial burden;" (2) if they so conclude, they can grant a broad exemption to that statute; (3) without regard to third party harm; (4) without requiring notification to either the government or the affected third parties; and, (5) when agencies do grant broad exemptions, the Court must give them "leeway" and only reverse their action in the narrow circumstance where the action is "arbitrary and capricious." This interpretation would convert RFRA into the most far-reaching delegation of legislative authority, doing great harm to the separation of powers principles that undergird the American system of government and violate the nondelegation doctrine. *See Panama Ref. Co. v. Ryan*, 293 U.S. 388 (1935) (unlimited delegation to President to prohibit interstate and foreign commerce in petroleum, with no requirement for factual findings or conditions for prohibition violated nondelegation doctrine); *Cf. Whitman*, 531 U.S. at 473 (no

violation of the nondelegation doctrine because Congress set concrete limits on the EPA's discretion, providing the requisite "intelligible principles" to guide agency action); *Gundy v. United States*, 2019 WL 2527473, at *4 (U.S. June 20, 2019). As discussed below, this interpretation would also have far-reaching consequences beyond this case.[18]

Third, adopting Defendants' theory will mean that federal agencies will have the ability to pick and choose religious winners and losers. They alone will select which religious exemptions to laws of general applicability that they want to grant—without consequence and with limited judicial review—thereby allowing the government to recognize some religious objections, while ignoring others. *Clark v. Martinez*, 543 U.S. 371, 380-81 (2005) (court should not adopt a statutory construction that would "raise a multitude of constitutional problems"). For example, in the healthcare context alone, Americans across the country have sincerely held religious beliefs and moral objections to several modern medical services and practices. *See, e.g.*, *Robinson v. Children's Hospital Boston*, 2016 WL 1337255 (D. Mass. Apr. 5, 2016) (religious objections to influenza vaccination).[19] This Court should not accept Defendants' invitation to construe RFRA so broadly as to allow the executive to make unchecked decisions about which religions to prefer.[20]

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[18] Moreover, Congress did not delegate to Defendants the right to solely determine whether the government substantially burdens a person's exercise of religion. *Gundy*, 2019 WL 2527473, at *4 (explaining the "nondelegation inquiry always begins (and often almost always ends) with statutory interpretation," including evaluation of the "context, purpose, and history"). As noted, RFRA states that it seeks to restore the compelling interest test, as set forth in *Sherbert* and *Yoder*. 42 U.S.C. § 2000bb. In both of these cases, determination of whether a government action was a substantial burden was a *question of law*. *Sherbert*, 374 U.S. at 403; *Yoder*, 406 U.S. at 218.

[19] *See, e.g.*, *Haines v. N.H. Dep't of Health & Human Servs.*, 2009 WL 1307203 (D.N.H. Apr. 28, 2009) (religious objections to mental health screening); *Children's Healthcare Is a Legal Duty, Inc. v. Min De Parle*, 212 F.3d 1084, 1088 (8th Cir. 2000) (Christian Scientists and other religious groups object to all medical care and consider religion to be the "sole means of healing").

[20] To be clear, the States do not challenge RFRA. Rather, the States challenge Defendants' interpretation of RFRA to justify the broad Religious Exemption Rule at issue in this case. *See I.N.S. v. St. Cyr*, 533 U.S. 289, 299-300 (2001) ("if an otherwise acceptable construction of a statute would raise serious constitutional problems, and where an alternative interpretation of the statute is 'fairly possible,' . . . we are obligated to construe the statue to avoid such problems"); *Kent v. Dulles*, 357 U.S. 116, 130 (1958) (absent explicit terms, the Court will assume that Congress did not intend to raise constitutional questions).

2. To the Extent that RFRA Grants Agencies Some Authority, That Authority May Only Be Invoked Where Required Under the "Substantial Burden" Framework And Still Subject to Separate Limitations

The Exemption Rules exceed the scope of RFRA because the exemptions are not required by RFRA. *See supra* at 15-30. In addition, any exemptions created to comply with RFRA must necessarily be limited by Defendants' obligation to abide by other statutes, including the Women's Health Amendment and Sections 1554 and 1557 of the ACA and limitations imposed by the Establishment Clause. The Exemption Rules fail both of these tests as well.

RFRA itself has limitations. Principally, and as Defendants admit, RFRA is only implicated when there is a "substantial burden" on a person's religious exercise. Defs. Opp'n at 29; 42 U.S.C. § 2000bb(a), (b)(2); *Id.* § 2000bb-1. As this Court and eight courts of appeal have concluded, the accommodation does not impose a substantial burden. *California*, 351 F. Supp. 3d at 1287-88. Further, even if it did, "RFRA does not permit religious exercise to unduly restrict other persons, such as employees, in protecting their own interests, interests the law deems compelling." *Priests for Life*, 772 F.3d at 266; *see also Priests for Life*, 808 F.3d at 26 (Kavanaugh, J.) ("The government may of course continue to require religious organizations' insurers to provide contraceptive coverage to the religious organizations' employers, even if the religious organizations object.").

Defendants' reliance on *Ricci* is equally unavailing. Defs. Opp'n at 31; *Ricci v. DeStefano*, 557 U.S. 557, 582 (2009). As this Court previously concluded, *Ricci* "does not shed light on whether the federal agency has plenary discretion under RFRA to grant any exemption it chooses for laws passed by Congress, including broad exemptions that provide no notice and harms third parties." *California*, 351 F. Supp. 3d at 1293. Indeed, even if this Court were to adopt the *Ricci* standard, which requires the government to show both good faith and "a strong basis in evidence" of statutory liability, Defendants do not even attempt to demonstrate that they have met this standard. *Ricci*, 557 U.S. at 585; *id.* at 582 (agency must act with "extraordinary care"). Nor could they given the numerous courts of appeals that ruled to the contrary on the substantial burden inquiry and given that the Supreme Court itself instructed Defendants to craft a solution

that ensured women receive "full and equal" healthcare coverage. *Zubik*, 136 S. Ct. at 1559-60. Defendants have not provided a "strong basis in evidence" of liability, and have provided no authority that allows them to disregard the Supreme Court's instruction that Defendants ensure that their actions not result in third party harms. *See also Hobby Lobby*, 573 U.S. at 693 ("[W]e certainly do not hold or suggest that RFRA demands accommodation for a for-profit corporation's religious beliefs no matter the impact that accommodation may have on . . . thousands of women").

And, the Supreme Court has repeatedly emphasized that it is ultimately the *courts'* obligation to consider whether religious exemptions are required under RFRA. *See Gonzales v. O Centro*, 546 U.S. 418, 434 (2006) (explaining that "it is the obligation of the courts to consider whether exceptions are required"); *Holt*, 135 S. Ct. at 864 (to the extent that the Court respects agencies' expertise, for instance in running prisons, that "respect does not justify the abdication, conferred by Congress" to determine whether a RFRA exemption is warranted). And, Defendants confirm that they are not "entitled to deference in interpreting RFRA." Defs. Opp'n at 31 n.13.

To be sure, the States' position is not that this Court need come up with a bright-line test for agencies' invocation of RFRA. Rather, the States assert, and the record shows, that the Religious Exemption Rule exceeds the limits of what is lawful, given the Congressional command of the Women's Health Amendment and Sections 1554 and 1557, the requirement that agencies harmonize statutes (to the extent that they conflict), and the harm that these Rules impose on third parties—third parties that the underlying statute itself was designed to aid. *See, e.g.*, *Hosanna-Tabor v. EEOC*, 565 U.S. 171, 190-191 (2012) (declining "to adopt a rigid formula for deciding when an employee qualifies as a minister" under Title VII exemption, and instead concluding that "[i]t is enough" that in the case before the Court, "given all the circumstances," the exception applied). On this record, Defendants' attempt to use any permissive authority under RFRA must fail.

Second, as detailed here, the Women's Health Amendment and Sections 1554 and 1557 place certain mandates on Defendants. *See infra* at 7-14, 39-43. Defendants are not free to disregard the will of Congress expressed in these statutes. *See Texas v. U.S.*, 809 F.3d 134, 183

n.191 (5th Cir. 2015) (concluding that agency had no "leeway" to implement Deferred Action for Parents of American and Lawful Permanent Residents program because "it may not exercise its authority 'in a manner that is inconsistent with the administrative structure that Congress enacted into law.'"). Rather, to the extent there is a conflict (which there is not, as noted above) the agencies are obligated to harmonize the statutes. *Watt v. Alaska*, 451 U.S. 259, 267 (1981) ("We must read the statutes to give effect to each if we can do so while preserving their sense and purpose."). Strikingly, Defendants fail to respond to the States' argument that the agencies must harmonize statutes. States' Mot. at 34. Instead, they argue that because "RFRA does not prescribe the precise remedy," the agencies have free rein, absent a judicial determination that their exercise of that purported authority is "arbitrary and capricious," to craft any remedy they want. Defs. Opp'n at 29-31. This argument is incompatible with the requirement that statutes must be harmonized. *Citizens to Save Spencer Cnty. v. U.S. EPA*, 600 F.2d 844, 871 (D.C. Cir. 1979) (explaining that if there are conflicting statutes the agency must seek to "pursue a middle course that vitiates neither provision but implements to the fullest extent possible the directives of each, and it is the task of a reviewing court to ensure that the agency has effected an appropriate harmonization of the conflicting provisions while remaining within the bounds of that agency's statutory authority"). The accommodation that predated the Exemption Rules is the answer to harmonizing any purported conflict because it is consistent with the "underlying goals and purposes of the legislature in enacting" the Women's Health Amendment and RFRA, "avoid[s] unnecessary hardship or surprise on affected parties" (i.e. women who are entitled statutory benefits and religious objectors who are no longer substantially burdened), and "remain[s] within the general statutory bounds prescribed." *Id.*[21]

[21] And to the extent that there is an irreconcilable conflict, the maxim of statutory construction that a more recent specific statute prevails over an earlier and more general statute would apply. *Security Pacific Nat. Bank v. Resolution Trust Corp.*, 63 F.3d 900, 904 (9th Cir. 1995) (explaining that "[g]enerally a more specific provision of an enactment prevails, in the sense of making an exception to, a more general provision"). Here, the later-enacted and more specific Women's Health Amendment would prevail over the older and more general RFRA statute.

Third, to the extent Defendants have exemption-making authority under RFRA, their actions are still limited by the Establishment Clause, including the numerous Supreme Court cases holding unconstitutional religious accommodations that harm third parties. 42 U.S.C. § 2000bb-4; *see infra* at 27-29. In *Texas Monthly*, Texas defended its sales tax exemption for religious periodicals by arguing that there is play in the joints among the Religion Clauses. 489 U.S. at 17-21. Texas further asserted that it feared violating the Free Exercise Clause and the litigation that would ensue as a result, absent the sales tax exemption. *Id*. Despite these arguments, the Court still struck down Texas's religious exemption, in part, because of the burdens the law imposed on nonbeneficiaries. *Id.* at 15 & 18 n.8; *Lee v. Weisman*, 505 U.S. 577, 587 (1992); *Bd. of Educ. of Kiryas Joel Vill. Sch. Dist. v. Grumet*, 512 U.S. 687, 706 (1994) (Religious "accommodation is not a principle without limits."). As the Supreme Court has thus recognized, whatever play in the joints there is between the Free Exercise Clause and the Establishment Clause, it does not authorize third-party harm.

D. The Moral Exemption Rule Is Not Required or Permitted by Any Law

Aside from the Women's Health Amendment, the Defendants offer no authority for implementing the broad Moral Exemption Rule. *See* Defs. Opp'n at 21. For the reasons set forth above, the Women's Health Amendment does not authorize Defendants to carve out broad exceptions to the mandate. Without citation to authority, Defendants again assert that because *Congress* enacted a statutory exemption to the ACA, Congress also silently authorized Defendants to fashion whatever broad exemptions they might choose, to any and all ACA statutory mandates. *Id*. This theory holds no water. As the Ninth Circuit has held, "'[w]hen Congress provides exceptions in a statute . . . [t]he proper inference . . . is that Congress considered the issue of exceptions and, in the end, limited that statute to the ones set forth.'" *United States v. Valdez*, 911 F.3d 960, 966 (9th Cir. 2018); *Silvers v. Sony Pictures Entm't, Inc.*, 402 F.3d 881, 885 (9th Cir. 2005) (en banc) ("The doctrine of *expressio unius est exclusio alterius* 'as applied to statutory interpretation creates a presumption that when a statute designates certain persons, things, or manners of operation, all omissions should be understood as exclusions.'").

E. The Exemption Rules Violate Section 1554 By Creating Unreasonable Barriers to Care and Impeding Timely Access to Healthcare

Congress expressly prohibited HHS from promulgating "any regulation" that "creates any unreasonable barriers" to medical care *or* "impedes timely access to health care services." 42 U.S.C. § 18114(1), (2). The Rules here do just that, by permitting employers to deny women access to healthcare that has been guaranteed to them by statute. As Defendants have previously explained, requiring "women—and only women—to take burdensome steps 'to learn about, and to sign up for, a new government funded and administered health benefit' in order to get coverage for an important aspect of their medical care" "thwart[s] the basic purposes of the Women's Health Amendment, which was enacted to ensure that women receive *equal* health coverage and to remove barriers to use of preventive services." *Zubik* Resp. Br., 2016 WL 537623, at *29 (emphasis in original) (quoting *Hobby Lobby*, 573 U.S. at 732). Defendants do not defend the Rules as permissible under the statute, but instead argue that the statute does not apply. These arguments lack merit.

Defendants argue that Section 1554 claims are "not reviewable under the APA" because the statute is too broad to be enforced. Defs. Opp'n at 20. This argument is without merit. Several courts have applied Section 1554, and none have found it to be too "open-ended" to be enforced. *See, e.g.*, *California v. Azar*, 2019 WL 1877392, at *22-26 (N.D. Cal. 2019) ("[t]here is no question" that HHS's Title X rule violated Section 1554 because, among other things, "it obfuscate[s] and obstruct[s] patients from receiving information and treatment for their pressing medical needs."), *stayed on other grounds pending appeal*, 2019 WL 2529259 (9th Cir. June 20, 2019); *Mayor & City Council of Baltimore v. Azar*, 2019 WL 2298808, at *8-9 (D. Md. May 30, 2019); *Oregon v. Azar*, 2019 WL 1897475, at *12 (D. Or. Apr. 29, 2019), *stayed on other grounds pending appeal*, 2019 WL 2529259 (9th Cir. June 20, 2019); *Washington v. Azar*, 2019 WL 1868362, at *7 (E.D. Wash. Apr. 25, 2019), *stayed on other grounds pending appeal*, 2019 WL 2529259 (9th Cir. June 20, 2019). In the Oregon case, the court explicitly rejected HHS's argument that Section 1554 is too "overbroad" or "open-ended" to be enforced. *Oregon*, 2019 WL 1897475, at *12 ("[s]imply because Congress specifically sought to limit the general scope of

HHS's rulemaking abilities, . . ., does not render the limitations invalid") (citing *Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 208 (1988) ("It is axiomatic that an administrative agency's power to promulgate legislative regulations is limited to the authority delegated by Congress")); *see also Dep't of Commerce v. New York*, 2019 WL 2619473, at *10 (U.S. June 27, 2019) (statute that constrained Secretary's authority "in a number of ways" was reviewable). Moreover, Defendants' argument is that this Court should simply render Section 1554 entirely meaningless. *United States v. Thomsen*, 830 F.3d 1049, 1057 (9th Cir. 2016) (court is to make "every effort" not to interpret a statute in a manner that renders the statute "inconsistent" or "meaningless").

Here, there is no doubt that the Rules create unreasonable barriers to and impede timely access to care. As a direct result of these Rules and by Defendants' own admissions, over tens of thousands of women will no longer have access to contraceptive coverage. 83 Fed. Reg. 57551 n.26. Without complete coverage, women will need to pay out-of-pocket for their basic care, unless they secure funding from other sources. Ex. 57 (D10 00207394) (without coverage, contraceptives cost $50 per month or upwards of $600 per year); *id*. (cost of IUD exceeds $1000, which equates to a month's salary for a woman working full time at the federal minimum wage of $7.25 an hour); Ex. 57 (D10 00207315, 00207316-17); Ex. 58 (D10 00207500-02). Women who lose coverage will also need to locate and secure a separate qualified medical provider, which may require transferring medical records or re-providing a complete medical history to a new provider to ensure proper care. Ex. 57 (D10 00207368); Ex. 57 (D10 00207390, 00207401) (explaining the importance of seamless holistic coverage to ensure that women's "chosen provider" can "manage all health conditions and needs at the same time"). Women may also need to switch to a less expensive, less effective, contraceptive method given the cost. Ex. 57 (D10 00207395); Ex. 57 (D10 00207316-17). These numerous steps demonstrate that the Rules undeniably create barriers obstructing women's care because this disruption in continuity of care results in delayed or no access to contraception or an unintended pregnancy. Moreover, Defendants' imposition of these obstacles directly conflicts with Congress's intention to remedy these very problems in the first place. *Zubik* Resp. Br., 2016 WL 537623, at *74-75 (relying on

the Institute of Medicine report and explaining that "the medical evidence prompting the contraceptive coverage requirement showed that even minor obstacles to obtaining contraception led to more unplanned and risk pregnancies, with attendant adverse effects on women and their families"); *Priests for Life*, 772 F.3d at 235; *Hobby Lobby*, 573 U.S. at 737-39 (Kennedy, J., concurring).

These harms to women who lose coverage are not justified by the Rules, particularly where (a) there is no "substantial burden" to religious objectors and (b) they contravene the command of the Supreme Court to ensure "that women covered by [objectors'] health plans receive full and equal health coverage, including contraceptive coverage" *Zubik*, 136 S. Ct. at 1560-61. This unreasonableness of the barriers is compounded by the agencies' failure to respond to the numerous significant concerns raised by commenters and their about-face on central questions such as the safety and efficacy of contraception. *See infra* at 50-51. Specifically, Defendants fail to respond to the overwhelming evidence, including their *own* evidence, which demonstrates that the Rules impose unreasonable barriers and harm women; instead, Defendants contend that the Rules do not "impose affirmative barriers on access to contraception." Defs. Opp'n at 20. But nowhere in Section 1554 does the word "affirmative" appear. Congress specifically directed HHS not impede access to healthcare. Undeniably, these Rules will result in women losing coverage—which even Defendants admit (83 Fed. Reg. at 57551 n.26, 57581)—and as a result, women losing coverage will need to seek out that care from somewhere else, a fact that Defendants also admit and that the Ninth Circuit recognized (*id* at 57548, 57551, 57605, 57608; *California*, 911 F.3d at 572-73). Defendants cannot ignore this statutory command of Congress.

F. The Exemption Rules Violate the Nondiscrimination Provision of the ACA

The Rules also violate Section 1557 of the ACA because they permit employers to exclude women from full and equal participation in their employer-sponsored health plan, deny women full and equal healthcare benefits, and license employers to discriminate on the basis of sex. 42 U.S.C. § 18116; 20 U.S.C. § 1681(a). *See Flack v. Wis. Dep't of Health Servs.*, 328 F. Supp. 3d 931, 950 (W.D. Wisc. 2018) (concluding that government exclusion that expressly singled out and barred medically necessary treatments solely on the basis of individual's natal sex was "text-

book discrimination *based on sex*"); *Boyden v. Conlin*, 341 F. Supp. 3d 979, 995-97 (W.D. Wisc. 2018) (exclusion of treatment from insurance coverage for transgender employees violated ACA anti-discrimination provision).

Defendants wholly fail to respond to this argument. Instead, they erroneously equate their obligations under Section 1557 with an Equal Protection analysis, which is not the same as what the statute requires. Defs. Opp'n at 20. Section 1557 incorporates various nondiscrimination statutes, including Title IX of the Education Amendments of 1972, which prohibits discrimination based upon sex. 42 U.S.C. § 18116 (Section 1557); 20 U.S.C. § 1681. It also incorporates the enforcement mechanisms of various antidiscrimination statutes. *Id*. Consequently, numerous courts have held that Section 1557 provides a claim under the ACA that is separate and distinct from a claim for violation of the Equal Protection Clause. *See Flack*, 328 F. Supp. 3d at 951 ("As plaintiffs have already established substantially more than a negligible likelihood of success on their ACA claim, the court need not address plaintiffs' equal protection claim."); *Boyden*, 341 F. Supp. 3d at 998; *Edmo v. Idaho Dep't of Corr*., 2018 WL 2745898, at *8 (D. Idaho June 7, 2018); *Audia v. Briar Place, Ltd.*, 2018 WL 1920082, at *3 (N.D. Ill. Apr. 24, 2018); *see also Fitzgerald v. Barnstable Sch. Comm.*, 555 U.S. 246, 256 (2009). Thus, Defendants must independently refute the claim that the Exemption Rules violate Section 1557—something that they failed to do in their opposition brief, thus waiving any argument. *Ramirez v. City of Buena Park*, 560 F.3d 1012, 1026 (9th Cir. 2009) (claim waived where not addressed in opposition to a motion for summary judgment).

Even if Defendants did not waive their opportunity to respond, it is beyond dispute that employer-provided healthcare plans unlawfully discriminate when they exclude healthcare benefits "used only by women." *See Erickson v. Bartell Drug Co.*, 141 F. Supp. 2d 1266, 1269 (W.D. Wash. 2001) ("In light of the fact that prescription contraceptives are used only by women, [defendant's] choice to exclude that particular benefit from its generally applicable benefit plan is discriminatory."). Employer-sponsored benefits, like health insurance, are part of an employee's wages and benefits for purposes of asserting an anti-discrimination claim. *See Ariz. Governing Comm. For Tax Deferred Annuity & Deferred Comp. Plans v. Norris*, 463 U.S. 1073, 1081

(1983) (considering differential treatment on the basis of sex in retirement benefits). "When an employer decides to offer a prescription plan covering everything except a few specifically excluded drugs and devices, it has a legal obligation to make sure that the resulting plan does not discriminate based on sex-based characteristics and that it provides equally comprehensive coverage for both sexes." *Erickson*, 141 F. Supp. 2d at 1269.

Moreover, the preventive service mandate— 42 U.S.C. § 300gg-13—contains five subsections outlining the mandated preventive services, but Defendants have selected only the Women's Health Amendment for exceptions. Despite established religious objections to vaccines, including those held by Christian Scientists, Defendants have not created exemptions to the immunizations mandate (42 U.S.C. § 300gg-13((a)(2)); *See Real Alternatives v. Dep't Health &Human Servs*, 867 F.3d 338, 364 (3d Cir. 2017) (listing a range of medical treatments that some might find objectionable on religious grounds). Nor have they created an exemption for Jews or Muslims who object to coverage for medications derived from pigs. Nor have they created exemptions for Jehovah's Witnesses for health plans that provide coverage for blood transfusions.

Defendants' Rules inflict the very exclusion, denial, and discrimination that Section 1557 prohibits. The Rules single out a healthcare service utilized *exclusively* by women and permit employers to unilaterally exempt themselves from providing that service, with Defendants' stamp of approval. That the Rules on their face broadly permit employers to exempt themselves from abiding by a statutory requirement, thereby denying women full and equal participation in the health plan, is a direct violation of the ACA's nondiscrimination statute.

III. THE EXEMPTION RULES ARE ARBITRARY AND CAPRICIOUS

The Exemption Rules must be set aside because, as the record demonstrates, Defendants (1) failed to provide a reasoned explanation for their policy reversal, including disregarding record evidence about contraceptives, failing to account for the costs of the Rules, and overlooking congressional intent; (2) failed to provide a reasoned justification for the expansive Exemption Rules; and (3) failed to meaningfully respond to comments. *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) (*State Farm*).

A. Defendants' Unexplained, Unsupported, and Contradictory Findings Render the Rules Arbitrary and Capricious

As a threshold matter, Defendants do not dispute that there are reliance interests at stake. Defs. Opp'n at 33. As such, they must provide a reasoned and detailed explanation and justification for disregarding facts and circumstances that underlay their prior policy. *Encino Motorcars, LLC v. Navarro*, 136 S. Ct. 2117, 2127 (2016); *F.C.C. v. Fox Television Stations, Inc*., 556 U.S. 502, 515 (2009). Defendants have not done so.

Defendants dismiss the safety, efficacy, and benefits of contraception, but the record supports their prior policy rationale supporting the contraception mandate. Defs. Opp'n at 36; Ex. 24 (D9 668955-70); Ex. 25 (D9 669089-90); Ex. 17 (D9 571363, 69-70); Ex. 23 (D9 668358-68). The record shows that the benefits of contraceptives are well established. *See* States' Mot. at 39-43. Indeed, Defendants themselves previously recognized that the scientific and medical evidence demonstrates the health and other benefits of contraceptive services, and it is for a woman and her provider to consider benefits and risks in selecting treatment. 78 Fed. Reg. at 39872-73, 39887-88. They further acknowledged that "[r]esearchers have shown that access to contraception improves the social and economic status of women." 77 Fed. Reg. at 8728. "Contraceptive coverage, by reducing the number of unintended and potentially unhealthy pregnancies, furthers the goal of eliminating [ ] disparit[ies] by allowing women to achieve equal status as healthy and productive members of the job force." *Id*. That is, "by providing women broad access to preventive services, including contraceptive services," disparities are reduced. *Id*. While the Department may wish to disregard this evidence and these earlier findings, an agency action is arbitrary and capricious where the agency "offer[s] an explanation" "that runs counter to the evidence before the agency." *State Farm*, 463 U.S. at 43.

Defendants' assertion that it is unclear whether the mandate has increased contraceptive use (Defs. Opp'n at 34), is likewise unsupported by the record. Defendants previously took the position that the coverage mandate has the benefit of decreasing costs for women, which will improve access and use of contraceptives. States' Mot. at 42; *See Hobby Lobby*, 573 U.S. at 727. The Ninth Circuit recognized that as recently as January 2017, Defendants declined to change the

accommodation in light of the harms to women's access to full and equal healthcare coverage, and later, "failed to specify what developments necessitated the agencies to change their position" when they proposed the Interim Final Rules. *California*, 911 F.3d at 577 (describing Defendants' position as an "unexplained about-face," not entitled to deference); Ex. 19 (D9 666661-62). Defendants' Exemption Rules do not cure the deficiencies already identified by the Ninth Circuit. Defendants concede that the Exemption Rules are substantially the same as the IFRs. *See* Defs.' Supplemental Br., 2018 WL 6044850, at *1, 4 (9th Cir. Nov. 2018).

Defendants' assertion that it is not clear that the Exemption Rules will have a significant effect (Defs. Opp'n at 34), conflicts with their own determination that over 100,000 women will be impacted and their prior determination that the coverage requirement is necessary to address healthcare inequities and is beneficial to women, their families, and society as a whole. Defendants' "unexplained conflicting findings . . . violate the APA." *Organized Vill. of Kake v. Dep't of Agric.*, 795 F.3d 956, 969 (9th Cir. 2015) (en banc) ("[A]n agency may not simply disregard contrary or inconvenient factual determinations that it made in the past"); *see also Nat'l Cable & Telecomms. Ass'n v. Brand X Internet Servs.*, 545 U.S. 967, 981 (2005) (unexplained inconsistency renders an agency interpretation arbitrary and capricious). Defendants' failure to give the reasoned explanation for their reversal required by the APA renders the Rules arbitrary and capricious.

1. Defendants Are Not Entitled to Deference

Defendants invoke agency deference in an attempt to salvage their policy reversal. Defs. Opp'n at 35. But an agency merits no deference when it fails to give a reasoned explanation for its actions. *United Techs. Corp. v. Dep't of Def.*, 601 F.3d 557, 562 (D.C. Cir. 2010) ("[W]e do not defer to the agency's conclusory or unsupported suppositions."); *Arrington v. Daniels*, 516 F.3d 1106, 1113 n.5 (9th Cir. 2008) ("Although our review is deferential, the [agency] is not immune from its responsibility to articulate a rational connection between the facts found and the choices made."). "Where the agency has failed to provide a reasoned explanation, or where the record belies the agency's conclusion, [the court] must undo its action." *County of Los Angeles v. Shalala*, 192 F.3d 1005, 1021 (D.C. Cir. 1999).

Nor is deference warranted because Defendants purportedly applied their "scientific and technical expertise." Defs. Opp'n at 33, 35-36; March Opp'n at 37. The record does not demonstrate that Defendants actually applied any scientific or technical expertise in their conclusions regarding the efficacy and health benefits of contraceptives. Instead, Defendants cited to comments on both sides of the issue and then stated that they "do not take a position on the variety of empirical questions discussed above." 83 Fed. Reg. at 57555.

2. Defendants Fail to Reasonably Account for the Costs of the Exemption Rules

The Exemption Rules are also arbitrary and capricious because Defendants failed to consider all the relevant factors when considering the costs of the rules. As a general rule, the costs of an agency's action are "a relevant factor that the agency must consider before deciding whether to act," and is "an essential component of reasoned decisionmaking under the Administrative Procedure Act." *Mingo Logan Coal Co. v. EPA*, 829 F.3d 710, 732-33 (D.C. Cir. 2016); *see also Michigan v. EPA*, 135 S. Ct. 2699, 2707-08 (2015) ("Agencies have long treated costs as a centrally relevant factor when deciding whether to regulate"). In this case, although Defendants estimate "transfer costs" of $68.9 million (Religious Exemption Rule) and $8,760 (Moral Exemption Rule), Defendants admit that they did not calculate the "related costs [women] may incur for contraceptive coverage or the results associated with any unintended pregnancies." 83 Fed. Reg. at 57574, 57626; *see also* 82 Fed. Reg. at 47823 n.95 (explaining that Defendants' estimate "has a tendency toward underestimation"). Nor do they acknowledge several populations likely to be harmed by the Rules (*see* States' Mot. at 49-51) and the impact on the states' public fiscs. Ex. 57 (D10 00207358), Ex. 57 (D10 00207348-49), Ex. 57 (D10 00207409), Ex. 57 (D10 00207374). Defendants are required to consider these relevant costs as part of a reasoned decisionmaking process. *Michigan*, 135 S. Ct. at 2707. An agency may not "entirely fail[] to consider an important aspect of the problem" when deciding whether regulation is appropriate. *State Farm*, 463 U.S. at 43.

In essence, Defendants promulgated two broad exemptions to a statutory mandate that had benefited millions of women across the country, and they failed to take any reasonable steps to

determine the Rules' many impacts. For instance, Defendants did not survey regulated entities to estimate the possible impact of the Rules. Yet, Defendants know that in 2017, for self-insured plans, there were $38.4 million in contraception claims sought, and these claims were for plans covering approximately 1,823,000 plan participants, and for fully insured plans, the Departments have *no* information. 83 Fed. Reg. at 57576; 82 Fed. Reg. at 47796 (explaining that for fully insured plans, the issuer is expected to bear the costs of contraceptive coverage when an employer uses the accommodation, and thus is not eligible for reimbursement); *id*. at 47818 (in 2015, 60 self-insured plans used the contraceptive user fees adjustment). At a minimum, under the APA, a government agency must "deploy its expertise" to consider and determine an important aspect of the problem before it is chiseled into bureaucratic stone. *Vill. of Barrington, Ill. v. Surface Transp. Bd.*, 636 F.3d 650, 660 (D.C. Cir. 2011); *Genuine Parts Co. v. EPA*, 890 F.3d 304, 312 (2018); Defs. Opp'n at 38-39 (conceding that Defendants implemented the Exemption Rules without knowing the extent to which women would lose their statutorily entitled benefits).

Defendants assert that the alternative to the Exemption Rules proposed by the States and several commenters—that women discuss their healthcare needs, including any purported "uncertainty" or "risks" related to contraceptives, with their personal physician (States' Mot. at 41)—"would not satisfy or mitigate the conscience objections to providing contraceptive coverage." Defs. Opp'n at 38.[22] This response confirms that the Exemption Rules were not promulgated in response to any purported uncertainty about contraceptives, but were issued as a desire to end "years of litigation." But the Ninth Circuit has already rejected the "desire to avoid litigation" as a rational basis for rulemaking. *Organized Vill. of Kake*, 795 F.3d at 970 (rejecting the agency's litigation risk-based justification for rulemaking where the agency "traded one lawsuit for another").

[22] Notably, the States' suggestion is the precise suggestion that HHS made in April 2017, less than six months before the IFRs were issued. *See* Ex. 23 (D9 668356-57, 66) ("The type of birth control you use depends on your health . . . Your doctor can help you decide which type is best for you right now."). *See also* Ex. 24 (D 9 668955-56).

3. The Exemption Rules Do Not Accord with Congressional Intent

Defendants offer that the Exemption Rules comport with Congressional intent because HRSA is a component of HHS, and HRSA has modified guidelines to account for the Exemption Rules. Defs. Opp'n at 39-40. These arguments fail for two reasons. First, the congressional directive to HRSA was to develop "comprehensive guidelines," to ensure women preventive care and screenings without cost sharing. 42 U.S.C. § 300gg-13(a)(4). The directive was not to determine whether some employers are exempt from providing statutorily mandated preventive care, as Defendants' "guideline" modifications establish. *Id*. And, just because HRSA is a component of HHS, does not mean that HHS can direct HRSA to ignore or override a statutory mandate. *Compare Dep't of Commerce*, 2019 WL 2619473, at *12 (where Congress authorized the Secretary, not the Bureau, to make policy choices under the Census Act). Second and as set forth in the States' motion at pages 4-8, HRSA has, since enactment of the ACA in 2010, carried out this statutory duty by convening nationally recognized medical experts to develop and update the medically-approved women's preventive care guidelines. But in this case, Defendants' recent "guideline" modifications are contrary to the advice of its own experts. Ex. 46 (D10 00207106), Ex. 71 (D11 00328171-72), Ex. 58 (D10 00207496-502). Moreover, HHS has its own set of obligations under Sections 1554 and 1557, which it did not abide by in issuing the Rules. An agency acts arbitrarily and capriciously when it ignores its own experts' advice, as Defendants have done here. *Pac. Coast Fed'n of Fishermen's Ass'ns, Inc. v. Nat'l Marine Fisheries Serv.*, 265 F.3d 1028, 1037-38 (9th Cir. 2001); *see also Idaho Sporting Cong., Inc. v. Rittenhouse*, 305 F.3d 957, 969 (9th Cir. 2002).

B. The Exemption Rules Are Not Tailored to Address the Purported "Problems" the Rules Identify

Defendants assert that the Exemption Rules are narrowly tailored to the problems they are intended to address: "religious and moral objections to the provision of the contraceptive coverage" and "years of litigation." Defs. Opp'n at 40-41. As noted, a "desire to avoid litigation" is not a rational basis for rulemaking. *Organized Vill. of Kake*, 795 F.3d at 970; *see also California*, 351 F. Supp. 3d at 1293 ("the courts are not concerned, at all, with the Federal

Defendants' desire to 'avoid litigation,' especially where that avoidance means depriving a large number of women of their statutory rights under the ACA").[23]

Furthermore, Defendants concede that there is no evidence justifying the broad scope of the Religious or Moral Exemption Rules because there is no evidence that certain employers need the Rules. Specifically, Defendants again concede that they are not aware of any publicly traded entities that have religious objections to providing contraceptive coverage, but they nevertheless expand the exemption to include such entities. 83 Fed. Reg. at 57562; *see also* Defs. Opp'n at 41-42. Similarly, Defendants cite only three employers to justify the entirety of the Moral Exemption Rule—all of which have permanent injunctions. 83 Fed. Reg. at 57626 & n.74. This is arbitrary and capricious. *Sorenson Commc'ns Inc. v. FCC*, 755 F.3d 702, 708 (D.C. Cir. 2014) (finding arbitrary and capricious an FCC regulation designed to deter fraud where there was "no evidence of fraud to deter"); *see also Nat'l Fuel Gas Supply Corp. v. FERC*, 468 F.3d 831, 841 (D.C. Cir. 2006) (Kavanaugh, J.) (vacating FERC order where agency had "provided no evidence of a real problem"); *Ariz. Cattle Growers' Ass'n v. U.S. Fish & Wildlife*, 273 F.3d 1229, 1244 (9th Cir. 2001) (holding agency action to be arbitrary and capricious where the basis of the action is "speculation . . . not supported by the record.").

In *Del. Dep't of Nat. Res. & Envtl. Control v. EPA*, 785 F.3d 1, 17-18 (D.C. Cir. 2015) (*DNREC*), the court set aside Environmental Protection Agency (EPA) rules where the EPA failed to explain the need for a nationwide rule that could harm energy markets, and did not address the potential alternative of a more limited rule that could achieve the same result without harming energy markets. Similarly, in *State v. Bureau of Land Mgmt.*, 286 F. Supp. 3d 1054, 1066-67 (N.D. Cal. 2018), this court found that even if the agency had provided factual evidence to support its claim that a new waste reduction rule burdened small operators, a "blanket suspension" of the rule was arbitrary and capricious because the suspension was "not properly tailored" to address the allegedly offending provision. The Exemption Rules must be similarly

[23] Defendants also assert that they now believe "objections to complying with mandate are more *substantial*." Defs. Opp'n at 34. However, whether a government-imposed burden constitutes a substantial burden is a legal question for the court to decide. *See above* at 16-19.

set aside because they are not narrowly tailored to address the purported problems raised by Defendants, particularly where, in light of Defendants' stipulation to injunctions across the country there is serious doubt as to whether these Rules are even needed.[24]

C. Defendants Failed to Respond to the Comments Outlining the Negative Health Impact and Financial Burdens to Women

As they do in the Exemption Rules, Defendants once again summarily dismiss significant comments addressing the negative health impacts and financial burdens of the Rules. *See* States' Mot. at 46-51. Defendants blithely wash their hands of any accountability for the grave consequences likely to result from their Rules, lumping all concerns under the general descriptor of "societal inequality." Defs. Opp'n at 43 (citing 83 Fed. Reg. at 57548, 57549-50). Under the incorrect premise that the ACA does not require contraceptive care, they conclude that "if some third parties do not receive contraception coverage from private parties" "that result exists in the absence of government action—it is not a result the government has imposed." Defs. Opp'n at 43. But Defendants' affirmatively changing the regulatory scheme can hardly be characterized as government "inaction." Moreover, as explained in the Section 1554 section herein, Defendants' Exemption Rules are the direct cause of thousands of women losing coverage. Before the Rules, these women had the coverage and as a direct consequence of the Rules, they will now lose that coverage. As the numerous commenters explain, this will have short-term and long-term impacts on women, their families, and society. *See* States' Mot. at 46-50 (outlining extensive harms and impacts). Defendants' "wan responses to [the] comments" do not fulfil their "obligations under the APA to respond to 'relevant and significant comments.'" *DNREC*, 785 F.3d at 15. Defendants cannot excuse their inadequate responses by passing off on third parties the entirety of the issues raised by these comments. *Id.* "Administrative law does not permit such a dodge." *Id.*

[24] This issue is compounded by the fact that under the Rules, employers need not give any notice to the government or their employees so neither the public nor the government will ever know the extent to which employers are utilizing the Rules, depriving women of their healthcare benefits.

IV. THE EXEMPTION RULES VIOLATE THE ESTABLISHMENT CLAUSE

As explained in the States' motion, government conduct may not have a primary effect, which advances a particular religious practice. States' Mot. at 51-54; *Catholic League for Religious & Civil Rights*, 624 F.3d at 1054-55 (citing *Lemon v. Kurtzman*, 403 U.S. 602, 612-13 (1971)). Conduct unlawfully advances religion by favoring religion at the expense of the rights, beliefs, and health of others. *Corp. of Presiding Bishop of Church of Jesus Christ of Latter-day Saints v. Amos*, 483 U.S. 327, 334-35 (1987) ("At some point, accommodation may devolve into 'an unlawful fostering of religion.'"); *Lee*, 505 U.S. at 586–87. The Religious Exemption Rule unlawfully advances religion in two ways.[25]

First, Defendants replaced their prior regulatory system that imposed no cognizable burden on the exercise of religion, *see* Zubik Resp. Br., 2016 WL 537623, at *41, with expanded exemptions that advance religious objections at the expense of women and their families. *See Caldor*, 472 U.S. at 711 (O'Connor, J., concurring) (government accommodation of religious objections that comes at "the detriment of those who do not share [those objections]" unlawfully advances religion in violation of the Establishment Clause); *Texas Monthly*, 489 U.S. at 14–15, 18 n.8 (exemptions that impose burdens on third parties to permit others to act according to their religious beliefs, are unlawful); *Kiryas Joel*, 512 U.S. at 722 (Kennedy, J., concurring in the judgment) ("[A] religious accommodation demands careful scrutiny to ensure that it does not so burden nonadherents . . . as to become an establishment."). Defendants admit that thousands of women will lose their contraceptive coverage, incur millions of dollars in out-of-pocket costs, and encounter substantial obstacles to accessing care. *See, e.g.*, 78 Fed. Reg. at 39888 (the ACA "contemplates providing coverage of recommended preventive services through the existing employer-based system of health coverage so that women face minimal logistical and administrative obstacles"). By re-imposing obstacles, Defendants impose significant burdens on women and their families. Kost Decl. ¶¶ 37-45; Taylor Decl. ¶¶ 13-16; Grossman Decl. ¶ 9.

[25] Defendants do not argue that the exemptions are required by the Free Exercise Clause. And thus, the principle on which they rely, that the government may voluntarily "accommodate the practice of religious beliefs" in certain situations, "does not supersede the fundamental limitations imposed by the Establishment Clause." *Lee*, 505 U.S. at 587.

Given these harms on third parties, it is no surprise that the government has, to date, not cited an Establishment Clause case in which the court approved a sweeping agency-crafted exemption that harms the very individuals the statute itself was designed to benefit.

Second, Defendants elevated the religious beliefs of objectors over the health, welfare, safety, and autonomy of female employees, students, and dependents, in an absolute and unqualified way, without giving due weight to the affected women's interests. Ikemoto Decl. ¶ 4; Russell Decl. ¶ 6; Bates Decl. ¶ 7; Nelson Decl. ¶¶ 12-13. In so doing, Defendants essentially rewrite the Women's Health Amendment, "to conform with a particular religious viewpoint." *Edwards v. Aguillard*, 482 U.S. 578, 593 (1987); *see Caldor*, 472 U.S. at 710 ("'The First Amendment . . . gives no one the right to insist that in pursuit of their own interests others must conform their conduct to his own religious necessities.'"). Under the Exemption Rules, Defendants have delegated "explicitly religious" control over access to a statutory benefit, thereby advancing and promoting religious objections to contraception. *Larkin v. Grendel's Den, Inc.*, 459 U.S. 116, 125–26 (1982). Compounding this delegation of authority is that the Rule contains no exceptions or "special circumstances," including for women who require contraceptive coverage to preserve their health. *Caldor*, 472 U.S. at 709-10; *Hobby Lobby*, 573 U.S. at 737 (Kennedy, J., concurring) ("There are many medical conditions for which pregnancy is contraindicated."). Whereas there is no "substantial burden" on employers, the Exemption Rules have the unconstitutional effect of "subject[ing] . . . employees to the religious views of the[ir] employer." 77 Fed. Reg. at 8728; *Lee*, 455 U.S. at 261 (accommodating Amish employer would operate to impose employer's faith on employee, and noting that "[e]very person cannot be shielded from all burdens incident to exercise"); *see also Amos*, 483 U.S. at 348 (O'Connor, J., concurring in the judgment) ("In order to perceive the government action as a permissible accommodation of religion, there must in fact be an identifiable burden *on the exercise of religion* that can be said to be lifted by the government action.").

Defendants assert that because they determined that the accommodation violates RFRA, their legal "conclusion precludes any finding that the Religious Exemption Rule exceeds the agencies' authority under RFRA." Defs. Opp'n at 44 (explaining that the agencies concluded that

"the burden" the accommodation imposes "is greater than previously thought"). But religious exemptions created pursuant to statutes like RFRA are still subject to Establishment Clause scrutiny. 42 U.S.C. § 2000bb-4; *Hobby Lobby*, 573 U.S. 729 n.37; *Cutter v. Wilkinson*, 544 U.S. 709, 721-22 (2005) (the Establishment Clause limits accommodations under RLUIPA, RFRA's sister statute). Indeed, on two occasions, the Supreme Court has struck down religious accommodations as unconstitutional based on the harm the accommodations would inflict on nonbeneficiaries—over the government's argument that the statutes were necessary to alleviate burdens on religious adherents. *See Caldor*, 472 U.S. at 709; *Texas Monthly*, 489 U.S. at 18.[26]

Defendants argue that the Religious Exemption Rule is not a "burden" because before the Women's Health Amendment "women had no entitlement to contraceptive coverage." Defs. Opp'n at 44. Defendants provide little support for this theory, and as the Church-State scholars explain in their amicus brief, if this argument were correct, then *Lee* would have been an easy case and the religious objector should have won. 455 U.S. at 260; Dkt. No. 325 at 10-11. In *Lee*, the Amish employer sought an exemption from paying social security taxes. 455 U.S. at 260. The Court refused to grant the exemption because doing so would "operate[] to impose the employer's religious faith on the employees," even though the employees had no entitlement to social security before the law passed. *Id*. at 261; Dkt. No. 325 at 11.

Moreover, Defendants' argument suggests that guaranteeing contraceptive coverage was a matter of administrative grace, rather than a Congressional directive that Defendants are required

[26] Defendants suggest that *Caldor* is distinguishable because (1) the statute "involved government interference with private contracts" and (2) "intruded on private relationships." Defs. Opp'n at 46. Neither purported distinction undermines the Court's holding that the government cannot command that "religious concerns automatically control over all secular interests at the workplace," given the impact on the employer and other employees. *Caldor*, 472 U.S. at 709. Further, several other federal statutes, including those involving discrimination in housing and employment also "involve[] government interference with private contracts" and "intrude[] on private relationships." Such involvement does not make those laws unconstitutional. For instance, under Defendants' own reasoning, Title VII of the Civil Rights Act, which prohibits employers from discriminating against employees on the basis of religion, would also be unconstitutional because it involves government interference with private contracts and intrudes on private relationships. In *Caldor*, the statute was unconstitutional because the government was accommodating religious adherents despite the harms such an accommodation imposed on employers and fellow employees. *Caldor*, 472 U.S. at 709-710.

to implement. *Amos* underscores this point. Defs. Opp'n at 44. In *Amos*, Congress itself created a statutory religious exemption to Title VII. 483 U.S. at 329-31. There, the plaintiff employee was thus not encompassed within the statute and as a result, there were no reliance interests at stake. *Id.*; *see also Kong v. Scully*, 341 F.3d 1132 (9th Cir. 2003) (upholding statutory exception). In contrast, here, Congress passed the Women's Health Amendment and for nearly a decade since then women have benefited from and relied on receiving full and equal healthcare, including contraceptive coverage.[27]

Defendants describe the Exemption Rules as "lifting" a substantial burden on religious believers (Defs. Opp'n at 44), but such a description suffers from two fatal flaws: (1) it assumes a "substantial burden" on employers—which there is not—and (2) it ignores that in "lifting" the purported "substantial burden," Defendants are imposing harms on third parties, without exceptions. *See Cutter*, 544 U.S. at 722 ("[A]n accommodation must be measured so that it does not override other significant interests."). As a result of the Rules, one group of citizens—here women—is being singled out to bear significant costs of another person's religious exercise. Such conduct is unconstitutional. *See Hobby Lobby*, 573 U.S. at 693 ("[W]e certainly do not hold or suggest that 'RFRA demands accommodation of a for-profit corporation's religious beliefs no matter the impact that accommodation may have on . . . thousands of women'"); *Sherbert*, 374 U.S. at 409 (providing unemployment benefits to Seventh Day Adventist does not "abridge any other person[ ]"); *Yoder*, 406 U.S. at 205 (accommodating Amish students would not result in harm to the students or the public). "Courts must take adequate account of the burdens a requested accommodation may impose on nonbeneficiaries." *Cutter*, 544 U.S. at 720; *Hobby Lobby*, 573 U.S. at 729 n.37. [28]

[27] As Amicus Church-State Scholars and the Religious and Civil Organizations explain, *Amos* is the "exception," not the rule. Church-State Scholars Amicus Br. at 7-8 (Dkt. No. 325) (*Amos* concerned the "institutional autonomy of religious congregations and religious non-profits to control their own leadership and membership"); Religious and Civil Rights Organizations at 6 (Dkt. No. 346).

[28] Defendants seek to minimize the harm to women by stating that the burden women will face is "merely the loss of subsidized coverage." Defs. Opp'n at 44. This is a mischaracterization of the interests at stake in this case. There is a very human cost to the Exemption Rules. Before the Women's Health Amendment, over half of all women delayed or avoided care due to costs. 155

V. THE EXEMPTION RULES VIOLATE THE EQUAL PROTECTION CLAUSE

The Exemption Rules create inequality in healthcare, by reinstating the fundamental inequities that the ACA was designed to remedy. Prior to the ACA, women and men were paying into the same employer-sponsored health plan and yet women were paying 68% more out-of-pocket for healthcare than men. *See* 77 Fed. Reg. at 8728 (explaining that "women in the workforce were at a disadvantage compared to their male co-workers"); *see also* Rabinovitz Decl. ¶ 4; Grossman Decl. ¶ 9. The ACA sought to cure this inequality by eliminating gender rating, providing maternity coverage, ensuring preventive care, and providing public health programs for women. Now, as a result of these Rules, women will once again be paying into the same employer-sponsored plan as their male colleagues but not receiving equal healthcare benefits. In this way, the Rules create a constitutionally impermissible gender-based classification that can be upheld if only Defendants provide an "exceedingly persuasive justification." *United States v. Virginia*, 518 U.S. 515, 533–34 (1996). They have not.

Rather than arguing that there is an "exceedingly persuasive justification," Defendants take issue with the sex-based classification, by arguing that "any sex-based distinctions flow from the statute," "not from Defendants." Defs. Opp'n at 49. Incorrect. The sex-based distinction flows directly from Defendants' decision to create exemptions exclusively for "women's preventive care and screenings." The Women's Health Amendment is one of five subparts to the preventive services mandate, but the Rules single out only women's healthcare for disadvantageous treatment. Moreover, the sex-based distinction in the Women's Health Amendment is based on an exceedingly persuasive justification (i.e., remedying inequities in healthcare), whereas the sex-based distinction created by the Rules has no such justification and in fact perpetuates those

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Cong. Rec. S12027 (Dec. 1, 2009) (Sen. Gillibrand). Without contraceptives, women are significantly more likely to become pregnant. Indeed, over 40% of all unintended pregnancies are caused by inconsistent access to contraceptives. Ex. 57 (D10 00207344 and 00207391). Approximately 70% of U.S. women of reproductive age, about 43 million women, are at risk of unintended pregnancy if they lose access to reliable contraceptives. Ex. 81 (D11 00804725). If a woman has an unintended pregnancy she must decide whether to carry to term and keep and raise a child or put the child up for adoption, or to obtain an abortion (if such an option is available to her, given her geographic and other circumstances). These are not "marginal" interests. Defs. Opp'n at 18.

inequities. As a result of the Rules, the law burdens women unequally. Kost Decl. ¶¶ 37-45; Ikemoto Decl. ¶ 5; Kish Decl. ¶ 12.

Defendants next argue that "any distinctions in coverage among women are not premised on sex, but on the existence of a religious or moral objection on the part of an employer." Defs. Opp'n at 49. But the *ability* of employers to exclude coverage for women is a result of the Rules. Under the Rules, men continue to enjoy full and equal healthcare, whereas women's access to healthcare is contingent on the religious and moral approval of their employers. *See Planned Parenthood of Se. Pa. v. Casey*, 505 U.S. 833, 856 (1992) (recognizing that access to contraceptive is necessary for women to fully and equally participate in public life); Kost Decl. ¶¶ 38-39; Ikemoto Decl. ¶ 5; Bates Decl. ¶¶ 4-5. [29]

VI. THE EXEMPTION RULES ARE PROCEDURALLY DEFICIENT

Defendants argue that, even if the adoption of the IFRs was procedurally deficient, the Exemption Rules were properly promulgated under the APA because they accepted comments after enacting the IFRs and the States have had an opportunity to comment. Defs. Opp'n at 52.[30] While the Ninth Circuit has yet to address the legality of this precise factual scenario, several sister circuits have weighed in and rejected the assertion that post-promulgation comments to an unlawfully promulgated IFR are the same as a properly noticed proposed rule that complies with the APA. *See NRDC v. EPA*, 683 F.2d 752, 767 (3d Cir. 1982); *Sharon Steel Corp. v. EPA*, 597 F.2d 377, 380 (3d Cir. 1979); *Leveque v. Block*, 723 F.2d 175, 188 (1st Cir. 1983).

Defendants' attempt to distinguish *NRDC* is unavailing. Defendants argue that in *NRDC*, the "question on which the public commented, . . , was not the question that would have been

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[29] Defendants also assert that there is no authority that "declining to require subsidization of contraception constitutes" sex-based discrimination. Defs. Opp'n at 49. As a threshold matter, the ACA requires that "[a] group health plan" and "a health insurance issuer" include preventive services. 42 U.S.C. § 300gg-13. This includes preventive services for men and women, but Defendants have exempted only women's healthcare from this statutory requirement. Thus, it is not the States that are mandating that women's healthcare coverage be included in employer-sponsored healthcare—it is Congress. As a secondary matter, under the accommodation, contraception is not "subsidized," by the employer. *See infra* at 15, 20-23 (explaining employers do not "pay" for the contraceptive coverage).

[30] Defendants argue that they had statutory authority to issue the IFRs. Defs. Opp'n at 52. As the Ninth Circuit has already determined that Defendants violated the APA, we do not address this argument, other than to affirm our agreement with that ruling. *California*, 911 F.3d 575-581.

asked had the APA been followed." Defs. Opp'n at 53-54. Defendants then assert that, here, the question posed to the public in the unlawful IFRs would have been the same had Defendants complied with the APA and issued a Notice of Proposed Rulemaking (NPRM). *Id.* at 54. Defendants misread *NRDC*. As one court recently explained, "[t]he Third Circuit did not invalidate the EPA action because of the degree of change affected [sic] by the procedurally invalid action. Rather, it held that the subsequent notice-and-comment rulemaking '[could not] replace [a rulemaking] on the question of whether the amendments should be postponed in the first place.'" *Pennsylvania*, 351 F. Supp. 3d at 815. Moreover, Defendants' interpretation of *NRDC* disregards the harm to the public. As several courts have explained, when agencies promulgate rules that take immediate effect and *then* take comments, the public's ability to fairly comment is impacted. *See Leveque*, 723 F.2d at 188 ("'We doubt that persons would bother to submit their views or that the Secretary would seriously consider their suggestions after the regulations are a fait accompli'" and thus, "[i]n view of these 'psychological and bureaucratic realities, . . . Congress specified that notice and an opportunity for comment are to *precede* rule-making'"); States' Mot. at 58. Furthermore, Defendants do not cite any authority to support their incorrect interpretation of *NRDC*. *Cf. United States v. Reynolds*, 710 F.3d 498, 519 (3d Cir. 2013) ("[a]ny suggestion that the postpromulgation comments to the Interim Rule can satisfy the[] purposes [of exposure to diverse public comment and developing evidence in the record] misses the point.").

Defendants also argue that there was no harm to the States because the States had the opportunity to submit comments prior to issuance of the Exemption Rules. Defs. Opp'n at 52. But the Court in *NRDC* already rejected this argument. *NRDC*, 683 F.2d at 768; *see also Riverbend Farms, Inc. v. Madigan*, 958 F.2d 1479, 1487 (9th Cir. 1992). Similarly, the First Circuit held that the ability of the public to comment, alone, is insufficient. *Leveque*, 723 F.2d at 188-89. Rather, to overcome the "presumption" that the subsequent rule is unlawful, the "quality" of agencies' response to the comments must demonstrate that the comment period "satisfied the requirements and purposes of section 553." *Id.* As explained above, Defendants

failed to meaningfully respond to comments, and thus cannot overcome this presumption that the Exemption Rules are invalid under the APA.

Moreover, Defendants' promulgation of the IFRs followed by notice and comment prejudiced the States. The purpose of the notice and comment period is to allow interested persons to participate in rule making, to allow the public voice to be heard by unrepresentative agencies, and to educate the agency. 5 U.S.C. § 553(c); *Paulsen v. Daniels*, 413 F.3d 999, 1005 (9th Cir. 2005); *see also Alcaraz v. Block*, 746 F.2d 593, 611 (9th Cir. 1984). Instead, here, the States had to simultaneously seek an injunction against the IFRs *and* draft a comment. Similarly, Defendants were defending the substance of IFRs in court while alleging that they would fairly and properly consider the comments about the IFRs they already made effective. And ultimately, Defendants issued Exemption Rules that were substantially identical to the IFRs. *See* Defs.' Supplemental Br., 2018 WL 6044850, at *1, 4. This put the States precisely in the position that concerned the *NRDC* court: the States had to "run the risk that the decisionmaker is likely to resist change" instead of reading comments with an open mind. *NRDC*, 683 F.2d at 768. Here, the record demonstrates that the States were not afforded a true comment period, and such injury taints the Exemption Rules.[31]

Defendants further argue that there is no remediable procedural injury because the only remedy would be the comment period afforded to the States. Defs. Opp'n at 54. The States disagree. They were never afforded an unbiased comment period before any rules became effective, and that is precisely what the Court could order: that the Rules be set aside and in the event that Defendants want to promulgate the same Rules, they must issue a NPRM, take comments on that proposal, and then issue a final rule. Compliance with the APA is not too much to ask given the import of the issues at stake.

[31] In fact, on numerous substantial issues on which the States commented, Defendants said that they were simply not going to take a position. *See* States' Mot. at 40; *see also* 83 Fed. Reg. at 57552, 57555.

VII. THE COURT SHOULD SET ASIDE THE EXEMPTION RULES AND ISSUE DECLARATORY RELIEF

Defendants admit that the proper remedy for an APA violation is setting aside the Rules. Defs. Opp'n at 55. Defendants then contend, however, that this Court has no authority to go beyond setting aside the Rules, despite the States' explicit requested relief for a declaratory judgment (Second Am. Compl. at 65)—and the States' showing that a declaratory judgment is warranted (States' Mot. at 60). Notably, Defendants do not dispute that Plaintiffs are entitled to a declaratory judgment under this Circuit's precedent. *See* 28 U.S.C. § 2201(a); *Biodiversity Legal Found. v. Badgley*, 309 F.3d 1166, 1174-75 (9th Cir. 2002); *Alliance for the Wild Rockies v. U.S. Forest Service*, 907 F.3d 1105, 1121 (9th Cir. 2018) (providing that, even in the APA context, courts have the authority to grant injunctive and declaratory relief).

Defendants then proceed to conflate nationwide *injunctions* with the congressional mandate that Rules be set aside under the APA where a violation has been found. Defs. Opp'n at 56-57. There is simply no authority for Defendants' proposition that the Rules be set aside only with respect to named plaintiffs. Indeed, such an assertion runs contrary to the plain language of the APA, which provides that the court shall ". . . hold unlawful and set aside *agency action*, findings, and conclusions found to be . . . arbitrary, capricious, an abuse of discretion, otherwise not in accordance with law; [or] without observance of procedure required by law." 5 U.S.C. § 706(2)(A) & (D). Nothing in the statutory text instructs that the agency action, findings, and conclusions may be set aside only for those plaintiffs who bring suit.

Furthermore, Defendants point to no case to support their distorted statutory interpretation. To the contrary, courts consistently set aside rules where an agency acts contrary to law or agency action is arbitrary and capricious. *See, e.g., Camp v. Pitts*, 411 U.S. 138, 143 (1973) (per curiam); *Alliance for the Wild Rockies*, 907 F.3d at 1121-1122 (holding federal agencies had "not overcome the presumption of vacatur"); *Nat. Res. Def. Council v. EPA*, 489 F.3d 1364, 1374 (D.C. Cir. 2007); *State v. Ross*, 358 F. Supp. 3d 965, 1050-51 (N.D. Cal. 2019); *Klamath-Siskiyou Wildlands Cir. v. Nat'l Oceanic & Atmospheric Admin.*, 109 F. Supp. 3d 1238, 1241 (N.D. Cal. 2015). As one court recently explained, the "'usual' remedy for violation of the APA" is vacatur

and remand. *New York v. U.S. Dep't of Commerce*, 351 F. Supp. 3d 502, 673 (D.D.C. 2019) ("Vacatur is consistent with both the plain language of the APA and the principle that agency action taken in violation of the APA 'cannot be afforded the force and effect of law'" (quoting *Chrysler Corp. v. Brown*, 441 U.S. 281, 313 (1979)), *reversed in part on other grounds*, *Dep't of Commerce*, 2019 WL 2619473. There, like here, Defendants objected to the normal APA remedy based on theories of Article III standing. *New York*, 351 F. Supp. 3d at 674-75. In rejecting that argument, the court explained that once Article III standing is established, the Court has the power to adjudicate the controversy and "the question of what relief it may or must order is a 'merits' question of substantive law that is ultimately for the legislature to decide." *Id*. The Court explained that in the context of the APA, "a court has both the power *and* the duty to order the remedy Congress created." *Id*.

CONCLUSION

The Court should deny Defendants' and Intervenors' motions to dismiss and motions for summary judgment, and grant the States' motion for summary judgment.

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