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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. DEPARTMENT OF HEALTH & HUMAN SERVICES; U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES;**	4:17-cv-05783-HSG **STATES' SUPPLEMENTAL BRIEF** Date: December 16, 2020 Time: 2:00 p.m. Dept: 2, 4th floor Judge: The Honorable Haywood S. Gilliam, Jr. Action Filed: October 6, 2017

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EUGENE SCALIA,[1] 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.

[1] Secretary Scalia replaces former Secretary Acosta as a defendant, in his official capacity, by operation of Federal Rule of Civil Procedure 25(d).

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INTRODUCTION

On July 8, 2020, the Supreme Court issued its decision in *Little Sisters of the Poor Saints Peter & Paul Home v. Pennsylvania* and *Trump v. Pennsylvania*, 140 S. Ct. 2367 (2020) ("*Little Sisters*"). The Court held that the ACA "gives [the Health Resources and Services Administration (HRSA)] broad discretion to define preventive care and screenings and to create religious and moral exemptions." *Id.* at 2381. The Court further held that the Exemption Rules are not procedurally invalid under the Administrative Procedure Act (APA). *Id.* at 2384-86. The Court's decision resolves the States' statutory authority and procedural claims. Accordingly, the States hereby simultaneously file a Notice of Voluntary Withdrawal of Certain Claims.

However, other claims asserted in this case, including the arbitrary and capricious claim, contrary to law claims, and constitutional claims, have not been resolved by the holdings in *Little Sisters* because the Court did not reach and left unresolved significant issues. For instance, the Court did not address whether that the Exemption Rules were required under the Religious Freedom Restoration Act (RFRA). Nor did the Court conclude that the accommodation—which allows religious employers to opt-out of the Mandate while still ensuring critical contraceptive coverage for their employees—constitutes a substantial burden on the free exercise rights of employers. The Court also did not reach the issue of whether the Rules are arbitrary and capricious. *See id.* at 2387 (Alito, J., concurring) ("[w]e now send these cases back to the lower courts, where the [States] are all but certain to pursue their argument that the current rule is flawed on yet another ground, namely, that it is arbitrary and capricious and thus violates the APA"); *id.* at 2398, 2399 (Kagan, J., concurring in judgment) (noting that the issue of whether the Rules are arbitrary and capricious "is now ready for resolution, unaffected by today's decision," and explaining that several "aspects of the Departments' handiwork may [] prove arbitrary and capricious"). Finally, the Court did not decide whether the Rules are contrary to Sections 1554 or 1557 of the ACA, or violate any constitutional provision.

With the opportunity to address the merits of the remaining issues on remand, this Court should conclude that these Rules are arbitrary and capricious. "An agency acting within its sphere of delegated authority can of course flunk the test of 'reasoned decisionmaking.'" *Little*

Sisters, 140 S. Ct. at 2398 (Kagan, J., concurring). "Assessed against that standard of reasonableness, the exemptions HRSA and the Departments issued give every appearance of coming up short." *Id*. at 2397. Indeed, this Court already concluded that "[g]iven the 'serious reliance interests' of women who would lose coverage to which they are statutorily entitled if the Final Rules go into effect, the Court believes that Plaintiffs are also likely to prevail on their claim that the agencies failed to provide 'a reasoned explanation . . . for disregarding facts and circumstances that underlay or were engendered by the prior policy.'" *California v. Health & Human Servs.*, 351 F. Supp. 3d 1267, 1296 (N.D. Cal. 2019). As the States outlined in prior briefing, Defendants' decisionmaking is arbitrary and capricious for several reasons. *See* States Mot. at 37-51, States Opp'n at 43-50, States Sur-Reply at 8-12. Drawing on recent case law, this supplemental brief highlights some of the ways that the Rules are arbitrary and capricious.

First, Defendants crafted Exemptions which suffer from a striking "mismatch between the scope of the" Exemptions "and the problem the agencies set out to address." *Little Sisters*, 140 S. Ct. at 2398 (Kagan, J., concurring). Although Defendants claim to be protecting employers with sincerely held religious beliefs against providing, arranging, or participating in plans that comply with the Mandate, 82 Fed. Reg. 47,792, 47,806 (Oct. 13, 2017), their "solution" was to create Exemption Rules that encompass entities with *no* objections to the accommodation, entities which cannot be said to have religious beliefs, and entities that do not even claim to have religious beliefs (such as those covered under the "moral objection" exemption). "The rule thus went beyond what the Departments' justification supported," and "lacks a 'rational connection' to the problem described." *Little Sisters*, 140 S. Ct. at 2399 (Kagan, J., concurring) (quoting *Motor Vehicle Mfrs. Assn. of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983)).

Second, Defendants failed to give adequate weight to the imperative of the Mandate and the serious reliance interests of the intended beneficiaries of the Women's Health Amendment. In their rulemaking, Defendants failed to adequately consider the interests of the millions of women who have benefitted from the contraceptive coverage mandate, and failed to provide adequate explanations for several of its decisions, particularly given that the effect of the Exemption Rules is to upend what Congress intended—to provide full and equal healthcare coverage to women.

Or. Nat'l Res. Council v. Thomas, 92 F.3d 792, 798 (9th Cir. 1996). Because they were "not writing on a blank slate," Defendants' failure to properly assess reliance interests and weigh those reliance interests against competing policy concerns renders the Rules arbitrary and capricious. *Dep't of Homeland Sec. v. Regents of the Univ. of Cal.*, 140 S. Ct. 1891, 1915 (2020) (*Regents*).

Third, Defendants failed to provide a reasoned explanation for their policy reversal. "'[T]he Rules provide no new facts and no meaningful discussion that would discredit their prior factual findings establishing the beneficial and essential nature of contraceptive healthcare for women.'" *California*, 351 F. Supp. 3d at 1296. Additionally, Defendants failed to meaningfully respond to comments and impermissibly weighed nonstatutory factors in promulgating the Moral Exemption. *Allied Local & Reg'l Mfrs. Caucus v. EPA*, 215 F.3d 61, 80 (D.C. Cir. 2000) ("For an agency's decisionmaking to be rational, it must respond to significant points raised during the public comment period."); *Little Sisters*, 140 S. Ct. at 2400 (Kagan, J., concurring) ("RFRA cast a long shadow over the Departments' rulemaking . . . [but] that statute does not apply to those with only moral scruples.").

The Rules are also contrary to Sections 1554 and 1557 of the ACA because they create barriers for women to obtain healthcare coverage, impede women's timely access to healthcare, and permit employers to exclude women from full and equal participation in their employer-sponsored health plan. *See* States Mot. at 35-37, States Opp'n at 39-43, States Sur-Reply at 7-8.

ARGUMENT

I. THE EXEMPTION RULES ARE ARBITRARY AND CAPRICIOUS

The Religious and Moral Exemption Rules are arbitrary and capricious and must be set aside under 5 U.S.C. § 706 of the APA because Defendants: (1) crafted Exemptions which are significantly broader in scope than the problem they purport to solve; (2) failed to give adequate weight to the imperative of the Mandate and the serious reliance interests of the intended beneficiaries of the Women's Health Amendment; (3) failed to provide a reasoned explanation for their policy reversal; (4) failed to meaningfully respond to comments; and (5) impermissibly weighed nonstatutory factors in promulgating the Moral Exemption Rule.

A. The Exemption Rules Are Too Broad for the Problem They Purport to Solve

Defendants promulgated the broad Religious and Moral Exemption Rules purportedly to protect employers who assert sincerely held religious beliefs or moral objections against providing contraceptive coverage or using the accommodation. 82 Fed. Reg. at 47,806; 83 Fed. Reg. 57,592, 57,593 (Nov. 15, 2018). To achieve this objective, Defendants vastly expanded the scope of the prior exemption to the contraceptive-coverage requirement by permitting ***any*** employer (regardless of corporate structure or religious affiliation), individual, or even a health insurer with religious objections to covering all or a subset of FDA-approved contraceptives, to self-exempt. The Moral Exemption Rule likewise provides that nearly any employer could stop covering contraceptive services for their employees if they have a "moral" objection. Like the Religious Exemption, the Moral Exemption extends to employers, insurers, and individuals. To be clear, under the Exemption Rules, employers do not need to use the regulatory accommodation, which ensures that women receive their statutorily guaranteed contraceptive coverage. The Rules also do not require that employers notify the federal government or even tell their affected employees. Rather, employers "object" by simply ceasing to provide contraceptive coverage. The only way a woman would discover that her employer has exempted itself is by examining her annual notice of benefits and coverage or by receiving a surprise medical bill.

Defendants concede that these broad Rules will sweep in employers without an objection to the accommodation and will allow them to switch from the accommodation to the exemption. *See* 83 Fed. Reg. 57,536, 57,577 (Nov. 15, 2018) ("Of course, some of the[ ] religious [institutions that 'do not conscientiously oppose participating in the accommodation'] may opt for the expanded exemption . . . but others might not"); *id*. at 57,561 ("[I]t is not clear to the Departments that all or most of such large nonprofit employers will choose to use the expanded exemption instead of the accommodation"). Indeed, during the Supreme Court oral argument, the Solicitor General "could offer no evidence that, since the rule took effect, employers without the Little Sisters' complicity beliefs had declined to avail themselves of the new exemption." *Little Sisters*, 140 S. Ct. at 2399 n.3 (Kagan, J., concurring) (citing Tr. of Oral Arg. 22). Thus, by their

own admissions, Defendants' "solution" sweeps much more broadly than their stated goal, thereby failing the test of "reasoned decisionmaking." *Michigan v. EPA*, 576 U.S. 743, 750 (2015); *see also Del. Dep't of Nat. Res. & Envtl. Control v. EPA,* 785 F.3d 1, 17-18 (D.C. Cir. 2015) (setting aside a regulation because it was not tailored to address the identified problems); *see also* States Mot. at 44-46, States Opp'n at 48-50.

Given Defendants' own rationale, at most Defendants "should have exempted only employers who had religious objections to the accommodation—not those who viewed it as a religiously acceptable device for complying with the mandate." *Little Sisters*, 140 S. Ct. at 2399 (Kagan, J., concurring). Defendants offer little reason for allowing employers who do not object to the accommodation to utilize the exemption, other than asserting that it is within their purview to do so.[2] This "significant mismatch" between the problem identified and the solution adopted demonstrates that the Rules are arbitrary and capricious. *Dep't of Commerce v. New York*, 139 S. Ct. 2551, 2575 (2019); *State v. Bureau of Land Mgmt.*, 286 F. Supp. 3d 1054, 1066-67 (N.D. Cal. 2018) (agency action "not properly tailored" and thus arbitrary and capricious where the agency asserted that the prior rule harmed small operators and as a "solution," the agency promulgated a "blanket suspension as to all operators, regardless of size"). And, while Defendants view the Exemption Rules as the "more straightforward choice," 83 Fed. Reg. at 57,545, Defendants continue to provide the accommodation to any employer who requests that option, thus maintaining a two-track system. Therefore, this choice does not support Defendants' "decision to offer the exemption more broadly than needed." *Little Sisters*, 140 S. Ct. at 2399 n.4 (Kagan, J., concurring).

Similarly, Defendants' decision to make publicly traded companies eligible for the exemption is likewise an illustration of the solution sweeping too broadly, and in and of itself "is

[2] *See* 83 Fed. Reg. at 57,544 ("[T]he Departments believe that agencies . . . have discretion in determining whether the appropriate response is to provide an exemption from the burdensome requirement, or to merely attempt to create an accommodation that would mitigate the burden"); *id*. at 57,544 ("even if RFRA does not compel the Departments to provide the religious exemptions set forth in the IFC, the Departments believe the exemptions are the most appropriate administrative response to the religious objections that have been raised"); 83 Fed. Reg. at 57,603 ("[T]he Departments have concluded that it is appropriate to provide moral exemptions and access to the accommodation, as set forth in these final rules.").

unusual enough to raise a serious question about whether the Departments adequately supported their choice." *Little Sisters*, 140 S. Ct. at 2399 (Kagan, J., concurring) (citing *Burwell v. Hobby Lobby Stores, Inc.*, 573 U.S. 682, 717 (2014) (noting the oddity of "a publicly traded corporation asserting RFRA rights")). Indeed, Defendants admit that they "are not aware of any publicly traded entities that have publicly objected to providing contraceptive coverage on the basis of religious belief." 83 Fed. Reg. at 57,562. With no evidence of any public company being forced to violate its sincerely held religious belief, and despite the improbability that "unrelated shareholders—including institutional investors with their own set of stakeholders—would agree to run a corporation under the same religious beliefs," *Burwell*, 573 U.S. at 717, Defendants nevertheless expanded the scope of the exemption to include such hypothetical employers—without regard for the women impacted by such an expansion. *See Ariz. Cattle Growers Ass'n v. U.S. Fish & Wildlife*, 273 F.3d 1229, 1244 (9th Cir. 2001) (agency action may not be based on mere "speculation"); *Massachusetts v. EPA*, 549 U.S. 497, 533 (2007) (agency does not have "roving license" to ignore underlying statute); *see also* States Mot. at 46; States Opp'n at 49.

While Defendants promulgated an exemption that reaches every possible type of employer who might have been covered by the provisions of the Women's Health Amendment, Defendants nevertheless insisted that this process would not be abused by those without sincere religious beliefs. 83 Fed. Reg. at 57,558. However, the record does not support Defendants' assertion. First, they offer conflicting information on this score: in one breath, they reason that contraceptive coverage is cost-neutral for issuers, therefore giving no financial incentives to misrepresent their beliefs, 83 Fed. Reg. at 57,564, while in another they suggest that "premiums would adjust to reflect changes in coverage," thus lowering employers' costs, 83 Fed. Reg. at 57,580. Second, as noted, Defendants "acknowledged the prospect that some employers without a religious objection to the accommodation would switch to the exemption." *Little Sisters*, 140 S. Ct. at 2399 n.3 (Kagan, J., concurring) (citing 83 Fed. Reg. at 57,576-57,577, 57,561). And, because there are no notice requirements, Defendants have been unable—and will always be unable—to ensure that employers without objections to the accommodation "had declined to avail themselves of the new exemption." *Id.* The consequence of such a broad rule is that women will

lose their contraceptive coverage when an employer whose religious objections would have been satisfied by the accommodation opts instead for the exemption or when an employer with no objection at all opts to exercise the exemption; that outcome "yield[s] all costs and no benefits," and is therefore "hard to see as consistent with reasoned judgment." *Id.* at 2397.

Defendants also make no serious effort to address alternatives to the Exemption Rules that would adequately protect the interests of women. *See Zubik v. Burwell*, 136 S.Ct. 1557, 1560 (2016) (per curiam) ("[T]he parties on remand should be afforded an opportunity to arrive at an approach . . . *ensuring* that women covered by petitioners' health plans 'receive full and equal health coverage, including contraceptive coverage.'" (emphasis added)); 83 Fed. Reg. at 57,544-57,546. Defendants merely provide conclusory assertions about alternatives.[3] "Because [Defendants] too cavalierly sidestepped [their] responsibility to address reasonable alternatives, [their] action was not rational and must, therefore, be set aside." *Del. Dep't of Nat. Res. & Envtl. Control*, 785 F.3d at 18. As the Supreme Court recently emphasized, where an agency's earlier rulemaking stressed the importance of an underlying program, the agency must consider alternatives before implementing a subsequent rule. *Regents*, 140 S. Ct. at 1912 ("given DHS's earlier judgment that forbearance is 'especially justified' for 'productive young' people who were brought here as children and 'know only this country as home,' the DACA Memorandum could not be rescinded in full 'without any consideration whatsoever' of a forbearance-only policy" (internal citations omitted)).

B. Defendants Ignored the Harm the Exemption Rules Cause to Women

Defendants cannot ignore and minimize the serious reliance interests of women with employer-provided healthcare coverage, particularly when the U.S. Supreme Court has repeatedly

[3] 83 Fed. Reg. at 57,544 ("[I]t would be inadequate to merely attempt to amend or expand the accommodation process instead of expanding the exemption"); *id.* at 57,544 ("[M]erely amending that accommodation process without expanding the exemptions would not adequately address religious objections"); *id.* at 57,545 ("[T]he Departments reaffirmed their conclusion that there is not a way to satisfy all religious objections by amending the accommodation"); *id.* at 57,545-57,546 ("the Departments are not aware of the authority, or of a practical mechanism, for using section 2713(a)(4) to require contraceptive coverage be provided specifically to persons covered by an objecting employer, other than by using the employer's plan, issuer, or third party administrator, which would likely violate some entities' religious objections.").

stressed the importance of those interests. *See also* States Mot. at 38-39.[4] As outlined below, Defendants: (1) failed to meaningfully consider women's interests, foisting upon women all of the burdens associated with obtaining full healthcare coverage and allowing employers to provide unequal benefits to their female employees; and (2) provided inadequate explanations for disregarding their prior rules. Defendants' failure to appreciate the reliance interests at stake falls squarely within the type of arbitrary rulemaking the Supreme Court recently outlined in *Regents*.

1. Throughout this rulemaking Defendants discussed the interests of employers at length, while addressing the interests of millions of American women who stand to lose their contraceptive coverage only in terse and dismissive statements.[5]

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[4] *See Zubik*, 136 S.Ct. at 1560 (HHS shall "ensur[e] that women covered by petitioners' health plans receive full and equal health coverage, including contraceptive coverage." (internal quotation marks omitted)); *Wheaton College v. Burwell*, 573 U.S. 958, 959 (2014) ("Nothing in this interim order affects the ability of applicant's employees and students to obtain, without cost, the full range of [FDA] approved contraceptives."); *Hobby Lobby*, 573 U.S. at 692 ("HHS has already devised and implemented a system that seeks to respect the religious liberty of religious nonprofit corporations while ensuring that the employees of these entities have precisely the same access to all FDA-approved contraceptives as employees of [other] companies."); *id.* at 729 (the accommodation serves "a Government interest of the highest order," *i.e.*, providing women "with cost-free access to all FDA-approved methods of contraception").

[5] *See, e.g.,* 83 Fed. Reg. at 57,548 ("Some commenters contended that obtaining contraceptive coverage from other sources could be more difficult or more expensive for women than obtaining it from their group health plan or health insurance plan. The Departments do not believe that such differences rise to the level of a compelling interest or make it inappropriate for us to issue the expanded exemptions set forth in these final rules. Instead, after considering this issue, the Departments conclude that the religious liberty interests that would be infringed if we do not offer the expanded exemptions are not overridden by the impact on those who will no longer obtain contraceptives through their employer sponsored coverage as a result."); 83 Fed. Reg. at 57,552 ("Because of the importance of the religious liberty values being accommodated, the limited impact of these rules, and uncertainty about the impact of the Mandate overall according to some studies, the Departments do not believe these rules will have any of the drastic negative consequences on third parties or society that some opponents of these rules have suggested."); 83 Fed. Reg. at 57,556 ("Moreover, we conclude that the best way to balance the various policy interests at stake in the Religious IFC and these final rules is to provide the expanded exemptions set forth herein, even if certain effects may occur among the populations actually affected by the employment of these exemptions. These rules will provide tangible protections for religious liberty, and impose fewer governmental burdens on various entities and individuals, some of whom have contended for several years that denying them an exemption from the contraceptive Mandate imposes a substantial burden on their religious exercise."); 83 Fed. Reg. at 57,574 ("These final rules will result in some persons covered in plans of newly exempt entities not receiving coverage or payments for contraceptive services. As discussed in the Religious IFC, the Departments did not have sufficient data on a variety of relevant factors to precisely estimate how many women would be impacted by the expanded exemptions or any related costs they may incur for contraceptive coverage or the results associated with any unintended pregnancies.").

As a threshold matter and by Defendants' own admissions, "[t]he 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). Expert panels involved in the reviews that underlie the HRSA guidelines recognized the importance of cost reductions in improving access to contraception, and increasing consistent and correct usage of contraception. Ex. 9 (D4 000405-07); Ex. 24 (D9 668960-65); *see also Hobby Lobby*, 573 U.S. at 727 ("HHS tells us that 'studies have demonstrated that even moderate copayments for preventive services can deter patients from receiving those services.'"); Ex. 57 (D10 00207393-98). As Defendants previously asserted, "[c]ontraceptive coverage also furthers the compelling interest in ensuring that women have *equal* health coverage." *Zubik* Resp. Br., 2016 WL 537623 at *58.

Despite these findings and admissions, Defendants failed to explain why it was rational to so strongly prioritize employers' interests, at the expense of the millions of women who have benefitted from the Women's Health Amendment. For instance, Defendants do not require any form of reporting, self-certification, or notice from exempt entities because of their concern for the "additional paperwork burden" imposed on employers. 83 Fed. Reg. at 57,558. But this "paperwork" would enable the Defendants to track the number of employers who might opt in to the new exemption regime. Given that HHS itself estimated that 30 million women gained access to contraceptive coverage due to the Women's Health Amendment, it flouts reason to enact a rule allowing unlimited numbers of employers to exempt themselves from the Mandate, without any way of tracking the millions of women potentially impacted. Ex. 17 (D9 571363); 83 Fed. Reg. at 57,551 (estimating that up to 126,400 women stand to lose contraceptive coverage due to the Religious Exemption Rule). Defendants also fail to explain their rationale for allowing all employers the ability to access the Exemption as quickly as possible, despite the fact that Defendants did not identify employers in need of immediate relief. 83 Fed. Reg. at 57,570. Likewise, Defendants go so far as to allow publicly-held for-profit entities to exempt themselves

without any evidence that such entities need an exemption,[6] and allow closely held for-profit corporations to exempt themselves so as not to inconvenience them when they might at some point in the future wish to sell stock.[7] In myriad ways, Defendants failed to explain why it was so strongly privileging the interests of employers over the interests of the women who receive their contraceptive care through employer- and university-sponsored plans.

In so doing, Defendants have saddled women with the burdens of seeking out and obtaining contraceptive care—burdens Congress intended to remove by promulgating the Women's Health Amendment. By ignoring what the underlying statute—the Women's Health Amendment—makes "important," Defendants engaged in arbitrary and capricious rulemaking. *Or. Nat'l Res. Council v. Thomas*, 92 F.3d at 798 (part of arbitrary and capricious analysis requires considering what the underlying statute makes "'important'"); *see, e.g.*, *State Farm*, 463 U.S. at 43 (agency's failure to consider adopting a rule requiring airbags in new cars arbitrary and capricious, where agency's own evidence showed such a rule would save lives and the National Highway Transportation Safety Act required agency to make rules enhancing auto safety); *see also Nat'l Urban League v. Ross*, 977 F.3d 770, 2020 WL 5940346, at *4 (9th Cir. 2020) (agency action arbitrary and capricious where the government failed to address the reliance interests of the public).

2. Defendants' explanations fall short of the reasoned decisionmaking that would be necessary to justify such a dramatic departure from the Departments' prior policies, at the expense of the fundamental policy interests underlying the Women's Health Amendment. For instance, Defendants averred that women "in plans that reduce or eliminate contraceptive benefits

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[6] *But see* 83 Fed. Reg. at 57,562 ("[T]he Departments are not aware of any publicly traded entities that have publicly objected to providing contraceptive coverage on the basis of religious belief."); 83 Fed. Reg. at 57,602 ("Although… the Departments assume the number of entities and individuals that may seek exemption from the Mandate on the basis of moral convictions, as these two sets of litigants did, will be small, the Departments know from the litigation that it will not be zero.").

[7] 83 Fed. Reg. at 57,563 ("The Departments do not want to preclude such a closely held corporation from having to decide between relinquishing the exemption or financing future growth by sales of stock, which would be the effect of denying it the exemption if it changes its status and became [sic] a publicly traded entity.").

as a result of the exemption will know whether their health plan claims an exemption and will be able to raise appropriate challenges to such claims" by referencing their plan benefit documents. 83 Fed. Reg. at 57,558. This *ignores* that the Women's Health Amendment was designed to ensure women receive full and equal coverage (*see* States Mot. at 4)—not force them to scour their healthcare documents and then challenge their employer's religious claim or moral objection.[8] Defendants also fail to explain *how* women would "challenge" their employer's claim when HHS has not set forth any type of process for employees to assert such challenges.

Similarly, Defendants assume that women are able to both identify and select a potential future employer based on whether that employer will cover their contraceptive care. 83 Fed. Reg. at 57,560. Such an assumption ignores the socioeconomic and institutional barriers different women face. Defendants merely assume that all women have the luxury of choosing an employer on the basis of whether that employer will include full and equal healthcare coverage for women. Unsurprisingly, Defendants provide *no* evidence to support their assumption, which is also built on the entirely speculative notion that employers advertise the details of their health plans to prospective employees. Defendants' assumptions also fail to account for those women who are dependents on their parents' or partner's health plan and who have no opportunity to exercise their hypothetical choice at all. While Defendants' assumptions on this score strain the imagination for many women in the workforce, it is even more patently absurd when applied to seventeen-year old high school students choosing a college. For those women, Defendants blithely contend that "[n]o student is required to attend" an institution that does not provide full and equal healthcare to women. 83 Fed. Reg. at 57,564. "At a minimum, students who attend private colleges and universities have the ability to ask those institutions in advance what religious tenets they follow, including whether the institutions will provide contraceptives in insurance plans." *Id.* Once again, Defendants' rulemaking is premised upon baseless and pernicious assumptions, including that students choosing a college would—despite financial

[8] And, even once women learn that their employer is not providing them full and equal healthcare coverage, the plan documents themselves will not indicate that an employer is utilizing an exemption created by these Rules based on a religious belief or moral conviction. Impacted women would simply know that their employer dropped coverage—thus, further undermining Defendants' suggestion that women could allegedly challenge their employer's religious claim.

considerations and other factors—change their institution due to the restrictions of its healthcare coverage. For women of all ages, Defendants already conceded that requiring women "to take steps to learn about, and to sign up for, a new health benefit" imposes "additional barriers," "mak[ing] that coverage accessible to fewer women." 78 Fed. Reg. 39,870, 39,888 (July 2, 2013).

3. Defendants' general characterization of women's interests' in contraceptive coverage as incidental, and the protections offered by the Women's Health Amendment and the Mandate as lightly conferred and therefore easily removed,[9] demonstrates Defendants' complete failure to appreciate the reliance interests at stake, and is contrary to Supreme Court precedent.

The U.S. Supreme Court recently reiterated the importance of agencies' consideration of reliance interests. In *Regents*, the government alleged that DACA recipients had "no 'legally cognizable reliance interests' because the DACA Memorandum stated that the program 'conferred no substantive rights' and provided benefits only in two-year increments." 140 S. Ct. at 1913. The Court rejected this narrow view of reliance interests. *Id.* The Court held that when an agency changes course, it must give careful consideration to the reliance interests engendered by the previous policy, and must "consider the alternatives that are within the ambit of the existing policy." *Id.*

Like the government in *Regents*, Defendants here argue that the characteristics of the Contraceptive Coverage Mandate—"a subregulatory creation that does not apply in various contexts," 83 Fed. Reg. at 75,552—make its protections insubstantial. This Court should reject that argument as a basis for ignoring the substantial reliance interests of women, especially where, as here, the Mandate was the "the centerpiece of the policy." *Regents*, 140 S. Ct. at 1913; *see also Nat'l Urban League*, 2020 WL 5940346, at *4 (agency action is arbitrary and capricious where the agency's analysis fails to consider an important aspect of the problem—an analysis

[9] *See, e.g.*, 83 Fed. Reg. at 57,549 ("These final rules do not create a governmental burden; rather, they relieve a governmental burden"); *id.* ("If some third parties do not receive contraceptive coverage from private parties who the government chose not to coerce, that result exists in the absence of governmental action—it is not a result the government has imposed"); *id.* ("[T]he government has simply restored a zone of freedom where it once existed.").

which "'turns on what [the] relevant substantive statute makes 'important'"). Because Defendants were "not writing on a blank slate," their failure to "assess whether there were reliance interests, determine whether they were significant, and weigh any such interests against competing policy concerns" renders the rules arbitrary and capricious. *Regents*, 140 S. Ct. at 1915. Though Defendants may now tacitly acknowledge such reliance interests, *see* Defs. Opp'n at 33, merely claiming to have considered such interests does not make it so. *Getty v. Fed. Savs. & Loan Ins. Corp.*, 805 F.2d 1050, 1055 (D.C. Cir. 1986) ("[s]tating that a factor was considered . . . is not a substitute for considering it"); *Whitman-Walker Clinic, Inc. v. HHS*, --- F. Supp. 3d ---, 2020 WL 5232076, at *28 (D.D.C. Sept. 2, 2020) (concluding that where HHS's rulemaking "said almost nothing" about the important issues HHS raised in prior rulemaking, and failed to consider the "consequences" of religious exemptions for access to care, "despite the fact that 'the ACA's intended purpose [is] to broaden access to health care,'" it was arbitrary and capricious (quoting *Morris v. Cal. Physicians' Serv.*, 918 F.3d 1011, 1014 (9th Cir. 2019)). And, the Rules themselves do not reflect that Defendants engaged in the required consideration of reliance interests. *Regents*, 140 S. Ct. at 1907 ("judicial review of agency action is limited to 'the grounds that the agency invoked when it took the action'").

Given that HRSA continues to require that contraceptive coverage be provided, Defendants have "committed themselves to minimizing the impact on contraceptive coverage, even as they [seek] to protect employers with continuing religious objections." *Id.* at 2399 (Kagan, J., concurring) (citing *Women's Preventive Services Guidelines*, HRSA (Dec. 2019), www.hrsa.gov/womens-guidelines-2019; 83 Fed. Reg. at 57,537). By promulgating Exemption Rules that disregard the critical interests of the women who rely on the protections of the Women's Health Amendment, Defendants acted in an arbitrary and capricious manner and have "failed to fulfill that commitment to women." *Id.*; *see also California*, 351 F. Supp. 3d at 1296 ("[g]iven the 'serious reliance interests' of women who would lose coverage to which they are statutorily entitled if the Final Rules go into effect, the Court believes that Plaintiffs are also likely to prevail on their claim that the agencies failed to provide 'a reasoned explanation . . . for disregarding facts and circumstances that underlay or were engendered by the prior policy'").

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C. Defendants Failed to Provide a Reasoned Explanation for Their Policy Reversal

Defendants 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). They have not done so. *See* States' Mot. at 38-44; States' Opp'n at 44-48; States' Sur-Reply at 8-10. Indeed, in prior rulemaking, Defendants made several findings that the Exemption Rules do not reject—and, yet, the Exemption Rules fail to provide justification for such a fundamental change in course. For instance, Defendants previously stated:

- 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." 78 Fed. Reg. at 39,887.

- 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 39,872-73, 39,887-88.

- "Researchers have shown that access to contraception improves the social and economic status of women." 77 Fed. Reg. 8725, 8728 (Feb. 15, 2012).

- "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." 77 Fed. Reg. at 8728. That is, "by providing women broad access to preventive services, including contraceptive services," disparities are reduced. *Id*.

- 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." 78 Fed. Reg. at 39,888.

- "[W]omen in the workforce were at a disadvantage compared to their male co-workers." 77 Fed. Reg. at 8,728.

- 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.

- 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.

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- Requiring "women—and only women—to take burdensome steps . . . 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).

Given these prior findings, and the fact that the Exemption Rules do not challenge or disavow those findings, this Court already correctly concluded that the States are "likely correct that 'the Rules provide no new facts and no meaningful discussion that would discredit their prior factual findings establishing the beneficial and essential nature of contraceptive healthcare for women.'" *California*, 351 F. Supp. 3d at 1296. "Instead, the Final Rules on this point rest, at bottom, on new legal assertions by the agencies." *Id.*; *see also Bhd. of Locomotive Engineers & Trainmen v. Fed. R.R. Admin.*, 972 F.3d 83, 116-17 (D.C. Cir. 2020) (where rule contains a "total explanatory void" and the court comes up "empty-handed" in its review of the record for a reasoned explanation, the rule is vacated). Because the reasons that Defendants proffer "are inadequate," Defendants' Rules may not be sustained. *Regents*, 140 S. Ct. at 1907; *City of Oberlin v. FERC*, 937 F.3d 599, 606-607 (D.C. Cir. 2019) (Decision-making was arbitrary and capricious where Commission "failed to adequately answer" outstanding, fundamental questions).

D. Defendants Failed to Meaningfully Respond to Comments Concerning the Rules' Impact

Defendants failed to meaningfully respond to comments during the rulemaking process and ignored the overwhelming body of scientific evidence and expertise documented in those comments. *See* States Mot. at 46-50; States Opp'n at 50; States Sur-Reply at 11-12. "For an agency's decisionmaking to be rational, it must respond to significant points raised during the public comment period." *Allied Local & Reg'l Mfrs. Caucus*, 215 F.3d at 80; *see also Nat'l Urban League*, 2020 WL 5940346, at *5 (agency action arbitrary and capricious where agency fails to provide "'satisfactory explanation' to the numerous statements" that the proposed agency action would undermine the underlying statute). Although Defendants need not address every comment, Defendants must address "significant" comments or those "which, if true, raise points relevant to the agency's decision." *City of Portland v. EPA*, 507 F.3d 706, 715 (D.C. Cir. 2007);

1 *Gresham v. Azar*, 950 F.3d 93, 103 (D.C. Cir. 2020) (Agency must consider concerns raised in
2 public comments lest its action be deemed arbitrary and capricious). Defendants failed to meet
3 this standard. *See* States Mot. at 46-50; States Opp'n at 50; States Sur-Reply at 11-12.

4 **E. Defendants Impermissibly Weighed Nonstatutory Factors in Promulgating**
5 **the Moral Exemption**

As noted *supra*, the Religious Exemption Rule is unsupported and irrational and should
6 therefore be set aside. In the case of the Moral Exemption Rule, those arguments apply with even
7 greater force, as RFRA does not contemplate or protect such objections at all. *See Little Sisters*,
8 140 S. Ct. at 2400 (Kagan, J., concurring) ("RFRA cast a long shadow over the Departments'
9 rulemaking . . . and that statute does not apply to those with only moral scruples."). In the
10 absence of any competing statutory considerations such as those provided in RFRA, "a careful
11 agency would have weighed anew, in this different context, the benefits of exempting more
12 employers from the mandate against the harms of depriving more women of contraceptive
13 coverage." *Id.* at 2400 (Kagan, J., concurring). Defendants nonetheless chose to adopt a
14 sweeping Moral Exemption Rule, reflecting an impermissible consideration of non-religious
15 "moral" objections to contraceptive coverage without any indication that Congress intended the
16 agency to consider such objections. *See Massachusetts*, 549 U.S. at 533-34 (EPA's "laundry list"
17 of policy reasons for its rulemaking did not "amount to a reasoned justification for declining to
18 form a scientific judgment"); *State Farm*, 463 U.S. at 43 (proscribing reliance on factors "which
19 Congress has not intended it to consider.").

20
21 **II. THE RELIGIOUS AND MORAL EXEMPTION RULES ARE CONTRARY TO LAW**

22 As discussed in the States' pleadings, the Exemption Rules are contrary to Sections 1554
23 and 1557 of the ACA. *See* States Mot. at 35-37; States Opp'n at 39-43; States Sur-Reply at 7-8.

24 **A. The Exemption Rules Violate Section 1554 by Creating Unreasonable**
25 **Barriers to Care and Impeding Timely Access to Healthcare**

26 Section 1554 provides that "the Secretary of [HHS] shall not promulgate any regulation
27 that: (1) creates *any* unreasonable barriers to the ability of individuals to obtain appropriate
28 medical care; (2) impedes *timely access* to health care services; . . . or (6) *limits* the availability of

health care treatment for the full duration of a patient's medical needs." 42 U.S.C. § 18114(1), (2), (6) (emphases added). The Exemption Rules violate each of these proscriptions. *See* States Mot. at 35-36; States Opp'n at 39-41; States Sur-Reply at 7-8.

First, the Exemption Rules create unreasonable barriers to accessing contraceptive care. 42 U.S.C. § 18114(1). The Exemption Rules will cause—by Defendants' own estimates—up to 126,400 women to lose their contraceptive coverage. 83 Fed. Reg. at 57,551 n.26, 57,578. Without such coverage, women will need to pay out-of-pocket for contraceptives, which cost $50 per month or upwards of $600 per year. States Mot. at 2; *see also id.* at 36 (cost of IUD exceeds $1,000, which equates to a month's salary for a woman working full time at the federal minimum wage of $7.25 an hour). Because of the Contraceptive Coverage Mandate, "[w]omen now save an average of 20% annually in out-of-pocket expenses, including $248 savings for IUDs and $255 for the contraceptive pill." States Mot. at 2; *see also* 83 Fed. Reg. at 57,538 (predicting $68.9 million in "transfer costs" to be paid by "women previously receiving contraceptive coverage"). Cost is always a barrier to obtaining medical care, and the most effective forms of contraception (e.g. IUDs) have the highest upfront costs. Forcing women to pay for contraceptives will result in some women forgoing contraceptives or switching to cheaper, but less effective, methods of contraception. *See* States Mot. at 36 (collecting record evidence); States Opp'n at 5-6, 40 (same).

Second, the Exemption Rules impede timely access to contraceptives. 42 U.S.C. § 18114(2). As Defendants have acknowledged, providing preventive services through the existing, employer-based system of health coverage helps ensure that "women face minimal logistical and administrative obstacles." 78 Fed. Reg. at 39,888. Singling out and removing contraceptive coverage from that system will necessarily increase the administrative obstacles that the ACA sought to remove. For example, women who lose contraceptive coverage may need to locate and secure a separate, new qualified medical provider, which may require transferring medical records or submitting a complete medical history to the new provider to ensure proper care. *See* States Mot. at 36 (collecting record evidence); States Opp'n at 40 (same). Such efforts necessarily delay and impede timely access to contraceptives. And even minor obstacles to

1 obtaining contraception lead to more unplanned and risky pregnancies, with adverse effects on
2 women and their families. *See* States Opp'n at 41 (citing record).
3 The evidence in the record further demonstrates the importance of holistic coverage, to
4 ensure that a woman's "chosen provider" can "manage all health conditions and needs at the same
5 time." *See* States Mot. at 36 (citing record evidence). Eliminating coverage for one component
6 of a woman's healthcare—contraceptives—introduces hurdles which, "in turn, will increase those
7 women's risk of unintended pregnancy and interfere with their ability to plan and space wanted
8 pregnancies. These barriers could therefore have considerable negative health, social and
9 economic impacts for those women and their families." *Id.*
10 Third, the Exemption Rules will "limit the availability" of contraceptives "for the full
11 duration" of time during which women need them. 42 U.S.C. § 18114(6). Contraceptives are a
12 routine and constant healthcare need for women of childbearing age. Nearly two-thirds of the
13 over 72 million women between the ages of 15-49 in the United States use contraceptives. States
14 Mot. at 1. A typical woman wishing to have only two children will, on average, spend three
15 decades avoiding unintended pregnancy. *Id.* at 45. Because contraceptives must be used without
16 interruption for such an extended period of time, the Exemption Rules will curb the availability of
17 contraceptives for some women during the multi-decade period when they need them. For all of
18 these reasons, the Exemption Rules violate multiple requirements imposed by Section 1554.
19 The Ninth Circuit's recent *en banc* decision in *California v. Azar*, 950 F.3d 1067 (9th Cir.
20 2020), *petitions for cert. filed* is readily distinguishable. In that case, HHS promulgated a rule
21 imposing new limitations on the Title X family planning program, including forbidding funding
22 recipients from making referrals for abortion services and requiring recipients to be physically
23 and financially separated from abortion-related activities. *Id.* at 1081-82. The Ninth Circuit
24 determined that these new Title X funding requirements did not run afoul of Section 1554
25 because of the "distinction between regulations that impose burdens on health care providers and
26 their clients, and those that merely reflect Congress's choice not to subsidize certain activities."
27 *Id.* at 1092. Federal funding restrictions "ensure that government funds are spent for the purposes
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for which they were authorized" and, as the Ninth Circuit opined, Section 1554 is not meant "to affect Title X funding decisions." *Id*. at 1094.

The Exemption Rules, however, are not restrictions imposed on a federally-funded program and thus the holding of *California* is wholly inapplicable. The loss of contraceptive coverage caused by the Exemption Rules will directly interfere with the ability of women to access the contraceptive healthcare that they need. *California,* 950 F.3d at 1094 (Section 1554 "is meant to prevent direct government interference with health care"). Providers may be unable to prescribe contraceptives that are not covered by their patients' insurance, or those prescriptions will go unfilled because of the out-of-pocket costs that women will bear. That is precisely the type of governmental regulatory burden that Section 1554 was intended to prevent. *See, e.g.*, *Planned Parenthood of Md., Inc. v. Azar*, No. 20-361, 2020 WL 3893241, at *9–10 (D. Md. July 10, 2020) (holding regulation violated Section 1554 by requiring insurers to provide two separate bills to policyholders, as opposed to one combined bill, thereby "mak[ing] it harder for consumers to pay for insurance," and distinguishing *California* because that case concerns "ensuring government funds are not spent on unauthorized purposes").

In promulgating Section 1554, Congress intended to "ensure that HHS, in implementing the broad authority provided by the ACA, does not improperly impose regulatory burdens on doctors and patients." *California*, 950 F.3d at 1094. The Exemption Rules violate this provision by creating unreasonable barriers to care, impeding women's timely access to services, and limiting the availability of care for the full span of time during which women need it.

B. The Exemption Rules Violate Section 1557 By Discriminating Against Women

Section 1557 of the ACA states that an "individual shall not . . . be excluded from participation in, be denied the benefits of, or be subjected to discrimination under, any health program or activity" on the basis of sex. 42 U.S.C. § 18116(a); 20 U.S.C. § 1681(a). The Exemption Rules must be held unlawful and set aside 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; *see* States Mot. at 36-37; States Opp'n at 41-43; States Sur-Reply at 8.

The Exemption Rules permit employers to exempt themselves from providing only one type of preventive service: contraceptives, which women (and only women) use. Women are forced either to accept incomplete health coverage unequal to that received by male colleagues or forgo employer-provided coverage and purchase a comprehensive healthcare package out-of-pocket. That unfair choice directly violates Section 1557 by subjecting female employees (and employees' female dependents) to discrimination on the basis of sex with respect to access to federally-entitled coverage. 45 C.F.R. § 92.1.

This conclusion is bolstered by the Supreme Court's recent decision in *Bostock v. Clayton County*, 140 S. Ct. 1731 (2020). In *Bostock*, the Court held that discrimination based on transgender status or sexual orientation "necessarily entails discrimination based on sex," and accordingly falls within Title VII's sweep. *Id.* at 1747.[10] Even assuming that "sex" "refer[red] only to biological distinctions between male and female," the Court determined that "it is impossible to discriminate against a person for being homosexual or transgender without discriminating against that individual based on sex." *Id.* at 1739, 1741. Here, as Defendants 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" necessarily discriminates on the basis of sex. *Zubik* Resp. Br., 2016 WL 537623, at *29 (quoting *Hobby Lobby*, 573 U.S. at 732).

CONCLUSION[11]

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

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[10] Section 1557 incorporates the definition of "on the basis of sex" under Title IX, 42 U.S.C. § 18116(a), and "Title VII case law has often informed Title IX case law with respect to the meaning of" sex discrimination. 83 Fed. Reg. 37,160, 37,168 (Aug. 18, 2020).

[11] Because the States' APA and contrary to law claims demonstrate that this Court should set aside the Exemption Rules, this Court need not reach the Constitutional claims. *See In re Ozenne*, 841 F.3d 810, 814 (9th Cir. 2016) ("as a 'fundamental rule of judicial restraint,' [the court] 'must consider nonconstitutional grounds for decision' before 'reaching any constitutional questions'").

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