

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

COMMONWEALTH OF)
PENNSYLVANIA and)
STATE OF NEW JERSEY,)

Plaintiffs,)

v.)

Civil Action No. 2:17-cv-04540 (WB)

DONALD J. TRUMP, in his official)
capacity as President of the United States;)
ALEX M. AZAR II, in his official)
capacity as Secretary of Health and)
Human Services; UNITED STATES)
DEPARTMENT OF HEALTH AND)
HUMAN SERVICES; STEVEN T.)
MNUCHIN, in his official capacity as)
Secretary of the Treasury; UNITED)
STATES DEPARTMENT OF THE)
TREASURY; RENE ALEXANDER)
ACOSTA, in his official capacity as)
Secretary of Labor; and UNITED STATES)
DEPARTMENT OF LABOR,)

Defendants.)

**FEDERAL DEFENDANTS' STATEMENT OF UNDISPUTED FACTS AND RESPONSE
TO PLAINTIFFS' STATEMENT OF UNDISPUTED FACTS**

**RESPONSE TO PLAINTIFFS' STATEMENT OF
UNDISPUTED MATERIAL FACTS**

The Agencies respond to “Plaintiffs’ Statement of Undisputed Material Facts” (ECF No. 170-3) as follows:

The Agencies object generally to Plaintiffs’ reliance on their own characterization of the Final Rules and the administrative record to the extent those characterizations differ from the text of the documents themselves or omit contextual information that is necessary to understand those characterizations. The Court should refer to the documents cited by the parties for a true and accurate statement of their contents.

The Agencies object generally to reliance on the Plaintiffs’ Statement of Undisputed Material Facts to resolve the legal questions presented in this case. “[D]istrict courts reviewing agency action under the . . . [APA] do not resolve factual issues, but operate instead as appellate courts resolving legal questions.” *James Madison Ltd. By Hecht v. Ludwig*, 82 F.3d 1085, 1096 (D.C. Cir. 1996). The Court must rely upon “the full administrative record that was before the [agency] at the time’ it took the action under review.” *SIH Partners LLLP v. Commissioner of Internal Revenue*, 923 F.3d 296, 302 (3d Cir. 2019) (quoting *C.K. v. N.J. Dep’t of Health & Human Servs.*, 92 F.3d 171, 182 (3d Cir. 1996)).

The Agencies dispute the following specific assertions made by the Plaintiffs:

Paragraph 32: The Agencies dispute this statement on the grounds that the ACA did not generally impose a “requirement that plans cover preventive services.” For example, “grandfathered plans” have never been required to provide this coverage. J.A. 6.

Paragraph 33: The Agencies state that although “HRSA adopted and released guidelines for women’s preventive services based on recommendations of the independent Institute of

Medicine,” J.A. 270-71, the Agencies dispute the suggestion that HRSA “adopted” the IOM Report in its entirety.

Paragraph 34: The Agencies dispute this statement on the grounds that the HRSA guidelines did not require all “health plans to cover ‘All Food and Drug Administration approved contraceptive methods, sterilization procedures, and patient education and counseling for all women with reproductive capacity.’” J.A. 311. For example, “grandfathered plans” have never been required to provide this coverage. J.A. 6.

Paragraph 35: For the reasons stated above with respect to paragraph 34, the Agencies dispute that all plans were subject to the requirement to cover contraception methods and counseling after HRSA updated the Guidelines in 2016. J.A. 6.

Paragraph 36: For the reasons stated above with respect to paragraph 34, the Agencies dispute that all plans were subject to the requirement to cover contraception methods and counseling after HRSA updated the Guidelines in 2017. J.A. 6.

Paragraph 37: Plaintiffs do not cite to any evidence in support of this statement, and the Agencies dispute it on that basis. The Agencies further dispute the statement to the extent it assumes all entities were subject to the contraceptive mandate, for the reasons stated above with respect to Paragraph 34. J.A. 6. The Agencies further state that the Government’s position in prior litigation was that the contraceptive mandate “furthers a compelling government interest in securing for women the full and equal health coverage the Affordable Care Act provides.” *Zubik v. Burwell*, No. 14-1418, Brief for the Respondents, at 53–54 (U.S. Feb. 10, 2016).

Paragraph 40: Although the February 2012 Final Rules stated that “Congress determined that both existing health coverage and existing preventive services recommendations often did not adequately serve the unique health needs of women,” J.A. 301, this is a characterization of

congressional intent, and the Agencies dispute that the question of congressional intent is a question of fact appropriate for a statement of material facts.

Paragraph 42: The Agencies dispute that Congress determined “one of the unique health care needs” of women arises from women’s ability to become pregnant,” as the question of what Congress “determined” is one of law, not fact, as explained with respect to Paragraph 40.

Paragraph 43: None of the sources cited by Plaintiffs state that the Agencies “adopted the IOM Report and other studies demonstrating that unintended pregnancy poses health risks for women and fetuses.” J.A. 241, 256, 300. Specifically, although “HRSA adopted and released guidelines for women’s preventive services based on recommendations of the independent Institute of Medicine,” J.A. 270–71, HRSA did not adopt the IOM Report as a whole.

Paragraph 45: The Agencies do not dispute this statement insofar as the February 2012 Final Rules state, “Researchers have shown that access to contraception improves the social and economic status of women.” J.A. 301.

Paragraph 46: Although the July 2013 Final Rules state, “Research also shows that cost sharing can be a significant barrier to access to contraception. . . . Thus, eliminating cost sharing is particularly critical to addressing the gender disparity of concern here,” J.A. 242, the Agencies dispute that Congress’s “motivat[i]ons” are a question of fact appropriate for a statement of material facts.

Paragraph 48: The Agencies state that, as set forth in the Rules, they “received over 56,000 public comment submissions” on the religious rules, J.A. 5, and “received over 54,000 public comment submissions” on the moral rules, J.A. 60.

Paragraph 49: Plaintiffs cite no record evidence to support this statement. Moreover, the religious rule and moral rule specifically state how many public comment submissions were received for each rule. J.A. 5, 60.

Paragraph 50: To the extent Plaintiffs suggest the Agencies did not accurately represent the number of public comment submissions received, the Agencies dispute this paragraph. Both rules accurately represented how many public comment submissions were received. J.A. 5, 60.

Paragraph 52: Disputed as Plaintiffs cite no record evidence for the proposition that only 27 of the 110,000 comments supported the Final Rules.

Paragraph 53: Disputed as Plaintiffs cite no record evidence for the proposition that 13 comments did not clearly take a position for or against the rules.

Paragraph 54: Disputed as Plaintiffs cite no record evidence for the proposition that .025% of commenters supported the Final Rules.

Paragraph 61: The Agencies dispute Plaintiffs' paraphrasing of the Agencies' estimates of how many women would lose contraceptive coverage under the Rules, without explaining the weight, accuracy, or purpose of the Agencies' estimates. The Agencies refer the Court to the Rules themselves for a complete statement of the grounds for the Agencies' estimates. J.A. 40–47 (religious rule); J.A. 89–92 (moral rule).

Paragraph 62: The Agencies dispute Plaintiffs' paraphrasing of the estimate of the number of women affected by the Rules based on the number of employers who have litigated against the contraceptive mandate or taken advantage of the accommodation, without explaining the weight, accuracy, or purpose of the Agencies' estimates. The Agencies refer the Court to the Rules themselves for a complete statement of the grounds for the Agencies' estimates. J.A. 40–47 (religious rule); J.A. 89– 92 (moral rule).

Paragraph 63-69: The Agencies dispute Plaintiffs’ paraphrasing of the estimate of the number of women affected by the religious rule based on litigating entities, without explaining the weight, accuracy, or purpose of the Agencies’ estimates. The Agencies refer the Court to the religious rule for a complete statement of the grounds for the Agencies’ estimates. J.A. 40–47.

Paragraph 64: The Agencies dispute Plaintiffs’ statement that 49,000 persons remained employed by entities “still litigating over the mandate” to the extent that the number actually refers to litigating entities that have not received “permanent injunctions against the enforcement of section 2713(a)(4) to the extent it supports a contraceptive Mandate.” J.A. 40.

Paragraph 65: The Agencies dispute Plaintiffs’ suggestion that the Agencies miscalculated the number of employees covered by the health benefits of employers who would rely on the expanded exemptions in the religious rule. The religious rule states: “The average percent of workers at firms offering health benefits that are actually covered by those benefits is 60 percent. This amounts to *approximately* 29,000 employees covered under those plans.” J.A. 41 (emphasis added).

Paragraph 66: The Agencies dispute Plaintiffs’ suggestion that the Agencies miscalculated the number of individuals covered by the health benefits of employers who would rely on the expanded exemption in the religious rule, as explained above with respect to Paragraph 65. The religious rule states: “EBSA estimates that for each employee policyholder, there is approximately one dependent. This amounts to approximately 58,000 covered persons.” J.A. 41.

Paragraphs 70-80: The Agencies dispute Plaintiffs’ paraphrasing of the Agencies’ estimate of the number of women who will be affected by currently accommodated employers that will choose the expanded exemption in the religious rule, without explaining the weight, accuracy,

or purpose of the Agencies' estimates. The Agencies refer the Court to the Rules themselves for a complete statement of the grounds for the Agencies' estimates. J.A. 40–47.

Paragraph 71: The Agencies dispute Plaintiffs' characterization that they “began by noting” their estimate of 1,823,000 employees and beneficiaries covered by plans offered by self-employed entities who took advantage of the accommodation and sought reimbursement under fee adjustment provisions for doing so. The Agencies refer the Court to the full statement in the religious rule about their estimate of individuals covered by employers who took advantage of the accommodation and whose Third Party Administrators (TPAs) sought reimbursement under the fee adjustment provision of 45 C.F.R. § 156.50(d)(3)(iii), which notes, among other things, that “[s]ome users do not enter all of the requested data,” and that “not all data for the 2017 plan year is complete” before stating the estimate of individuals covered by plans offered by these employers. J.A. 41.

Paragraph 73-74: Plaintiffs' paraphrasing of the religious rule contains an inaccurate figure in Paragraph 73 and does not provide a complete and accurate statement of the basis of the Agencies' estimate of employees and beneficiaries covered by fully-insured plans using the accommodation. The religious rule states: “DOL estimates that, among persons covered by employer-sponsored insurance in the private sector, 62.7 percent are covered by self-insured plans and 37.3 percent are covered by fully insured plans. Therefore, corresponding to the approximately 1,823,000 persons covered by self-insured plans using user fee adjustments, we estimate an additional 1,084,000 persons were covered by fully insured plans using the accommodation. This yields approximately 2,907,000 persons of all ages and sexes whom the Departments estimate were covered in plans using the accommodation under the previous regulations.” J.A. 42.

Paragraphs 75-76: Plaintiffs’ paraphrasing of the religious rule does not provide a complete and accurate statement of the basis for the Agencies’ estimate of the number of entities that would continue to use the accommodation. The religious rule states: “Although recognizing the limited data available for our estimates, the Departments estimate that 100 of the 209 entities that were using the accommodation under the previous regulations will continue to opt into it under these final rules and that those entities will cover the substantial majority of persons previously covered in accommodated plans.” J.A. 42.

Paragraph 77: Plaintiffs’ paraphrasing of the religious rule does not provide a complete and accurate statement of the basis for the Agencies’ estimate of how many individuals would be covered by plans that continue to use the accommodation. The religious rule states: “The Departments do not have specific data on which plans of which sizes will actually continue to opt into the accommodation, nor how many will make use of self-insured church plan status. The Departments assume that the proportions of covered persons in self-insured plans using contraceptive user fees adjustments also apply in fully insured plans, for which the Departments lack representative data. Based on these assumptions and without better data available, the Departments assume that the 100 accommodated entities that will remain in the accommodation will account for 75 percent of all the persons previously covered in accommodated plans. In comparison, the Departments assume the 109 accommodated entities that will make use of the expanded exemption will encompass 25 percent of persons previously covered in accommodated plans.” J.A. 42–43.

Paragraph 78: Plaintiffs’ paraphrasing of the religious rule contains an inaccurate figure and does not provide a complete and accurate statement of the basis for the Agencies’ estimate of employees and beneficiaries covered by fully-insured plans using the accommodation. The

religious rule states: “Applying these percentages to the estimated 2,907,000 persons covered in previously accommodated plans, the Departments estimate that approximately 727,000 persons will be covered in the 109 plans that use the expanded exemption, and 2,180,000 persons will be covered in the estimated 100 plans that continue to use the accommodation.” J.A. 43.

Paragraphs 81-87: The Agencies dispute Plaintiffs’ paraphrasing of the Agencies’ estimate of the number of women who would lose contraceptive coverage due to the moral rule, without explaining the weight, accuracy, or purpose of the Agencies’ estimates. The Agencies refer the Court to the Rules themselves for a complete statement of the grounds for the Agencies’ estimates. J.A. 89–92.

Paragraph 82: Plaintiffs’ paraphrasing of the moral rule does not provide a complete and accurate statement of the rationale behind the Agencies’ estimate of how many nonprofit entities would claim the exemption. The moral rule states: “With respect to the exemption for nonprofit organizations with objections based on moral convictions, as noted above, the Departments are aware of two small nonprofit organizations that have filed lawsuits raising non-religious moral objections to coverage of some contraceptives. . . . Based on comments submitted in response to rulemakings prior to the Moral and Religious IFCs, the Departments believe that at least one other similar entity exists. However, the Departments do not know how many similar entities exist and are currently unable to estimate the number of such entities. Lacking other information, we assume that the number is small. The Departments estimate it to be less than 10 and assume the exemption will be used by nine nonprofit entities. The Departments also assume that those nine entities will operate in a fashion similar to the two similar entities of which we are aware, so that their employees will likely share their views against coverage of certain contraceptives. This is consistent with the conclusion in previous regulations that no significant burden or costs would

result from exempting houses of worship and integrated auxiliaries. . . . Therefore, the Departments expect that the moral exemption for nonprofit entities will have a minimal effect of reducing contraceptive coverage with respect to employees who want such coverage.” A.R. 90.

Paragraph 84-86: Plaintiffs’ paraphrasing of the moral rule does not provide a complete and accurate statement of the Agencies’ assumptions with respect to the number of individuals working at for-profit entities that would be affected by the moral exemption. The moral rule states: “It is not known how many employees would be employed by the for-profit employers that might claim this exemption, but as discussed above these final rules do not include publicly traded companies, and both of the two nonprofit entities that challenged the Mandate based on moral objections included fewer than five policyholders in their group plans. Therefore, the Departments assume that the for-profit entities that may claim this expanded exemption will have fewer than 100 employees and an average of 9 policyholders. For 9 entities, the total number of policyholders would be approximately 81. DOL estimates that for each policyholder, there is approximately one dependent. This amounts to approximately 162 covered persons.” A.R. 91.

Paragraphs 88-96: The Agencies dispute Plaintiffs’ paraphrasing of the Agencies’ estimate of the number of women who would lose contraceptive coverage based on data regarding employers who did not provide contraceptive coverage prior to the ACA, without explaining the weight, accuracy, or purpose of the Agencies’ estimates. The Agencies refer the Court to the Rules themselves for a complete statement of the grounds for the Agencies’ estimates. J.A. 40-47.

Paragraph 94: The Agencies dispute Plaintiffs’ paraphrasing of the Agencies’ estimates of the number of Catholic churches and integrated auxiliaries in the United States. The religious rule states: “There are 17,651 Catholic parishes in the United States, 197 Catholic dioceses, 5,224 Catholic elementary schools, and 1,205 Catholic secondary schools. Not all Catholic schools are

integrated auxiliaries of Catholic churches, but there are other Catholic entities that are integrated auxiliaries that are not schools, so the Departments use the number of schools as an estimate of the number of integrated auxiliaries.” A.R. 45.

Paragraph 96: Plaintiffs’ paraphrasing of the religious rule does not provide a complete and accurate statement of the Agencies’ assumptions with respect to its estimate of how many private, non-publicly traded employers that did not cover contraception pre-ACA and are not exempt under the Church Exemption would claim the new religious exemption. The religious rule states: “The Departments do not have data indicating how many of the entities that omitted coverage of contraception pre-Affordable Care Act did so on the basis of sincerely held religious beliefs that might qualify them for exempt status under these final rules, as opposed to having done so for other reasons. Besides the entities that filed lawsuits or submitted public comments concerning previous regulations on this matter, the Departments are not aware of entities that omitted contraception pre-Affordable Care Act and then opposed the contraceptive coverage requirement after it was imposed by the Guidelines. For the following reasons, however, the Departments believe that a reasonable estimate is that no more than approximately one third of the persons covered by relevant entities—that is, no more than approximately 126,400 affected women—would likely be subject to potential transfer impacts under the expanded religious exemptions offered in these final rules.” A.R. 45.

FEDERAL DEFENDANTS' STATEMENT OF UNDISPUTED MATERIAL FACTS

The Agencies object generally to reliance on statements of undisputed material facts to resolve the legal questions presented in this case. “[D]istrict courts reviewing agency action under the . . . [APA] do not resolve factual issues, but operate instead as appellate courts resolving legal questions.” *James Madison Ltd. By Hecht v. Ludwig*, 82 F.3d 1085, 1096 (D.C. Cir. 1996). The Court must rely upon “‘the full administrative record that was before the [agency] at the time’ it took the action under review.” *SIH Partners LLLP v. Commissioner of Internal Revenue*, 923 F.3d 296, 302 (3d Cir. 2019) (quoting *C.K. v. N.J. Dep’t of Health & Human Servs.*, 92 F.3d 171, 182 (3d Cir. 1996)).

Subject to this objection, the Agencies provide the following statement of undisputed material facts, in compliance with the Court’s Policies and Procedures:

1. In August 2011, the Health Resources and Services Administration (HRSA) adopted the recommendation of the Institute of Medicine, a part of the National Academy of Sciences, to issue guidelines requiring coverage of, among other things, the full range of FDA-approved contraceptive methods. J.A. 298.
2. Coverage for the FDA-approved contraceptive methods defined by HRSA was required for plan years beginning on or after August 1, 2012. *See* J.A. 306.
3. At the same time HRSA’s guidelines were promulgated, the Agencies, invoking their statutory authority under 42 U.S.C. § 300gg-13(a)(4), promulgated interim final rules authorizing HRSA to exempt churches and their integrated auxiliaries from the contraceptive-coverage mandate. *See* J.A. 306, 298.

4. Various religious groups asked the Agencies to expand the exemption to all religious not-for-profit organizations and other organizations with religious or moral objections to providing contraceptive coverage. *See* J.A. 272.

5. In a subsequent rulemaking, the Agencies offered an “accommodation” for religious not-for-profit organizations with religious objections to providing contraceptive coverage. *See* J.A. 243–51.

6. The accommodation allowed a group health plan established or maintained by an eligible objecting employer to opt out of any requirement to directly “contract, arrange, pay, or refer for contraceptive coverage,” by providing notice of its objection. J.A. 243.

7. Once an eligible employer provided notice of an objection, the regulations then generally required the employer’s health insurer or third-party administrator to provide or arrange contraceptive coverage for plan participants. J.A. 244–49.

8. Because church plans are exempt from the Employee Retirement Income Security Act of 1974 under section 4(b)(2) of that Act, the accommodation could not require the third-party administrators of church plans—and, by extension, many nonprofit religious organizations participating in those plans—to provide or arrange for such coverage or to impose fines or penalties for failing to provide such coverage. J.A. 231 (fn. 8).

9. Self-insured church plans that were eligible to use the accommodation and whose third party administrators could not then be required to provide contraceptive coverage or payments to persons covered by those plans included many non-profit religious organizations that were not otherwise exempt under the church and integrated auxiliary exemption to the contraceptive mandate. J.A. 6.

10. Today, the Agencies estimate that over 25 million individuals are enrolled in “grandfathered” health plans (generally, those plans that have not made specified changes since the ACA’s enactment), which are exempt from the ACA’s preventive services requirement, including the contraceptive coverage mandate. J.A. 6.

11. In response to the Supreme Court’s decision in *Burwell v. Hobby Lobby Stores, Inc.*, 573 U.S. 682 (2014), the Agencies promulgated rules extending the accommodation to closely held for-profit entities with religious objections to providing contraceptive coverage. J.A. 193–98.

12. In response to the Supreme Court’s order in *Zubik v. Burwell*, 136 S. Ct. 1557 (2016) (per curiam), the Agencies requested public comment to determine whether further modifications to the accommodation could resolve the religious objections asserted by various organizations while providing a mechanism for coverage for their employees. J.A. 183.

13. The Agencies received over 54,000 comments, but concluded “that no feasible approach has been identified at this time that would resolve the concerns of religious objectors, while still ensuring that the affected women receive full and equal health coverage, including contraceptive coverage.” J.A. 172.

14. The Agencies concluded that it was “appropriate to reexamine” the extant exemption and accommodation to the contraceptive mandate in order “to resolve the pending litigation and prevent future litigation from similar plaintiffs.” J.A. 105.

15. The Agencies determined “that an expanded exemption, rather than the existing accommodation, [was] the most appropriate administrative response to the religious objections raised by certain entities and organizations.” They further explained that, “[d]espite multiple rounds of rulemaking,” the Agencies “ha[d] not assuaged the sincere religious objections to contraceptive coverage of numerous organizations.” J.A. 105.

16. In October 2017, the Agencies issued two interim final rules:
 - a. The first rule expanded the religious exemption to all nongovernmental plan sponsors, as well as institutions of higher education in their arrangement of student health plans, to the extent that those entities have sincere religious objections to providing contraceptive coverage, and to individuals able to obtain a religiously compliant plan from willing employers and issuers. J.A. 98–141.
 - b. The second rule created a similar exemption for entities and individuals with sincerely held moral objections to providing contraceptive coverage; unlike the religious exemption, though, this rule did not apply to publicly traded companies. J.A. 142–66.
17. The Agencies “received over 56,000 public comment submissions” on the religious rules, J.A. 5, and “received over 54,000 public comment submissions” on the moral rules, J.A. 60.
18. The Agencies issued final versions of the religious exemption rule and the moral exemption rule on November 15, 2018. J.A. 1–55 (religious rule); J.A. 56–95 (moral rule).
19. The Agencies also made changes to their initial proposed rules in response to the comments received. J.A. 21–38 (religious rule); J.A. 77–90 (moral rule).
20. The Agencies explained that the religious rule “finalize[s] exemptions [for] the same types of organizations and individuals for which exemptions were provided in the Religious [IFR]: Non-governmental plan sponsors including a church, an integrated auxiliary of a church, a convention or association of churches, or a religious order; a non-profit organization; for-profit entities; an institution of higher education in arranging student health insurance coverage; and, in certain circumstances, issuers and individuals.” The final religious rule also “maintain[s] a previously

created accommodation process that permits entities with certain religious objections voluntarily to continue to object while the persons covered in their plans receive contraceptive coverage or payments arranged by their health insurance issuers or third party administrators.” J.A. 2.

21. The Agencies explained that the final moral exemption rule “protect[s] sincerely held moral objections of certain entities and individuals” to providing the coverage required by the contraceptive mandate, and that changes to the rule were made to “ensure clarity in implementation of the moral exemptions so that proper respect is afforded to sincerely held moral convictions in rules governing this area of health insurance and coverage, with minimal impact on HRSA’s decision to otherwise require contraceptive coverage.” J.A. 45–46.

22. The Agencies reached the determination that the administrative record does not contain adequate evidence to meet the high standard of demonstrating a compelling interest, and provided five independent reasons for their finding. J.A. 11–13.

- a. First, the Agencies observed that “the structure of section 2713(a)(4) and the ACA evince a desire by Congress to grant a great amount of discretion on the issue of whether, and to what extent, to require contraceptive coverage in health plans pursuant to section 2713(a)(4).” J.A. 11–12.
- b. Second, the Agencies explained that the contraceptive mandate “has not been applied in many circumstances,” including grandfathered plans and church plans. J.A. 12.
- c. Third, the Agencies explained that they “now believe the administrative record on which the Mandate rested was—and remains—insufficient to meet the high threshold to establish a compelling governmental interest in

ensuring that women covered by plans of objecting organizations receive cost-free contraceptive coverage through those plans.” J.A. 12–13.

- d. Fourth, the Agencies explained that “the availability of contraceptive coverage from other possible sources . . . detracts from the government’s interest to refuse to expand exemptions to the mandate.” J.A. 13. The Agencies noted that, “prior to the implementation of the ACA, many women were able to access contraceptive methods at low or no cost through publicly funded family planning centers and Medicaid; existence of these safety net programs may have dampened any impact that the ACA could have had on contraceptive use.” J.A. 13 (quoting J.A. 2654-55).
- e. Fifth, the Agencies concluded “that guaranteeing seamlessness between contraceptive access and employer sponsored insurance does not constitute a compelling interest that overrides employers’ religious objections to the contraceptive Mandate.” J.A. 13.

23. The Agencies discussed the efficacy and health effects of contraceptive use in the Final Rules. J.A. 17–21. The discussion included citations to numerous articles, including several from peer-reviewed medical journals such as the New England Journal of Medicine, The Lancet, and the Journal of the American Medical Association. J.A. 17–18 nn.28-34; Exs. 157–76. The Agencies also considered research analyzing the effect of ACA implementation on contraceptive use. J.A. 13 (citing Ex. 156).

24. The Agencies “[did] not take a position on” the empirical questions about the efficacy and health effects of contraceptives, but concluded that “re-examination of the record and review of the public comments has reinforced the [Agencies’] conclusion that significantly more uncertainty

and ambiguity exists on these issues than the [Agencies] previously acknowledged when we declined to extend the exemption to certain objecting organizations and individuals. The uncertainty surrounding these weighty and important issues makes it appropriate to maintain the expanded exemptions and accommodation if and for as long as HRSA continues to include contraceptives in the Guidelines.” J.A. 20.

25. The Agencies considered comments that the contraceptive mandate had “led women . . . to change from less effective, less expensive contraceptive methods to more effective, more expensive contraceptive methods,” J.A. 21, and comments contending “[b]etween 2008 and 2014, there were no significant changes in the overall proportion of women who used a contraceptive method both among all women and among women at risk of unintended pregnancy,” J.A. 21 (quoting Ex. 156) and “there was no significant increase in the use of methods that would have been covered under the ACA (most or moderately effective methods) during the most recent time period (2012-2014) excepting small increases in implant use,” J.A. 76, and concluded it was “not clear that merely expanding exemptions as done in these rules will have a significant effect on contraceptive use and health, or workplace equality, for the vast majority of women benefitting from the Mandate,” J.A. 21.

26. The Agencies acknowledged “[t]here is conflicting evidence regarding whether the Mandate alone, as distinct from birth control access more generally, has caused increased contraceptive use, reduced unintended pregnancies, or eliminated workplace disparities, where all other women’s preventive services were covered without cost sharing. Without taking a definitive position those issues, however,” the Agencies “conclude[d] that the Religious IFC and these final rules—which merely withdraw the Mandate’s requirement from what appears to be a small group

of newly exempt entities and plans—are not likely to have negative effects on the health or equality of women nationwide.” J.A. 21.

27. In response to comments about “the effects of some FDA-approved contraceptives on embryos,” the Agencies noted that “some people have sincere religious objections to providing contraception coverage” on the basis that certain covered contraceptives purportedly have abortifacient effects, but the Agencies “d[id] not take a position on the scientific, religious, or moral debates on this issue” in the final rules. J.A. 18–19.

28. In response to comments on the “effects of the expanded exemptions on teen sexual activity,” the Agencies “note[d] that studies suggesting various causes of teen pregnancy and unintended pregnancy in general support the Departments’ conclusion that it is difficult to establish causation between granting religious exemptions to the contraceptive Mandate and either an increase in teen pregnancies in particular, or unintended pregnancies in general.” J.A. 19.

29. The Agencies determined that the individual exemption “does not undermine the governmental interests furthered by the contraceptive coverage requirement, because, when the exemption is applicable, the individual does not want the coverage, and therefore would not use the objectionable items even if they were covered.” J.A. 32–34.

30. The Agencies determined in 2013, in creating exemptions for churches and integrated auxiliaries and the accommodation process (including its inability to impose coverage or payment obligations on third party administrators of self-insured church plans that use the accommodation), that such rulemaking “does not undermine the governmental interests furthered by the contraceptive coverage requirement,” and “[h]ouses of worship and their integrated auxiliaries that object to contraceptive coverage on religious grounds are more likely than other employers to employ people of the same faith who share the same objection, and who would therefore be less

likely than other people to use contraceptive services even if such services were covered under their plan.” A.R. 243.

31. To satisfy the directives of Executive Order 12,866, the Agencies provided estimates of the number of women who would be impacted by the Final Rules. J.A. 40–47 (religious rule); 89–92 (moral rule).

DATED: June 14, 2019

Respectfully submitted,

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