

**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)	
<i>et al.</i> ,)	
)	
Defendants.)	
_____)	

**FEDERAL DEFENDANTS’ CROSS-MOTION FOR SUMMARY JUDGMENT AND
OPPOSITION TO PLAINTIFFS’ MOTION FOR SUMMARY JUDGMENT**

Pursuant to Federal Rule of Civil Procedure 56, Defendants Donald J. Trump, President of the United States, in his official capacity; Robert F. Kennedy, Jr., Secretary of Health and Human Services, in his official capacity; Scott Bessent, Secretary of the Treasury, in his official capacity; Lori Chavez-DeRemer, Secretary of Labor, in her official capacity; the United States Departments of Health and Human Services, Labor, and the Treasury; and the United States of America (“Federal Defendants”) respectfully move this Court to enter summary judgment in their favor. The accompanying memorandum containing a concise statement of the legal contentions and authorities relied upon in support of this motion.

Dated: April 18, 2025

Respectfully submitted,

ERIC J. HAMILTON
Deputy Assistant Attorney General

MICHELLE R. BENNETT
Assistant Director, Federal Programs Branch

/s/ Daniel Riess

DANIEL RIESS

MICHAEL GERARDI

Trial Attorneys

U.S. Department of Justice, Civil Division

Federal Programs Branch

1100 L Street, NW

Washington, D.C. 20005

(202) 353-3098

Daniel.Riess@usdoj.gov

Attorneys for Federal Defendants

CERTIFICATE OF SERVICE

I hereby certify that, on April 18, 2025, a copy of the forgoing document was electronically filed with the Clerk of the Court using the CM/ECF system, which will send notification of such filing to all counsel of record.

DATED this 18th day of April, 2025.

/s/ Daniel Riess

DANIEL RIESS

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

COMMONWEALTH OF)
PENNSYLVANIA and STATE OF)
NEW JERSEY,)
)
Plaintiffs,)
v.)
)
DONALD J. TRUMP, in his official)
capacity as President of the United States,)
et al.,)
)
Defendants.)
_____)

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

**MEMORANDUM IN SUPPORT OF FEDERAL DEFENDANTS'
CROSS-MOTION FOR SUMMARY JUDGMENT AND OPPOSITION
TO PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT**

TABLE OF CONTENTS

INTRODUCTION	1
BACKGROUND	2
I. The Affordable Care Act and the Contraceptive-Coverage Mandate.....	2
II. Challenges to the Contraceptive-Coverage Mandate and Accommodation	4
III. The Interim Final Rules	6
IV. Plaintiff’s Challenge to the IFRs and the Court’s Opinion.....	7
V. The Final Rules	8
VI. Plaintiffs’ Amended Complaint and the Second Preliminary Injunction	9
VII. The Supreme Court’s Decision in <i>Little Sisters</i>	10
VIII. The Present Status of This Case.....	11
LEGAL STANDARD.....	12
ARGUMENT	12
I. The Rules Are Not Arbitrary and Capricious	12
A. The Religious Exemption Rule Reasonably Addresses the Problems It Aimed to Resolve.....	12
B. The Agencies Reasonably Addressed RFRA.	16
C. The Agencies Thoroughly Explained the Bases for the Rules.	18
D. The Moral Exemption Rule Is Well Justified.	24
E. The Agencies Adequately Considered Regulatory Alternatives.	25
F. The Agencies Considered Significant Comments.	31
G. The Agencies Performed a Reasonable Regulatory Impact Analysis.	34
H. Because the Religious Exemption Rule Is Required by RFRA, Plaintiffs’ Arbitrary and Capricious Arguments Would Be Harmless Error.	37
II. The Court Should Enter Summary Judgment on the Claims Addressed by the Supreme Court in <i>Little Sisters</i>	42

III. Any Relief Should Be Limited to the Parties Before the Court.....	43
CONCLUSION.....	45

TABLE OF AUTHORITIES

CASES

<i>Advoc. Health Care Network v. Stapleton</i> , 581 U.S. 468 (2017).....	4
<i>Advocates for Highway & Auto Safety v. Fed. Motor Carrier Safety Admin.</i> , 429 F.3d 1136 (D.C. Cir. 2005).....	17
<i>Am. Hosp. Ass’n v. NLRB</i> , 499 U.S. 606 (1991).....	45
<i>Am. Mining Congress v. EPA</i> , 965 F.2d 759 (9th Cir. 1992)	32
<i>Am. Radio Relay League, Inc. v. FCC</i> , 524 F.3d 227 (D.C. Cir. 2008).....	31
<i>Ameron, Inc. v. U.S. Army Corps of Eng’rs</i> , 787 F.2d 875 (3d Cir. 1986).....	44
<i>Associated Dog Clubs of N.Y., Inc. v. Vilsack</i> , 75 F. Supp. 3d 83 (D.D.C. 2014).....	12
<i>Bondi v. VanDerStok</i> , No. 23-852, 2025 WL 906503 (U.S. Mar. 26, 2025).....	45
<i>Burwell v. Hobby Lobby Stores, Inc.</i> , 573 U.S. 682 (2014).....	<i>passim</i>
<i>Califano v. Yamasaki</i> , 442 U.S. 682 (1979).....	43
<i>California v. Azar</i> , 950 F.3d 1067 (9th Cir. 2020)	31
<i>Camp v. Pitts</i> , 411 U.S. 138, (1973).....	21
<i>Church of Lukumi Babalu Aye v. City of Hialeah</i> , 508 U.S. 520 (1993).....	39
<i>Citizens to Preserve Overton Park, Inc. v. Volpe</i> , 401 U.S. 402 (1971).....	30
<i>City of Portland v. EPA</i> , 507 F.3d 706 (D.C. Cir. 2007).....	32

<i>Clapper v. Amnesty Int’l USA</i> , 568 U.S. 398 (2013).....	43
<i>Coinbase, Inc. v. SEC</i> , 126 F.4th 175 (3d Cir. 2025)	30
<i>Consumer Elecs. Ass’n v. FCC</i> , 347 F.3d 291 (D.C. Cir. 2003).....	34
<i>Ctr. for Auto Safety v. Peck</i> , 751 F.2d 1336 (D.C. Cir. 1985).....	34
<i>DHS v. Regents of the University of California</i> , 591 U.S. 1 (2020).....	44
<i>Douglas v. Pension Benefit Guar. Corp.</i> , No. 06-cv-3170, 2008 WL 2805604 (E.D. Pa. July 18, 2008)	25
<i>Encino Motorcars, LLC v. Navarro</i> , 579 U.S. 211 (2016).....	15, 18
<i>FCC v. Fox Television Stations, Inc.</i> , 556 U.S. 502 (2009).....	18, 19
<i>FERC v. Elec. Power Supply Ass’n</i> , 577 U.S. 260 (2016).....	26
<i>Fla. Power & Light Co. v. Lorion</i> , 470 U.S. 729 (1985).....	43
<i>Fox v. Clinton</i> , 684 F.3d 67 (D.C. Cir. 2012).....	37
<i>Garland v. Ming Dai</i> , 593 U.S. 357 (2021).....	34
<i>Geneva Coll. v. Sec’y of HHS</i> , 778 F.3d 422 (3d Cir. 2015).....	41
<i>Gill v. Whitford</i> , 585 U.S. 48 (2018).....	44
<i>Gonzales v. O’Centro Espirita Beneficiente Uniao do Vegetal</i> , 546 U.S. 418 (2006).....	39
<i>Home Box Office v. FCC</i> , 567 F.2d 9 (D.C. Cir. 1977).....	32

<i>James Madison Ltd. by Hecht v. Ludwig</i> , 82 F.3d 1085 (D.C. Cir. 1996)	12
<i>Kleissler v. U.S. Forest Serv.</i> , 183 F.3d 196 (3d Cir. 1999).....	22
<i>Kyzy v. U.S. Citizenship & Immigration Servs.</i> , 420 F. Supp. 3d 322 (E.D. Pa. 2019)	12
<i>Little Sisters of the Poor Saints Peter & Paul Home v. Pennsylvania</i> , 591 U.S. 657 (2020).....	<i>passim</i>
<i>March for Life v. Burwell</i> , 128 F. Supp. 3d 116 (D.D.C. 2015)	6
<i>Meyer v. CUNA Mut. Ins. Soc’y</i> , 648 F.3d 154 (3d Cir. 2011).....	44
<i>Michael H. v. Gerald D.</i> , 491 U.S. 110 (1989).....	25
<i>Montgomery Cnty., Md. v. FCC</i> , 863 F.3d 485 (6th Cir. 2017)	45
<i>Motor Vehicle Mfrs. Ass’n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.</i> , 463 U.S. 29 (1983).....	<i>passim</i>
<i>Nat. Res. Def. Council, Inc. v. EPA</i> , 822 F.2d 104 (D.C. Cir. 1987)	31
<i>Nat’l Ass’n of Home Builders v. EPA</i> , 682 F.3d 1032 (D.C. Cir. 2012)	19
<i>Nat’l Ass’n of Metal Finishers v. EPA</i> , 719 F.2d 624 (3d Cir. 1983).....	22
<i>Nat’l Shooting Sports Found., Inc. v. Jones</i> , 716 F.3d 200 (D.C. Cir. 2013)	12, 13, 26
<i>NVE, Inc. v. HHS</i> , 436 F.3d 182 (3d Cir. 2006).....	21
<i>Ohio v. EPA</i> , 603 U.S. 279 (2024).....	34
<i>Pennsylvania v. President United States</i> , 816 F. App’x 632 (3d Cir. 2020)	11

<i>Pennsylvania v. President United States</i> , 930 F.3d 543 (3d Cir. 2019).....	9
<i>Potoczny v. Aurora Loan Servs., LLC</i> , 33 F. Supp. 3d 554 (E.D. Pa. 2014)	25-26
<i>Priests for Life v. HHS</i> , 772 F.3d 229 (D.C. Cir. 2014)	5
<i>Priests for Life v. HHS</i> , 808 F.3d 1 (D.C. Cir. 2015)	38
<i>Pub. Citizen, Inc. v. FAA</i> , 988 F.2d 186 (D.C. Cir. 1993)	23
<i>Real Alternatives, Inc. v. Sec’y of HHS</i> , 867 F.3d 338 (3d Cir. 2017).....	6, 17, 41
<i>Sharpe Holdings, Inc. v. HHS</i> , 801 F.3d 927 (8th Cir. 2015)	5, 38
<i>Sherbert v. Verner</i> , 374 U.S. 398 (1963)	40
<i>SIH Partners LLLP v. Comm’r of Internal Revenue</i> , 923 F.3d 296 (3d Cir. 2019).....	16
<i>Stewart v. Spencer</i> , 344 F. Supp. 3d 147 (D.D.C. 2018)	24, 25
<i>Sw. Pa. Growth All. v. Browner</i> , 121 F.3d 106 (3d Cir. 1997).....	29
<i>Town of Chester v. Laroe Estates, Inc.</i> , 581 U.S. 433 (2017).....	44
<i>Trump v. Hawaii</i> , 585 U.S. 667 (2018).....	44
<i>United Ref. Co. v. EPA</i> , 64 F.4th 448 (3d Cir. 2023)	29
<i>United States v. Mendoza</i> , 464 U.S. 154 (1984).....	44
<i>Walter O. Boswell Mem’l Hosp. v. Heckler</i> , 749 F.2d 788 (D.C. Cir. 1984)	26

<i>Weinberger v. Romero-Barcelo</i> , 456 U.S. 305 (1982).....	43
<i>Yeboah v. U.S. Dep’t of Just.</i> , 345 F.3d 216 (3d Cir. 2003).....	26

STATUTES

5 U.S.C. § 702(1)	43
5 U.S.C. § 706.....	35, 37, 43
26 U.S.C. § 4980D.....	38
26 U.S.C. § 4980H.....	38
26 U.S.C. § 6033(a)(3)(A)(i)	39
29 U.S.C. § 1002(33)(C)(i)	4
42 U.S.C. § 300gg-13	2, 3, 10
42 U.S.C. § 2000bb-1(b).....	38, 39
42 U.S.C. § 18114.....	30

RULE

Federal Rule of Civil Procedure 56	12
--	----

REGULATIONS

Group Health Plans and Health Insurance Issuers Relating to Coverage of Preventing Services Under the Patient Protection and Affordable Care Act, 76 Fed. Reg. 46,621 (Aug. 3, 2011).....	3, 39
Group Health Plans and Health Insurance Issuers Relating to Coverage of Preventive Services Under the Patient Protection and Affordable Care Act, 77 Fed. Reg. 8,725 (Feb. 15, 2012).	3
Coverage of Certain Preventive Services Under the Affordable Care Act, 78 Fed. Reg. 8,456 (Feb. 6, 2013)	3
Coverage of Certain Preventive Services Under the Affordable Care Act, 78 Fed. Reg. 39,870 (July 2, 2013).....	3, 13, 23
Coverage of Certain Preventive Services Under the Affordable Care Act, 79 Fed. Reg. 51,092 (Aug. 27, 2014).....	4, 40

Coverage of Certain Preventive Services Under the Affordable Care Act, 80 Fed. Reg. 41,318 (July 14, 2015).....	5
Coverage for Contraceptive Services, 81 Fed. Reg. 47,741 (July 22, 2016).....	6
Religious Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act, 82 Fed. Reg. 47,792 (Oct. 13, 2017).....	6, 7, 28
Moral Exemptions and Accommodations for Coverage of Certain Preventative Services Under the Affordable Care Act, 82 Fed. Reg. 47,838 (Oct. 13, 2017).....	7
Religious Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act, 83 Fed. Reg. 57,536 (Nov. 15, 2018).....	<i>passim</i>
Moral Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act, 83 Fed. Reg. 57,592 (Nov. 15, 2018).....	9, 13
Coverage of Certain Preventive Services Under the Affordable Care Act, 88 Fed. Reg. 7236 (Feb. 2, 2023)	11, 29
Coverage of Certain Preventive Services Under the Affordable Care Act, 89 Fed. Reg. 106,393 (Dec. 30, 2024).....	11

INTRODUCTION

The Supreme Court in *Little Sisters of the Poor Saints Peter & Paul Home v. Pennsylvania*, 591 U.S. 657 (2020), sided with objectors to what is commonly called the contraceptive-coverage mandate. It held that Congress’s grant of unquestionably broad discretion in the Affordable Care Act (“ACA”) to determine the scope of the women’s preventive service mandate, as well as possible exemptions to that mandate, authorized the federal agencies responsible for administering the ACA (“the Agencies”)¹ to create religious and moral exemptions to any contraceptive-coverage mandate they might impose. *Id.* at 675-79. The Supreme Court further counseled that, in crafting the religious exemption, the Agencies were right to consider concerns that the mandate could violate the Religious Freedom Restoration Act (“RFRA”). *Id.* at 680-83. Accordingly, the Supreme Court reversed the Third Circuit’s decision upholding this Court’s preliminary injunction of the Agencies’ 2018 religious and moral exemption rules (the “Final Rules” or “Rules”).

As an initial matter, the Supreme Court’s opinion requires that this Court grant summary judgment to the Agencies with respect to Plaintiffs’ claims that the Agencies lacked statutory authority to enact the exemptions, Am. Compl. for Declaratory & Injunctive Relief (“Am. Compl.”) ¶ 182, ECF No. 89, could not consider RFRA, *id.* ¶ 185, and violated the notice-and-comment requirements of the Administrative Procedure Act (“APA”) by soliciting comments after issuing an interim final rule and by not maintaining an open mind, *id.* ¶¶ 174-76. Plaintiffs do not contend otherwise. Moreover, by strongly suggesting that the Agencies reasonably exercised their broad discretion in creating the religious and moral exemptions in the Final Rules, *Little Sisters* also demonstrates that Plaintiffs’ remaining challenges to the Final Rules have no merit.

¹ The Department of Health and Human Services, the Department of Labor, and the Department of the Treasury.

The Final Rules explained that the exemptions were necessary to alleviate substantial burdens on sincerely held religious and moral beliefs. Indeed, *Little Sisters* made clear that RFRA required the Agencies to consider the existence of such burdens. The Final Rules are not arbitrary and capricious under the APA; rather, they constitute a rational response to years of litigation over the scope of the contraceptive-coverage mandate, well-founded in the evidence before the Agencies, and responsive to the significant comments that were presented. Moreover, the Final Rules contain voluminous explanations of the Agencies’ previous position, their current position, the Agencies’ recognition that their position had changed, discussions of both sides of the issue from public comments, and extensive reasoning for the Agencies’ conclusions in the Final Rules. Lastly, the Final Rules fully comply with the minimal requirements of the Regulatory Flexibility Act. Federal Defendants therefore respectfully request that the Court deny Plaintiffs’ motion for summary judgment and enter judgment for Federal Defendants.

BACKGROUND

I. The Affordable Care Act and the Contraceptive-Coverage Mandate

The ACA requires most group health plans and health-insurance issuers that offer group or individual health coverage to provide coverage for certain preventive services without “any cost sharing requirements.” 42 U.S.C. § 300gg-13(a). The Act does not expressly delineate the types of women’s preventive care that must be covered. Instead, as relevant here, the Act requires coverage, “with respect to women,” of such “additional preventive care and screenings . . . as provided for in comprehensive guidelines supported by the Health Resources and Services Administration [“HRSA”].” *Id.* § 300gg-13(a)(4).

In August 2011, HRSA adopted the recommendation of the Institute of Medicine (now the National Academy of Medicine), a part of the National Academies of Sciences, Engineering, and

Medicine, to issue guidelines requiring coverage of, among other things, the full range of FDA-approved contraceptive methods, including oral contraceptives, diaphragms, injections and implants, emergency contraceptive drugs, and intrauterine devices. *See* Group Health Plans and Health Insurance Issuers Relating to Coverage of Preventive Services Under the Patient Protection and Affordable Care Act, 77 Fed. Reg. 8,725, 8,725 (Feb. 15, 2012). As a result, coverage for such contraceptive methods was required for plan years beginning on or after August 1, 2012. *See* Group Health Plans and Health Insurance Issuers Relating to Coverage of Preventing Services Under the Patient Protection and Affordable Care Act, 76 Fed. Reg. 46,621, 46,623 (Aug. 3, 2011).

At the same time, 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* 76 Fed. Reg. at 46,623; 77 Fed. Reg. at 8,725. Various religious groups urged 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* Coverage of Certain Preventive Services Under the Affordable Care Act, 78 Fed. Reg. 8,456, 8,459 (Feb. 6, 2013). Instead, in a subsequent rulemaking, the Agencies offered an “accommodation” for religious not-for-profit organizations with religious objections to providing contraceptive coverage. *See* Coverage of Certain Preventive Services Under the Affordable Care Act, 78 Fed. Reg. 39,870, 39,874-82 (July 2, 2013). 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,” *id.* at 39,874, by providing notice of its objection. The regulations then generally required the employer’s health insurer or third-party administrator to provide or arrange contraceptive coverage for plan participants. *See id.* at 39,875-80.

In the case of self-insured church plans, however, coverage by the plan’s third-party administrator under the accommodation was effectively voluntary.² Church plans are exempt from the Employee Retirement Income Security Act of 1974 (“ERISA”) under section 4(b)(2) of that Act, and the authority to enforce a third-party administrator’s obligation to provide separate contraceptive coverage derives solely from ERISA. The Agencies thus could not require the third-party administrators of self-insured 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. *See Coverage of Certain Preventive Services Under the Affordable Care Act*, 79 Fed. Reg. 51,092, 51,095 n.8 (Aug. 27, 2014).

II. Challenges to the Contraceptive-Coverage Mandate and Accommodation

Many employers objected to the contraceptive-coverage mandate. The Supreme Court in *Burwell v. Hobby Lobby Stores, Inc.*, 573 U.S. 682 (2014), held that RFRA prohibited applying the mandate to closely held for-profit companies with religious objections to providing contraceptive coverage. The Court held that the mandate “impose[d] a substantial burden on the exercise of religion” for employers with religious objections, *id.* at 726, and that even assuming a compelling governmental interest, application of the mandate to such employers was not the least restrictive means of furthering that interest, *id.* at 727. The Court observed that, at a minimum, the less-restrictive accommodation made available to not-for-profit employers by the Agencies could be extended to closely held for-profit companies with religious objections to the mandate but not the accommodation. *Id.* at 730. The Court did not decide, however, “whether an approach of this type complies with RFRA for purposes of all religious claims.” *Id.* at 731.

² A church plan can include a plan maintained by a “principal purpose” organization (typically, a religious nonprofit) regardless of who established it. *See Advoc. Health Care Network v. Stapleton*, 581 U.S. 468, 471-84 (2017); *see also* 29 U.S.C. § 1002(33)(C)(i).

In response to *Hobby Lobby*, the Agencies promulgated rules extending the accommodation to closely held for-profit entities with religious objections to providing contraceptive coverage. *See* Coverage of Certain Preventive Services Under the Affordable Care Act, 80 Fed. Reg. 41,318, 41,323-28 (July 14, 2015). But numerous entities continued to challenge the mandate. They argued that the accommodation did not alleviate the burden imposed on their exercise of religion by the mandate because they sincerely believed that the required notice and the provision of contraceptive coverage in connection with their health plans made them complicit in providing such coverage, in contravention of their faith.

A circuit split developed,³ and the Supreme Court granted certiorari in several of the cases. The Court vacated those judgments and remanded the cases to the respective courts of appeals. *See Zubik v. Burwell*, 578 U.S. 403 (2016) (per curiam). The Court “d[id] not decide whether [the plaintiffs’] religious exercise ha[d] been substantially burdened, whether the Government ha[d] a compelling interest, or whether the current regulations [we]re the least restrictive means of serving that interest.” *Id.* at 409. Instead, the Court held that, on remand, the Courts of Appeals should afford the parties an opportunity to resolve the dispute. In the meantime, the Court precluded the government from “impos[ing] taxes or penalties on [the plaintiffs] for failure to provide the [notice required under the accommodation].” *Id.*

In response to the Supreme Court’s *Zubik* order, the Agencies requested public comments 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

³ Compare, e.g., *Priests for Life v. HHS*, 772 F.3d 229 (D.C. Cir. 2014) (accommodation does not substantially burden religious exercise), *vacated and remanded*, *Zubik v. Burwell*, 578 U.S. 403 (2016), with *Sharpe Holdings, Inc. v. HHS*, 801 F.3d 927 (8th Cir. 2015) (accommodation violates RFRA), *vacated by HHS v. CNS Int’l Ministries*, 578 U.S. 968 (2016).

employees. *See* Coverage for Contraceptive Services, 81 Fed. Reg. 47,741 (July 22, 2016). The Agencies received over 54,000 comments, but they could not find a way to amend the accommodation to both account for employers’ religious obligations and provide coverage to their employees. *See* Religious Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act, 82 Fed. Reg. 47,792, 47,798-47,799, 47,814 (Oct. 13, 2017). The then-pending litigation—more than three dozen cases brought by more than 100 separate plaintiffs—thus remained unresolved.

In addition, some nonreligious organizations with moral objections to providing contraceptive coverage challenged the mandate. That litigation also led to conflicting decisions by the courts. *Compare Real Alternatives, Inc. v. Sec’y of HHS*, 867 F.3d 338 (3d Cir. 2017) (rejecting challenge), with *March for Life v. Burwell*, 128 F. Supp. 3d 116 (D.D.C. 2015) (issuing permanent injunction against the government), *appeal dismissed*, 2018 WL 4871092 (D.C. Cir. Sept. 17, 2018).

III. The Interim Final Rules

In an effort “to resolve the pending litigation and prevent future litigation from similar plaintiffs,” the Agencies concluded that it was “appropriate to reexamine” the mandate’s exemption and accommodation. 82 Fed. Reg. at 47,799. In October 2017, the Agencies issued two interim final rules (“IFRs”) that (i) expanded the exemption while continuing to offer the existing accommodation as an optional alternative and (ii) requested public comments. *Id.* The first IFR expanded the religious exemption to all non-governmental plan sponsors and institutions of higher education that arrange student health plans, to the extent that these sponsors and institutions have sincere religious objections to providing contraceptive coverage, as well as to

individuals with similar religious objections who were able to obtain religiously compliant plans from willing employers and issuers. *See id.* at 47,806.

The Agencies acknowledged that contraceptive coverage is “an important and highly sensitive issue, implicating many different views.” 82 Fed. Reg. at 47,799. But “[a]fter reconsidering the interests served by the [m]andate,” the “objections raised,” and “the applicable Federal law,” the Agencies “determined that an expanded exemption, rather than the existing accommodation, [wa]s the most appropriate administrative response to the religious objections raised by certain entities and organizations.” *Id.* The Agencies also explained that the new approach was necessary because “[d]espite multiple rounds of rulemaking,” and even more litigation, they “ha[d] not assuaged the sincere religious objections to contraceptive coverage of numerous organizations” or resolved the pending legal challenges that had divided the courts. *Id.*

The second IFR created a similar exemption for entities with sincerely held moral objections to providing contraceptive coverage; unlike the religious exemption, though, this rule did not apply to publicly traded companies. *See Moral Exemptions and Accommodations for Coverage of Certain Preventative Services Under the Affordable Care Act*, 82 Fed. Reg. 47,838 (Oct. 13, 2017). This rule was issued “in part to bring the [m]andate into conformity with Congress’s long history of providing or supporting conscience protections in the regulation of sensitive health-care issues,” *id.* at 47,844, as well as similar efforts by states, including Plaintiffs, *id.* at 47,847. The IFR further reflected the Agencies’ attempts to address conflicting court decisions in legal challenges from moral objectors. *Id.* at 47,843.

IV. Plaintiff’s Challenge to the IFRs and the Court’s Opinion

Pennsylvania brought suit challenging the IFRs. The Court granted Plaintiff’s motion for preliminary injunctive relief, concluding that Plaintiff was likely to succeed on its claims that the

Agencies lacked the authority to issue interim final rules and were instead required to engage in notice and comment rulemaking. Opinion at 19-29, ECF No. 59 (“First PI Opinion”). The Court also held that Plaintiff was likely to succeed on its claim that the IFRs violated the text of the ACA. *Id.* at 29-37.

V. The Final Rules

The Agencies requested public comments on the IFRs. After considering, for over 11 months, the more than 110,000 comments submitted on the IFRs, on November 15, 2018, the Agencies issued final versions of the religious exemption and the moral exemption rules. The Final Rules address the significant comments received by the Agencies. The Agencies made changes in response to questions and concerns raised in various comments, but the fundamental substance of the exemptions was finalized as set forth in the IFRs.

As was true of the religious exemption IFR, the final religious exemption rule is “necessary to expand the protections for the sincerely held religious objections of certain entities and individuals.” Religious Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act, 83 Fed. Reg. 57,536, 57,537 (Nov. 15, 2018). It “minimize[s] the burdens imposed on their exercise of religious beliefs, with regard to the discretionary requirement that health plans cover certain contraceptive services with no cost-sharing.” *Id.* The rule “do[es] not remove the contraceptive coverage requirement generally from HRSA’s Guidelines.” *Id.* What it does is “finalize exemptions” for “[n]on-governmental plan sponsors including a church, an integrated auxiliary of a church, a convention or association of churches, or a religious order; a nonprofit organization; for-profit entities; an institution of higher education in arranging student health insurance coverage; and, in certain circumstances, issuers and individuals.” *Id.*

“In addition, the [religious exemption] 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.” *Id.*

The final moral exemption rule continues to fulfill the purpose that it did in interim form: to “protect sincerely held moral objections of certain entities and individuals.” Moral Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act, 83 Fed. Reg. 57,592, 57,592 (Nov. 15, 2018). The Agencies considered public comments asking for the moral exemption to be expanded to publicly traded or government entities, but declined to do so. *Id.* at 57,616-19. Importantly, like the religious exemption rule, the moral exemption rule “do[es] not remove the contraceptive coverage requirement generally from HRSA’s guidelines.” *Id.* at 57,593.

VI. Plaintiffs’ Amended Complaint and the Second Preliminary Injunction

Following the issuance of the Final Rules, New Jersey joined Pennsylvania’s suit and the two States filed an amended complaint challenging the Final Rules. Am. Compl. ¶ 33. The Court granted Plaintiffs’ second motion for a preliminary injunction. Opinion, ECF No. 136 (“Second PI Opinion”). The Court rejected Plaintiffs’ argument that in promulgating the Final Rules, the Agencies failed to adequately address comments. *Id.* at 25-27. But the Court found that Plaintiffs were likely to succeed on their notice-and-comment claim, *id.* at 27-33, and their claim that the Final Rules were contrary to law because neither the ACA nor RFRA justified the expanded exemptions from the mandate. *Id.* at 34-52. The Third Circuit affirmed the Court’s decision. *Pennsylvania v. President United States*, 930 F.3d 543 (3d Cir. 2019).

VII. The Supreme Court's Decision in *Little Sisters*

The Supreme Court granted petitions for a writ of certiorari to the Third Circuit filed by the Agencies and Intervenor, reversed the court of appeals, and remanded the case for further proceedings consistent with its opinion. *Little Sisters*, 591 U.S. at 687. In its decision, the Court rejected Plaintiffs' claims that the Agencies lacked statutory authority to enact the exemptions, Am. Compl. ¶ 182, could not consider RFRA, *id.* ¶ 185, and violated the notice-and-comment requirements of the APA by soliciting comments after issuing an interim final rule and by not maintaining an open mind, *id.* ¶¶ 174-76. *Little Sisters*, 591 U.S. at 674-86.

In so doing, the Court also addressed three issues that are relevant to the remaining claims. First, the Court recognized the Agencies' care in responding to comments on the IFRs and the strength of the Agencies' analysis generally, noting that the Final Rules "responded to post-promulgation comments," and "explain[ed] their reasons for neither narrowing nor expanding the exemptions beyond what was provided for in the IFRs." *Little Sisters*, 591 U.S. at 672-73. The Court also observed that the "final rule creating the religious exemption [] contained a lengthy analysis of the Departments' changed position regarding whether the self-certification process violated RFRA" and that the Agencies explained that "in the wake of the numerous lawsuits challenging the self-certification accommodation and the failed attempt to identify alternative accommodations after the 2016 request for information, 'an expanded exemption rather than the existing accommodation is the most appropriate administrative response to the substantial burden identified'" in *Hobby Lobby*. *Id.* at 673 (quoting 83 Fed. Reg. at 57,544-45).

Second, the Court emphasized the "extraordinarily broad general directive" that 42 U.S.C. § 300gg-13(a)(4) gave HRSA to define preventive care and screenings and to create the religious and moral exemptions: "HRSA has virtually unbridled discretion to decide what counts as

preventive care and screenings,” and “to identify and create exemptions from its own Guidelines.” *Little Sisters*, 591 U.S. at 676, 679 (quotation omitted).

Third, the Court rejected Pennsylvania’s argument that the Agencies “could not even consider RFRA as they formulated the religious exemptions.” *Id.* at 680. To the contrary, the Court held that, given “the potential for conflict between the contraceptive mandate and RFRA” and the Court’s prior opinions, it was “appropriate for the [Agencies] to consider RFRA” and “unsurprising that RFRA would feature prominently in the [Agencies’] discussion of exemptions.” *Id.* at 680, 681. Indeed, the Court observed that, had the Agencies not considered RFRA, they “would certainly be susceptible to claims that the rules were arbitrary and capricious for failing to consider an important aspect of the problem.” *Id.* at 682.

VIII. The Present Status of This Case

Following the Supreme Court’s decision, the Third Circuit reversed this Court’s decision and remanded the matter to this Court for further proceedings. *Pennsylvania v. President United States*, 816 F. App’x 632, 633 (3d Cir. 2020). As directed by the Court, the parties filed summary judgment briefs. *See* ECF Nos. 252, 254-55, 257, 259-60, 262-63. The Court stayed this case in 2021 (and subsequently denied without prejudice the parties’ cross motions for summary judgment) based on the Agencies’ expectation that they would initiate rulemaking that would affect this litigation. After issuing a notice of proposed rulemaking in 2023, *see* 88 Fed. Reg. 7236 (Feb. 2, 2023), and receiving comments, the Agencies decided to withdraw the notice, *see* 89 Fed. Reg. 106,393 (Dec. 30, 2024). The Court has ordered the parties to file renewed summary judgment motions.

LEGAL STANDARD

The Court should enter summary judgment for Defendants on all of Plaintiffs' claims under Federal Rule of Civil Procedure 56. "[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). And "because the district judge sits as an appellate tribunal in such cases," "summary judgment is the proper mechanism for deciding, as a matter of law, whether an agency's action is supported by the administrative record and consistent with the APA standard of review." *Kyzy v. U.S. Citizenship & Immigration Servs.*, 420 F. Supp. 3d 322, 326 (E.D. Pa. 2019) (citation omitted).

ARGUMENT

I. The Rules Are Not Arbitrary and Capricious

A. The Religious Exemption Rule Reasonably Addresses the Problems It Aimed to Resolve.

Plaintiffs assert that the religious exemption is arbitrary and capricious because an entity whose religious objections to contraception could be satisfied through the accommodation may nevertheless employ the religious exemption, which is in some respects broader. Mem. in Supp. of Pls.' Mot. for Summ. J. at 18-19, ECF No. 341-1 ("Pls.' MSJ"). But "[t]he APA does not . . . require agencies to tailor their regulations as narrowly as possible to the specific concerns that generated them." *Associated Dog Clubs of N.Y., Inc. v. Vilsack*, 75 F. Supp. 3d 83, 92 (D.D.C. 2014). Rather, "[a]n agency has wide discretion in making line-drawing decisions" and "is not required to identify the optimal threshold with pinpoint precision." *Nat'l Shooting Sports Found., Inc. v. Jones*, 716 F.3d 200, 214-15 (D.C. Cir. 2013) (quotation marks omitted); *see also Little Sisters*, 591 U.S. at 676-77 (recognizing broad discretion of Agencies to identify and create

exemptions). The line drawn need only be “within a zone of reasonableness.” *Nat’l Shooting Sports Found.*, 716 F.3d at 214.

The Religious Exemption Rule easily satisfies this standard. The Rule is intended to alleviate the burden on those whose religious objections to the mandate are not adequately addressed by the accommodation, which it does by exempting such entities from the mandate.⁴ *See* 83 Fed. Reg. at 57,556. That others whose objections to the mandate could be addressed by the accommodation might be able to invoke the exemption does not render the rule unreasonable, and to hold otherwise would be to demand the pinpoint precision the APA does not require. Furthermore, there is no reason to think that, in practice, the exemption will be overinclusive. Providing coverage for contraceptives is cost neutral for an employer or school, 78 Fed. Reg. at 39,877, and such coverage is a valuable benefit to some employees and students. Thus, there is no reason that an employer or school that does not object to providing contraceptive coverage as part of its plan, whether through the accommodation or otherwise, would invoke the exemption, since doing so would deprive its employees or students of a valuable benefit to which it does not object and that does not cost it anything. The line drawn by the Agencies, then, is well “within a zone of reasonableness”: It provides relief for those with sincere religious objections to the accommodation without being meaningfully overinclusive.

Plaintiffs also assert that the religious exemption is arbitrary and capricious because it is available to an entity that “merely *objects* [to contraception] based on its sincerely held religious

⁴ Plaintiffs refer to the Moral Exemption Rule in a footnote in this section. Pls.’ MSJ at 18 n.6. But the Moral Exemption Rule cannot “share[] th[e] flaw” of allowing an employer to take an exemption when “the Accommodation would fully resolve [any conflict with RFRA],” *id.*, because the Moral Exemption Rule was not intended to alleviate conflicts with RFRA, but instead to provide relief to entities with a non-religious, moral objection to using the accommodation. *See, e.g.*, 83 Fed. Reg. at 57,593.

beliefs” and does not require objecting employers to claim “a substantial burden.” Pls.’ MSJ at 18. This argument is confounding. Requiring such an objecting entity to provide contraceptive coverage would lead to a substantial burden, be it the provision of contraceptive coverage in violation of its sincerely held beliefs, or the devastating financial penalties that would follow from the refusal to do so. *Hobby Lobby*, 573 U.S. at 720; *see also Little Sisters*, 591 U.S. at 681 (“[W]e made it abundantly clear that, under RFRA, the Departments must accept the sincerely held complicity-based objections of religious entities.”). And Plaintiffs offer no support for the suggestion that the Agencies were somehow required to use the legal term “substantial burden,” instead of spelling out the factual predicate that the Supreme Court has determined is sufficient to establish that the contraceptive mandate imposes a substantial burden.

Plaintiffs also argue that the Religious Exemption Rule “improperly covers publicly traded corporations.” Pls.’ MSJ at 19. But there is nothing arbitrary or capricious about including publicly traded entities within the scope of the Religious Exemption Rule. Although Plaintiffs complain that the Agencies’ explanation of the reasoning for the exemption was “too thin,” *id.*, the Agencies discussed their thinking on this point at length. 83 Fed. Reg. at 57,562-63. Their treatment of the issue is more than sufficient to meet the deferential standard for arbitrary-and-capricious review, which requires only that an agency’s decision “was the product of reasoned decisionmaking.” *Motor Vehicle Mfrs. Ass’n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 52 (1983).

Plaintiffs further object that the Supreme Court in *Hobby Lobby* only determined that RFRA covers closely held for-profit corporations, and has not yet held that RFRA covers publicly traded corporations. Pls.’ MSJ at 19. While no publicly traded corporation was before the Court in *Hobby Lobby*, that case’s logic likewise teaches that, if a publicly held corporation had a

sincerely held religious objection, RFRA would require the Agencies to accommodate it. *Cf. Hobby Lobby*, 573 U.S. at 708 (“No known understanding of the term ‘person’ includes some but not all corporations.”) (emphasis omitted). Moreover, in reviewing an arbitrary-and-capricious claim, the question is only whether there was a “rational connection between the facts found and the choice made,” *State Farm*, 463 U.S. at 43 (citation omitted), and “[t]hat requirement is satisfied when the agency’s explanation is clear enough that its path may reasonably be discerned,” *Encino Motorcars, LLC v. Navarro*, 579 U.S. 211, 221 (2016) (citation omitted). Here, the Agencies were considering the need to provide exemptions for entities with religious objections to contraceptive coverage, and were aware of the Supreme Court’s decision in *Hobby Lobby* that even for-profit corporations are entitled to RFRA’s protections. Accordingly, the Agencies’ path in crafting an exemption that would cover even publicly traded corporations with religious objections—should any such corporations exist—can be clearly discerned.

In any event, it is not necessary for the Supreme Court to have spoken on this precise issue in order for the Agencies to have acted reasonably in exempting publicly traded corporations. Even if RFRA does not extend to publicly traded companies, the Agencies could—in light of the broad discretion afforded to them in the ACA to craft religious exemptions, *Little Sisters*, 591 U.S. at 675-79—reasonably exercise their discretion to extend the protection of the religious exemption to such companies to accommodate their religious interests.

Finally, while Defendants are not aware of any publicly traded entity with a sincere religious objection to providing contraceptive coverage, if one were to exist, then it would not be arbitrary and capricious to address that objection. And conversely, if no such entity exists—and as Plaintiffs note, Pls.’ MSJ at 19-20, and as the Agencies acknowledged, 83 Fed. Reg. at 57,562,

there are several reasons to infer that an objection from a publicly traded corporation is unlikely—then the mere availability of the exemption on paper harms neither Plaintiffs nor anyone else.

Plaintiffs also object that the exemptions do not require entities to provide notice to the government or their insurer or third-party administrator (“administrator”), and thus that there is no “mechanism for the sincerity of an employer’s religious belief to be evaluated.” Pls.’ MSJ at 20. As an initial matter, it would seem that, regardless of what the Rules require, an employer seeking to provide insurance that excludes coverage for contraceptives will in fact need to communicate that direction to their insurer or administrator. In any event, while Plaintiffs hypothesize that the lack of a notice requirement will permit insincere religious objections, *see id.*, the Agencies considered this issue in the Rule and reasonably concluded that the PHS Act, the Internal Revenue Code, and ERISA provide adequate mechanisms for enforcement against any entities that raise insincere religious objections. 83 Fed. Reg. at 57,558. That Plaintiffs disagree with the Agencies’ conclusions does not make them arbitrary or capricious. *See SIH Partners LLLP v. Comm’r of Internal Revenue*, 923 F.3d 296, 303 (3d Cir. 2019) (“A court is not to ask whether a regulatory decision is the best one possible or even whether it is better than the alternatives.”) (citation omitted). The reasonableness of the Agencies’ course is further demonstrated by the fact that the prior exemptions also did not include notice requirements. 83 Fed. Reg. at 57,558.

B. The Agencies Reasonably Addressed RFRA.

Plaintiffs also argue that the religious exemption rule was not a reasonable response to the Agencies’ duty to consider RFRA. Pls.’ MSJ at 21-23. As an initial matter, RFRA required the Agencies to adopt the religious exemption rule. *See infra* § I.H. But even if it did not, Plaintiffs are far from meeting the high bar necessary to show that the Agencies’ conclusions on RFRA were so lacking in reasoned decisionmaking as to be arbitrary or capricious.

Plaintiffs criticize the rule for, in their view, insufficiently citing and analyzing cases dealing with RFRA, including *Real Alternatives*. Pls.’ MSJ at 21-22. Of course, Plaintiffs offer no authority for the proposition that an agency acts arbitrarily or capriciously if it does not survey a particular volume of caselaw. Here, in any event, the Agencies were clearly aware of the important issues surrounding RFRA and discussed them at length in the Rule. 83 Fed. Reg. at 57,546-48. Indeed, as Plaintiffs acknowledge, the Rule cites *Real Alternatives* and a number of other cases addressing RFRA. Pls.’ MSJ at 21-22. This is more than enough to satisfy the lenient arbitrary and capricious standard by showing that the Agencies did not “entirely fail[] to consider an important aspect of the problem.”⁵ *State Farm*, 463 U.S. at 43. That the Agencies’ conclusion was different than the one the Plaintiffs would have reached is not a violation of the APA. *See Advocates for Highway & Auto Safety v. Fed. Motor Carrier Safety Admin.*, 429 F.3d 1136, 1150 (D.C. Cir. 2005). Moreover, to the extent Plaintiffs are arguing that the Religious Rule is contrary to law (rather than arbitrary and capricious) based on Third Circuit precedent, that argument fails. *See infra* § I.H.

Plaintiffs reiterate their contention that “conclusively resolving what RFRA requires is the job of the courts,” Pls.’ MSJ at 22, but to the extent that that contention is meant to suggest that the Agencies should ignore RFRA, it flatly ignores the Supreme Court’s statement in *Little Sisters* that “[p]articularly in the context of these cases, it was appropriate for the Departments to consider RFRA” because declining to consider RFRA would itself have been arbitrary and capricious. *Little Sisters*, 591 U.S. at 680-83; *see also id.* at 682-83 (“[R]espondents’ argument that the Departments erred by looking to RFRA as a guide when framing the religious exemption is without merit.”).

⁵ Nor were the Agencies’ conclusions inconsistent with *Real Alternatives*, because the Third Circuit in that case addressed only whether the accommodation substantially burdened employees—not objecting employers or schools. *See Real Alternatives*, 867 F.3d at 355 & n.17.

And while Plaintiffs assert that the Agencies should have further considered the least restrictive means to proceed, Pls.’ MSJ at 22, the Agencies had already determined that there was no compelling interest, rendering that analysis unnecessary. In any event, Plaintiffs are incorrect to suggest that the government is allowed to accommodate religions only to the bare minimum level required by RFRA, and that if it exceeds that threshold, it violates the law.

C. The Agencies Thoroughly Explained the Bases for the Rules.

Plaintiffs contend that “the Rules lack a detailed—or even reasoned—explanation for the Agencies’ changed stance on the safety, efficacy, and benefits of contraceptive care.” Pls.’ MSJ at 23. This contention has no merit. As *Little Sisters* makes clear, the Agencies’ explanation of the Final Rules was thorough and rational, appropriately considering the need for exemptions under RFRA, and offering a “lengthy analysis of the [Agencies’] changed position regarding whether the self-certification process violated RFRA.” 591 U.S. at 673.

“The scope of review under the ‘arbitrary and capricious’ standard is narrow.” *State Farm*, 463 U.S. at 43. An agency generally need not demonstrate “that the reasons for the new policy are better than the reasons for the old one[,]” but only that “the new policy is permissible under the statute, that there are good reasons for it, and that the agency believes it to be better.” *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009) (emphasis omitted). In situations where the “prior policy has engendered serious reliance interests that must be taken into account,” or an agency has reached different factual conclusions, an agency need only provide a “reasoned explanation” for treating differently “facts and circumstances that underlay or were engendered by the prior policy.” *Id.* at 515-16; *see also Encino Motorcars*, 579 U.S. at 223-24.

The Agencies easily satisfy this standard. The Final Rules contain voluminous explanations of the Agencies’ previous position, their current position, the Agencies’ recognition

that their position had changed, discussions of both sides of the issue from public comments, and extensive reasoning for the Agencies' conclusions in the Final Rules. *See, e.g.*, 83 Fed. Reg. at 57,546-56. The Agencies did not ignore their prior findings or any reliance interests—over the course of four pages of the Federal Register, *id.* at 57,552-56, the Agencies discussed the efficacy and health effects of contraceptive use as well as the effect, if any, the mandate had on contraceptive use. *See Fox Television*, 556 U.S. at 526 (rejecting argument that agency had offered an inadequate explanation in a remand order by noting, in part, that the order “devote[d] four full pages of small-type, single-spaced text . . . to explaining” the relevant conclusion).⁶

Through this discussion in the Rules, the Agencies demonstrated why, in their judgment, the policy interests in favor of expanding the exemptions outweigh the interests in leaving the contraceptive-coverage mandate unchanged: the evidence on the benefits of the contraceptive-coverage mandate is more mixed—and the religious and conscientious objections to complying with the mandate more substantial—than the Agencies previously acknowledged. 83 Fed. Reg. at 57,555-56. *See Nat'l Ass'n of Home Builders v. EPA*, 682 F.3d 1032, 1038 (D.C. Cir. 2012) (a “[policy] reevaluation is well within an agency’s discretion,” even without new facts). And in light of the fact that the ACA does not itself impose a contraceptive mandate in the first place, the Agencies reasonably concluded that it is consistent with the government’s interests under the ACA to provide exemptions for entities and individuals with non-religious moral objections to the

⁶ Plaintiffs contend that the Agencies had “rejected expanding the exemption to other employers [than houses of worship and their integrated auxiliaries] precisely because female employees of non-religious employers are less likely than individuals in plans of religious employers to share their employer’s (or institution of higher education’s) faith and objection to contraceptive coverage on religious grounds,” and, they add, “[t]he Agencies have not abandoned that position.” Pls.’ MSJ Mem. at 42 n.9 (quotations omitted). This latter contention is incorrect. In the Final Rules, the Agencies explain that they “no longer adhere” to their previous position that women who work at religious non-profits are less likely to share the faith of their employer than women who work at houses of worship or their integrated auxiliaries. 83 Fed. Reg. at 57,561.

mandate. *See Little Sisters*, 591 U.S. at 677 (concluding that “the ACA leaves the Guidelines’ content to the exclusive discretion of HRSA” and thus “gives HRSA broad discretion to define preventive care and screenings and to create the religious and moral exemptions”).

Plaintiffs contend not only that the Agencies did not provide an adequate explanation for each of the Rules, but that, in fact, the Agencies’ conclusions “run[] counter to the evidence before [them].” *State Farm*, 463 U.S. at 43. Not so. Plaintiffs first contend that, in the course of suggesting that there is uncertainty about the side effects and efficacy of contraception, the Agencies “irrationally treat[ed] all 18 forms of FDA-approved contraception as indistinguishable.” Pls.’ MSJ at 25. Relatedly, they add: “The Agencies do not identify any new evidence that all 18 forms of FDA-approved contraception are *categorically* unsafe for women, or any evidence contradicting their prior conclusion that unintended pregnancy is a health risk for women.” *Id.*

Plaintiffs’ argument misses the mark. Some entities with conscience objections to contraceptives object to all FDA-approved contraceptives. *See* 83 Fed. Reg. at 57,575. Thus, it makes sense for the Agencies to assess the overall effects of Rules that permit—but do not require—those entities to decline to provide coverage for all FDA-approved contraceptives. The effects of the Rules, even if indirect, include not only any costs associated with an entity declining to provide contraceptive coverage of any of the drugs or devices, but also the benefits—such as possible side effects avoided for each drug. In this context, it was entirely reasonable for the Agencies to assess the health effects of contraceptives categorically when assessing the effects of the Rules. And there was no need for the Agencies to “identify any new evidence that all” FDA-approved contraceptives are unsafe or that there are no health risks for unintended pregnancies, Pls.’ MSJ at 25, because the Rules do not reach those conclusions. The Rules instead reach the much more modest conclusion that the net benefits of employer-provided contraceptive coverage

are less certain than previously acknowledged and do not justify demanding that those with sincere conscience objections be required to provide such coverage. 83 Fed. Reg. at 57,556.

Next, Plaintiffs erroneously contend that the Agencies “ma[d]e commenters’ religious views [that certain forms of contraception are abortifacients] part of the rationale for reversing course on scientific and medical questions.” Pls.’ MSJ at 26. Relatedly, Plaintiffs insist that the Agencies’ “new position” on the operation of certain contraceptives employs a definition of pregnancy that contradicts HHS’s current definition. *Id.* These arguments fail because Plaintiffs have misinterpreted the Rules. The Agencies did not rely on the fact that some commenters view certain contraceptives as abortifacients to assess the health effects of contraception (or to redefine pregnancy), but instead as further evidence that some entities have conscience objections to the provision of contraceptive coverage where the contraceptives at issue interfere with implantation: “The Departments . . . recogniz[e] that some people have sincere religious objections to providing contraception coverage on this basis.” 83 Fed. Reg. at 57,554. Indeed, contrary to Plaintiffs’ argument, the Agencies explicitly declined to “take a position on the scientific . . . debate[] on th[e] issue” of whether some contraceptives are abortifacients. *Id.*

Plaintiffs also argue that the Rules “disregard” prior conclusions that HHS has reached about the efficacy of contraceptives in reducing teen pregnancy. Pls.’ MSJ at 27. *See* Ex. 152 to Pls.’ MSJ. Plaintiffs’ argument relies on a document outside the administrative record, and for this reason alone, the argument should be rejected. *See, e.g., Camp v. Pitts*, 411 U.S. 138, 142, (1973) (“In applying [the arbitrary and capricious] standard, the focal point for judicial review should be the administrative record already in existence, not some new record made initially in the reviewing court.”); *NVE, Inc. v. HHS*, 436 F.3d 182, 189 (3d Cir. 2006) (same). In any event, in the exhibit referenced by Plaintiffs, HHS does not reach a definitive conclusion about the efficacy

of contraceptives in reducing teen pregnancy. First, HHS simply states that contraceptives play a role in reducing teen pregnancy “according to recent research,” Ex. 152, without clearly adopting the conclusion as its own. Second, the exhibit also notes that “according to recent research” another factor was at play: namely, teenagers delaying sexual intercourse. *Id.* Nor do Plaintiffs dispute the presence of other factors. *See* Pls.’ MSJ at 27. And HHS does not reach a conclusion about the extent to which contraceptives, as opposed to this other factor, contribute to any reduction in teen pregnancy rates. This is entirely consistent with the Rules, which state: “[I]t 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.” 83 Fed. Reg. at 57,554.

Plaintiffs also incorrectly insist that the Agencies have not explained their conclusion that the Rules “are not likely to have negative effects on the health or equality of women nationwide.” Pls.’ MSJ at 27 (citing 83 Fed Reg. at 57,556). “Under the arbitrary and capricious standard [a court’s] deference to the agency is greatest when reviewing technical matters within [the agency’s] expertise.” *Nat’l Ass’n of Metal Finishers v. EPA*, 719 F.2d 624, 657 (3d Cir.1983), *rev’d on other grounds sub nom. Chem. Mfrs. Ass’n v. NRDC*, 470 U.S. 116 (1985); *see also Kleissler v. U.S. Forest Serv.*, 183 F.3d 196, 198 (3d Cir. 1999) (“When reviewing scientific and technical data we defer to the findings and expertise of the [agency].”). Under this deferential standard, the Agencies furnished ample support for their conclusion that the benefits of contraceptives and the mandate are more mixed than previously recognized. 83 Fed. Reg. at 57,552-56. For example, the Agencies cited numerous articles, including several from well-established peer-reviewed medical journals such as the New England Journal of Medicine, The Lancet, and the Journal of the American Medical Association, *id.* at 57,552-53 nn.28-34, to support their conclusion that the benefits of

contraceptives are more uncertain than previously recognized, *see, e.g.*, 78 Fed. Reg. at 39,872 (discussing the benefits of contraceptives); Supplement to J.A., Ex. 156-176 (attached). The Rules similarly support the conclusion regarding the benefits of the mandate. 83 Fed. Reg. at 57,555-56. Crucially, the Agencies did not conclude that contraceptives and the contraceptive-coverage mandate have no benefits. Rather, they determined that the net benefits are less certain than previously acknowledged and do not justify demanding that those with sincere conscience objections be required to provide contraceptive coverage.

Plaintiffs finally contend that the Agencies ignored “several comments proving that Colorado’s contraceptive mandate, for example, reduced the unintended pregnancy and abortion rate” and comments showing that the contraceptive-coverage mandate has allowed women to choose more effective methods of contraception. Pls.’ MSJ at 28. These contentions are meritless.

This Court has already rejected similar arguments. In its decision on Plaintiffs’ second motion for a preliminary injunction, the Court explained that “a review of the Final Rules demonstrates that the Agencies acknowledged the comments and provided an explanation as to why the Agencies did (or did not) amend the Final Rules based on the comment.” Second PI Opinion at 26. In any event, the Agencies explicitly considered comments that the mandate has “led women . . . to change from less effective, less expensive contraceptive methods to more effective, more expensive contraceptive methods,” 83 Fed. Reg. at 57,556. And as for the Colorado-related comments, the Agencies did not ignore them, but also relied on other evidence submitted by commenters, such as the study showing the federal mandate did not have an appreciable effect on contraceptive use in general or use of more effective contraceptive methods. *Id.* at 57,555; *see Pub. Citizen, Inc. v. FAA*, 988 F.2d 186, 197 (D.C. Cir. 1993) (explaining that an agency “is not required to discuss every item of fact or opinion included in the submissions;”

rather, its “response to public comments need only enable us to see what major issues of policy were ventilated and why the agency reacted to them as it did”) (citations and internal punctuation omitted). Based on the conflicting evidence, and the fact that the Rules did not repeal the contraceptive mandate entirely but only expanded the exemption to a small subset of covered entities, the Agencies reasonably concluded that some evidence of effects from local contraceptive coverage mandates did not override the reasons the Agencies had to issue the Final Rules.

D. The Moral Exemption Rule Is Well Justified.

Plaintiffs’ various challenges to the Moral Exemption Rule fail. *See* Pls.’ MSJ at 29-32. Congress did not prohibit the Agencies from creating an exemption for those with moral objections to contraceptive coverage. Indeed, the Supreme Court concluded just the opposite in *Little Sisters*, holding: “Under a plain reading of the statute, then, we conclude that the ACA gives HRSA broad discretion to define preventive care and screenings and to create the religious and *moral* exemptions.” *Little Sisters*, 591 U.S. at 677 (emphasis added). That holding binds this Court, and it also refutes Plaintiffs’ contention that either the APA or ACA must explicitly authorize considering moral objections before the agency can do so. *See id.* (“Congress could have limited HRSA’s discretion in any number of ways, but it chose not to do so.”); *see also Stewart v. Spencer*, 344 F. Supp. 3d 147, 157 (D.D.C. 2018) (concluding that an agency could consider a specific factor—personnel records—because “there is no indication here that Congress did not intend the Secretary to rely on personnel records” and “[t]his is the sort of material that would logically inform a decision maker”), *aff’d sub nom. Stewart v. McPherson*, 955 F.3d 1102 (D.C. Cir. 2020). Similarly, the Supreme Court’s holding obviates Plaintiffs’ argument that Congress’s rejection of a conscience amendment to the ACA prohibited the Agencies from enacting a moral exemption.

It was also reasonable for the Agencies to consider litigation history, conscience protections in other federal and state statutes, and “founding-era respect for conscientious objections,” Pls.’ MSJ at 32, when determining whether to exercise their discretion to enact a moral exemption. *Cf. Douglas v. Pension Benefit Guar. Corp.*, No. 06-cv-3170, 2008 WL 2805604, at *3 (E.D. Pa. July 18, 2008) (APA arbitrary and capricious review proceeds under a “very narrow and highly deferential standard under which an agency’s action is presumed valid”). These are the sorts of factors that “would logically inform a decision maker.” *Stewart*, 344 F. Supp. 3d at 157. Litigation by those with moral objections to the mandate illustrates the usefulness of a moral exemption for addressing non-religious conscience objections in the context of contraceptive coverage. 83 Fed. Reg. at 57,602-03. The existence of conscience protections in other federal and state statutes reflects the “tradition of protecting moral convictions in certain health contexts,” *id.* at 57,601, and tradition is a relevant consideration when assessing the appropriateness of legal protections, *see generally Michael H. v. Gerald D.*, 491 U.S. 110, 124 (1989) (discussing role of “history and tradition” in interpreting due process clause). Finally, and relatedly, there was nothing unreasonable about the Agencies “highlight[ing] th[e] tradition of respect for conscience from the Nation’s Founding Era to provide background support for the Departments’ decision,” 83 Fed. Reg. at 57,602; *see generally Michael H.*, 491 U.S. at 124.

E. The Agencies Adequately Considered Regulatory Alternatives.

Although Plaintiffs’ renewed summary judgment brief contends that the Agencies did not adequately explain their reasons for rejecting certain regulatory alternatives, *see* Pls.’ MSJ at 32-37, this contention is absent from both Plaintiffs’ amended complaint and their initial summary judgment briefing. *See generally* Am. Compl., ECF No. 89; *see also* ECF Nos. 251-1, 261 (Plaintiffs’ prior merits briefs); *Potoczny v. Aurora Loan Servs., LLC*, 33 F. Supp. 3d 554, 559

(E.D. Pa. 2014) (declining to “consider claims asserted by the plaintiff for the first time in his motion for summary judgment”), *aff’d*, 636 F. App’x 115 (3d Cir. 2015). In any event, the Agencies rationally explained why they rejected regulatory alternatives that would not accomplish their policy objectives. In evaluating an agency’s consideration of alternatives, courts do not “ask whether a regulatory decision . . . is better than the alternatives.” *FERC v. Elec. Power Supply Ass’n*, 577 U.S. 260, 292 (2016). “Rather, an agency must consider only significant and viable and obvious alternatives,” *Nat’l Shooting Sports Found.*, 716 F.3d at 215 (citations and internal punctuation omitted), and “explain its reasons for rejecting [such] alternatives in sufficient detail to permit judicial review,” *Walter O. Boswell Mem’l Hosp. v. Heckler*, 749 F.2d 788, 797 (D.C. Cir. 1984) (citation omitted); *see also Yeboah v. U.S. Dep’t of Just.*, 345 F.3d 216, 223 (3d Cir. 2003) (agency action “will not be deemed arbitrary, capricious, or an abuse of discretion simply because one may happen to think it ill-considered, or to represent the less appealing alternative solution available”) (citation omitted).

Plaintiffs argue that the Agencies did not adequately consider three regulatory alternatives: (1) limiting the exemptions’ scope to employers with complicity-based objections to the accommodation or enlarging or adjusting the accommodation to address complicity-based objections, Pls.’ MSJ at 33-35; (2) providing a more limited exemption (or just the accommodation) for entities with moral objections to contraceptive coverage, *id.* at 35; and (3) creating an entirely separate process for women of exempted employers to obtain contraceptive coverage, *id.* at 35-36. However, the Agencies have appropriately explained their decision to reject the alternatives preferred by Plaintiffs.

First, the Agencies explained why adopting more limited exemptions or “simply expand[ing] or adjust[ing] the accommodation process” was not viable and would not accomplish

the Agencies' policy objectives. 83 Fed. Reg. at 57,542. Limiting the exemptions to address only employers with complicity-based objections to the accommodation would result in some religious objections by plan sponsors and individuals being favored with exemptions, some objectors not being subjected to the contraceptive coverage mandate if they fall under the indirect exemption for certain self-insured church plans, and other objectors having to choose between the mandate and the accommodation even though they object to both. *Id.* The scope of the present exemptions is necessary "to avoid inconsistency in respecting religious objections in connection with the provision of contraceptive coverage." *Id.* Contrary to Plaintiffs' contention, this is no mere "vague desire for uniformity," Pls.' MSJ at 34, but an "appropriate" decision to treat like cases alike and "avoid instances where the Mandate is applied in a way that violates the religious beliefs of certain plan sponsors, issuers, or individuals." 83 Fed. Reg. at 57,542.

In any event, the rationale for the Agencies' decision does not include only a desire for consistent treatment of religious objectors. "Congress has also established a background rule against substantially burdening sincere religious beliefs except where consistent with the stringent requirements" of RFRA. *Id.* Additionally, "Congress has consistently provided additional, specific exemptions for religious beliefs in statutes addressing federal requirements in the context of health care and specifically concerning issues such as abortion, sterilization, and contraception," and the scope of the religious exemption is "generally consistent with the scope of exemptions that Congress has established in similar contexts." *Id.*; *see also id.* (explaining that the scope of the exemptions is also "consistent with the intent of Executive Order 13535," declaring that under the ACA, "longstanding federal laws to protect conscience . . . remain intact" and that "numerous executive agencies have a role in ensuring that these restrictions are enforced").

Plaintiffs also fail to explain how their preferred options—such as exempting an employer who submitted a notice of its religious objection to the accommodation, or making the religious exemption available only to the extent that an employer has a religious objection to the accommodation—are compatible with these concerns. Moreover, the Agencies specifically addressed why it would be inadequate “to merely attempt to amend or expand the accommodation process.” *Id.* at 57,544. The accommodation process “did not actually accommodate the objections of many entities” because it “require[s] contraceptive coverage or payments in a way that is ‘seamless’ with the coverage provided by the objecting employer.” *Id.* And the Agencies were “unable to develop” an accommodation process “that would eliminate the religious objections of all plaintiffs” in pending litigation. *Id.* Because “merely amending that accommodation process without expanding the exemptions would not adequately address religious objections to compliance with the Mandate,” the Agencies concluded that “the most appropriate approach to resolve these concerns” is to expand the exemptions as they have done, while maintaining the accommodation as an option, “without forcing entities to choose between compliance with either the Mandate or the accommodation and their religious beliefs.” *Id.*; *see also* 82 Fed. Reg. at 47,800 (“[I]nformed by the Departments’ reassessment of the relevant interests, as well as by our desire to bring to a close the more than 5 years of litigation over RFRA challenges to the Mandate, the Departments have determined that the appropriate administrative response is to create a broader exemption, rather than simply adjusting the accommodation process.”).

Second, the Agencies also explained why they chose not to provide a more limited exemption for moral objectors to the contraceptive coverage mandate, or to amend or expand the accommodation process to account for moral objectors instead of providing the exemption.

Congress has long provided consistent exemptions for both religious beliefs and moral convictions in many federal statutes in the health care context. 83 Fed. Reg. at 57,603; *see also id.* at 57,600-02. The Agencies also wished to “avoid the stark disparity” resulting from respecting religious objectors “but not respecting parallel objections for moral convictions . . . because those objections are not specifically religious.” *Id.* at 57,603-04. And as was the case with the religious exemption, the Agencies specifically concluded that it would be inadequate to merely amend or expand the accommodation to account for moral objectors. *Id.* at 57,604. Because the accommodation process provides contraceptive coverage in a way that is seamless with the coverage provided by the objecting employer, it “did not actually accommodate the objections of many entities.” *Id.*

Third, Plaintiffs argue that the Agencies did not adequately consider another alternative: creating a separate process for women of exempt employers to obtain contraceptive coverage. Pls.’ MSJ at 35-36. As an initial matter, Plaintiffs appear to have waived this argument by not presenting it to the Agencies during the challenged rulemaking. *Sw. Pa. Growth All. v. Browner*, 121 F.3d 106, 111-12 (3d Cir. 1997); *but see United Ref. Co. v. EPA*, 64 F.4th 448, 456-58 (3d Cir. 2023). In any event, adoption of such a process would not necessarily be viable nor would it accomplish the Agencies’ policy objectives. The Agencies have specifically acknowledged that the creation of such a process “would not achieve the Women’s Health Amendment’s goal of ensuring that women have seamless cost-free coverage of contraceptives” because it would “require some additional action by the affected women and could require them to obtain contraceptive care from providers other than those from whom they typically receive women’s health care.” Coverage of Certain Preventive Services Under the Affordable Care Act, 88 Fed. Reg. 7,236, 7,254 (Feb. 2, 2023). Moreover, the Agencies have now considered such a process, as demonstrated by their issuance of the 2023 notice of proposed rulemaking, *see* 88 Fed. Reg. at

7252-54, and after receiving comments and having considered this alternative for several years, they decided to withdraw the proposal. Therefore, any purported failure to consider this alternative during the 2018 rulemaking process—where Plaintiffs did not suggest it—is harmless because the Agencies have now considered it. In any event, were the Court to find that the Agencies had not provided an adequate explanation for not adopting such a separate process, then the appropriate remedy would be remand without vacatur to provide additional explanation. *See infra* at III; *see also Coinbase, Inc. v. SEC*, 126 F.4th 175, 203 (3d Cir. 2025) (if a court “simply cannot evaluate the challenged agency action on the basis of the record before it, the proper course, except in rare circumstances, is to remand to the agency for additional investigation or explanation”) (citation omitted). This well-established remand rule is especially appropriate here, where the Agencies have been applying the challenged rules for more than six years without encountering any significant difficulties.

Finally, Plaintiffs err in contending that any purported inadequacy in the Agencies’ explanations for rejecting Plaintiffs’ proposed alternatives runs afoul of 42 U.S.C. § 18114. Pls.’ MSJ at 37. As an initial matter, that statute, which bars the promulgation of rules that “(1) create[] any unreasonable barriers to the ability of individuals to obtain appropriate medical care; [or] (2) impede[] timely access to health care services[,]” 42 U.S.C. § 18114(1), (2), is quite open-ended. Nothing in section 18114 specifies, for example, what constitutes an “unreasonable barrier[,],” “appropriate medical care[,]” or “timely access.” *Id.* This provision does not appear to have been the subject of any meaningful legislative history before the ACA’s enactment. Under these circumstances, section 18114 claims are not reviewable under the APA at all. *See Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 410 (1971) (APA bars judicial review of agency decision where, among other circumstances, “statutes are drawn in such broad terms that

in a given case there is no law to apply” (citation omitted)). In any event, the Final Rules do not implicate section 18114 because that section “is meant to prevent direct government interference with health care.” *California v. Azar*, 950 F.3d 1067, 1094 (9th Cir. 2020) (en banc). But Plaintiffs fail to identify any direct interference here. “The decision not to impose a governmental mandate is not the ‘creation’ of a ‘barrier.’” 83 Fed. Reg. at 57,552.

The Agencies have thus explained their reasons for deeming the alternatives suggested by Plaintiffs inadequate to meet their policy goals. Although Plaintiffs disagree with the Agencies’ decision, “[i]n offering an explanation for rejecting the[se] alternative[s], the [agencies were] not required to do more.” *Am. Radio Relay League, Inc. v. FCC*, 524 F.3d 227, 242 (D.C. Cir. 2008) (citation omitted).

F. The Agencies Considered Significant Comments.

Once again, Plaintiffs continue to press a line of argument that this Court rejected at the preliminary injunction stage, namely, that the Agencies inadequately responded to comments. In particular, they contend that the Final Rules are fatally flawed because numerically fewer comments supported the religious and moral exemptions, and because the Agencies purportedly ignored certain comments. Pls.’ MSJ at 38-40.

The former argument is easily dispensed with. Under the APA, agencies are not required to count comments and then pick the version of the rule that has the most votes. “The substantial-evidence standard has never been taken to mean that an agency rulemaking is a democratic process by which the majority of commenters prevail by sheer weight of numbers.” *Nat. Res. Def. Council, Inc. v. EPA*, 822 F.2d 104, 122 n.17 (D.C. Cir. 1987). Rather, an agency considers any comments that it receives on a proposed or interim final rule and determines, in the exercise of its discretion, what rule to adopt in view of those comments, statutory requirements, past regulations, and other

relevant considerations. “The number and length of comments, without more, is not germane” to this inquiry. *Id.* Here, the Agencies considered the comments they received. *See, e.g.*, 83 Fed. Reg. at 57,537 (listing modifications to the religious exemption rule based on comments). That is all the APA requires.

Next, Plaintiffs claim that the Agencies purportedly ignored three categories of comments raising “significant and substantive concerns.” Pls.’ MSJ at 39. Specifically, Plaintiffs contend that the Agencies (1) “nowhere acknowledge[d] the importance of comments by medical professionals,” (2) “ignored” comments indicating that Title X had insufficient funding to support increased demand for contraceptive coverage, and (3) failed to examine the impact of potential loss of contraceptive counseling as a result of the Final Rules. *See id.* (citation omitted).

With respect to the medical professionals’ comments, Plaintiffs cite no authority for the proposition that such comments are entitled to greater weight in APA rulemaking. *See id.* Indeed, all the APA requires is that an agency “*respond* to ‘significant’ comments, *i.e.*, those which raise relevant points and which, if adopted, would require a change in the agency’s proposed rule.” *Am. Mining Congress v. EPA*, 965 F.2d 759, 771 (9th Cir. 1992) (per curiam) (quoting *Home Box Office v. FCC*, 567 F.2d 9, 35 & n.58 (D.C. Cir. 1977) (emphasis added)). What is considered a “[s]ignificant comment[.]” depends on the content of the comment, not the identity of the commenter, *see City of Portland v. EPA*, 507 F.3d 706, 715 (D.C. Cir. 2007). In any event, Plaintiffs state that the medical professionals commented on the scientific bases for the Rules and the Rules’ possible effects on women, Pls.’ MSJ at 39, and the Agencies addressed these considerations. *See, e.g.*, 83 Fed. Reg. at 57,552-56.

With respect to Plaintiffs’ arguments regarding Title X, Pls.’ MSJ at 39, it is simply incorrect that the Agencies failed to respond to comments regarding the interaction between the

Final Rules and Title X. *See* 83 Fed. Reg. 57,551 (“Some commenters said that, for lower income women, contraceptives can be available . . . through government programs [such as Title X] Other commenters contended that many women in employer-sponsored coverage might not qualify for those programs . . . because the programs were not intended to absorb privately insured individuals.”). Indeed, this Court already rejected Plaintiffs’ argument in its preliminary injunction opinion. Second PI Opinion at 26-27. In any event, the Agencies never stated that they believed that Title X would be able to help all such women at risk of losing contraceptive coverage; they simply stated that “contraceptives can be available at free or low cost through government programs (federal programs offering such services include, for example, Medicaid, Title X . . .),” and they explicitly recognized that these programs have limits, such as income restrictions. 83 Fed. Reg. at 57,551. Moreover, given the recognition of these limits, the Rules provide no indication that they are premised on Title X recipients being able to assist all women who might be affected by the Rules. *See id.* (“The Departments do not believe that these general considerations make it inappropriate to issue the expanded exemptions set forth in these rules.”).

Finally, Plaintiffs argue that the Final Rules ignored comments regarding contraceptive counseling. *See* Pls.’ MSJ at 39. But again, the Final Rules belie this assertion, because they specifically address, and reject, the comments regarding the counseling issue. *See* 83 Fed. Reg. 57,556 (“Some commenters lamented that exemptions would include exemption from the requirement to cover contraception counseling. . . . [I]t is not clear that merely expanding exemptions as done in these rules will have a significant effect on contraceptive use and health.”). The Agencies did not “fail to address” these comments—they disagreed with them and stated the

reasons why, which is all that the APA requires.⁷ None of these points renders the Final Rules arbitrary or capricious.

G. The Agencies Performed a Reasonable Regulatory Impact Analysis.

Finally, Plaintiffs err in contending that the Agencies’ regulatory impact analysis (“RIA”) is arbitrary and capricious. Pls.’ MSJ at 40-43. As an initial matter, review of cost-benefit analyses should be particularly deferential. The principle “that a court is not to substitute its judgment for that of the agency” is “especially true when the agency is called upon to weigh the costs and benefits of alternative policies.” *Consumer Elecs. Ass’n v. FCC*, 347 F.3d 291, 303 (D.C. Cir. 2003) (quoting *State Farm*, 463 U.S. at 43; and *Ctr. for Auto Safety v. Peck*, 751 F.2d 1336, 1342 (D.C. Cir. 1985)). Accordingly, when reviewing a challenge to an agency’s cost-benefit analysis, a court limits its role to determining whether “the decision was based on a consideration of the relevant factors and whether there has been a clear error of judgment.” *Ctr. for Auto Safety*, 751 F.2d at 1342 (quoting *State Farm*, 463 U.S. at 43). The RIA is plainly reasonable and contains no “clear error[s] of judgment.” *Id.*; see 83 Fed. Reg. at 57,573-81.

First, Plaintiffs argue that the exemption for individuals creates the risk of a loss of coverage for dependents, and that this amounts to “an entire class of people” improperly excluded from the RIA. Pls.’ MSJ at 40. But the Agencies reasonably determined that any economic impact

⁷ Plaintiffs misplace their reliance on *Ohio v. EPA*, 603 U.S. 279 (2024), in attempting to impose “additional judge-made procedural requirements on [the Agencies] that Congress has not prescribed and the Constitution does not compel.” *Garland v. Ming Dai*, 593 U.S. 357, 365 (2021) (citation omitted). The agency in *Ohio* had chosen not to respond at all to a significant comment raised during rulemaking but had instead inserted a severability provision into its final rule that “highlight[ed] that [the agency] was aware of the [commenters’] concern.” 603 U.S. at 295. In concluding that the agency had erred by failing to respond at all to a significant comment, the Supreme Court stressed the “narrow[ness]” of its conclusion, noting that the agency “did not need to address every possible permutation” raised by commenters. *Id.* at 295 n.11. By contrast, as explained in the text, the Agencies have responded to significant comments.

from the individual exemption would be minimal because spouses and dependents would likely share the faith of the policy holder. *See* 83 Fed. Reg. at 57,568-69. The RIA therefore does not improperly ignore the issue of dependents.

Second, Plaintiffs incorrectly assert that the Agencies' estimate of 209 employers using the accommodation renders the Final Rules arbitrary and capricious. In the relevant section of the Rules, the Agencies estimate "the number of women affected among entities using the expanded exemptions," 83 Fed. Reg. at 57,575, based on data regarding the number of women covered by plans of litigating entities and the number of women covered by plans making use of user fee adjustments, and not on the assumption that 209 employers are using the accommodation. *Id.* at 57,575-76. In other words, the estimate of the number of women affected would not have changed if the Agencies had assumed that 209, 309, or 409 employers were using the accommodation; the estimate of the number of employers using the accommodation simply provides added context to the estimate of the number of women affected. In any event, even if there were some error in estimation, the Agencies' assumption regarding the number of employers using the accommodation did not play a determinative role in the Rule's assessment of the number of women affected by the Rules. Any alleged error is, therefore, harmless. *See* 5 U.S.C. § 706 (stating that "due account shall be taken of the rule of prejudicial error" when assessing whether agency action is arbitrary and capricious).

Third, Plaintiffs argue that the Agencies "assume[d] without any basis" that the majority of people working for an employer using the accommodation will not lose contraceptive coverage. Pls.' MSJ at 41. But as the Final Rules illustrate, such a conclusion was reasonable—the Final Rules state that a "broad range of religious hospitals or health systems have publicly indicated that they do not conscientiously oppose participating in the accommodation," and that such hospitals

account for “more than 80 percent of the persons covered in all plans using contraceptive user fees adjustments.” 83 Fed. Reg. at 57,576. Plaintiffs appear to take issue with the fact that the Agencies relied on public statements of such hospitals. But it was fully reasonable to rely on such statements for an understanding of these hospitals’ views. Plaintiffs provide no reason to conclude otherwise.

Fourth, Plaintiffs incorrectly contend that the Final Rules improperly “deflat[e] the number of women who may be affected” by two-thirds. Pls.’ MSJ at 42. The Agencies estimated that “private, non-publicly traded employers that did not cover contraception pre-Affordable Care Act, and that were not exempt by the previous regulations nor were participants in self-insured church plans that oppose contraceptive coverage, covered approximately 379,000 women aged 15 to 44 [*i.e.*, of childbearing age] that use contraceptives covered by the Guidelines.” 83 Fed. Reg. at 57,580. But the Agencies sensibly reasoned that not all such employers would have a religious objection. *Id.* Based on this sensible conclusion, the Agencies estimated that about one-third of the 379,000 women “would likely be subject to potential transfer impacts under the expanded religious exemptions offered in these final rules.” *Id.* This estimate is reasonable. The Agencies were “not aware of information, or of data from public comments, that would lead [them] to estimate that all or most entities that omitted coverage of contraception pre-Affordable Care Act did so on the basis of sincerely held conscientious objections in general or, specifically, religious beliefs, as opposed to having done so for other reasons.” *Id.* The Agencies explained that “only 4% of Americans believe that using contraceptives is morally wrong (including from a religious perspective)” and that “various reasons exist for some employers not to return to a pre-ACA situation in which they did not provide contraceptive coverage,” such as “the difficulty of taking away a fringe benefit that employees have become accustomed to having, and avoiding the administrative cost of renegotiating insurance contracts.” *Id.* at 57,580-81. The Agencies provided

other reasons for this conclusion as well. *Id.* at 57,581. Plaintiffs may not agree with the Agencies’ well-reasoned conclusion, but that disagreement does not render the conclusion irrational.

Finally, Plaintiffs, in a single sentence, take issue with the fact that the Agencies purportedly did not conduct “this analysis” for the Moral Exemption Rule. Pls.’ MSJ at 43. But the Agencies did conduct an analysis of the anticipated effects of the Moral Exemption Rule, and a perfectly reasonable one at that. *See* 83 Fed. Reg. at 57,625 (estimating anticipated effect of the rule to be small based on the fact that only two entities, with fewer than five employees, have filed lawsuits challenging the exemptions on the basis of moral objections). The Moral Exemption Rule is not arbitrary or capricious.

H. Because the Religious Exemption Rule Is Required by RFRA, Plaintiffs’ Arbitrary and Capricious Arguments Would Be Harmless Error.

As noted above, Plaintiffs’ allegations that the Rules are arbitrary or capricious because they inadequately considered or explained certain issues lack merit. *See supra* §§ I.A.-I.G. But even if these allegations were meritorious, they would fail with respect to the Religious Exemption Rule under the APA’s harmless error clause. Under that clause, “due account shall be taken of the rule of prejudicial error.” 5 U.S.C. § 706. Any error here would be harmless. The arbitrary and capricious clause exists to ensure that agencies engage in reasoned decisionmaking. *See, e.g., Fox v. Clinton*, 684 F.3d 67, 74–75 (D.C. Cir. 2012). But the Agencies had no decision to make with regard to the Religious Exemption Rule: RFRA obligated the Agencies to issue it. To be sure, the Agencies nevertheless considered all the factors Plaintiffs identify and thoroughly explained that they would have issued the same Rule even if the matter were a discretionary one. But because RFRA required the religious exemption, it ultimately does not matter what the Agencies considered or did not consider, or how they explained their decision-making process.

The Religious Exemption Rule was required by RFRA, which prohibits the government from “substantially burden[ing] a person’s exercise of religion” unless the government “demonstrates that application of the burden to th[at] person is . . . the least restrictive means of furthering [a] compelling governmental interest.” 42 U.S.C. § 2000bb-1(b). The accommodation does not eliminate the substantial burden that the contraceptive-coverage mandate imposes on certain employers with conscientious objections. As became clear in litigation following *Hobby Lobby*, some employers hold the sincere religious belief that participating in a process by which their employees receive contraceptive coverage “makes them complicit in providing [that] coverage,” even if the coverage is actually paid for by other parties. *Priests for Life v. HHS*, 808 F.3d 1, 15 (D.C. Cir. 2015) (Kavanaugh, J., dissenting from denial of rehearing en banc). Those employers believe that the accommodation is such a process because it commandeers their own health plans to provide coverage and requires them to facilitate notification to the health plan issuer or third-party administrator that will, upon receiving such notification, provide contraceptive coverage in connection with their plans. *See id.* at 25 n.11; *see also Sharpe Holdings, Inc. v. HHS*, 801 F.3d 927, 939-43 (8th Cir. 2015), *vacated and remanded sub nom. HHS v. CNS Int’l Ministries*, 578 U.S. 968 (2016); 83 Fed. Reg. at 57,546. Offering the accommodation as an alternative means of compliance with the mandate thus leaves in place the same “substantial burden on the ability of the objecting parties to conduct business in accordance with their religious beliefs” that the Court identified in *Hobby Lobby*. 573 U.S. at 724 (emphasis omitted). If the objecting employers “d[id] not yield to th[e] demand” to violate their beliefs, the “economic consequences” would be every bit as “severe.” *Id.* at 720. Indeed, the very same \$100-per-day-per-employee tax, or \$2,000-per-year-per-employee penalty, would apply. *See id.*; 26 U.S.C. §§ 4980D, 4980H; *see also Priests for Life*, 808 F.3d at 19 (Kavanaugh, J., dissenting).

Because requiring religious objectors to comply with the mandate through the accommodation would impose a “substantial burden” on their religious exercise, the Agencies could demand such compliance only if they “demonstrate[] that application of the [accommodation] is the least restrictive means of furthering [a] compelling governmental interest.” 42 U.S.C. § 2000bb-1(b). The Agencies have now recognized that they cannot make that showing. *See* 83 Fed. Reg. at 57,546-57,548. Under RFRA, therefore, the Agencies were required to provide an exemption for religious objectors. *See Little Sisters*, 591 U.S. at 688 (Alito, J., concurring) (stating that “RFRA compels an exemption for the Little Sisters and any other employer with a similar objection to what has been called the accommodation to the contraceptive mandate.”). In assessing whether an asserted governmental interest is compelling, the Supreme Court has explained that “a law cannot be regarded as protecting an interest of the highest order . . . when it leaves appreciable damage to that supposedly vital interest unprohibited.” *Church of Lukumi Babalu Aye v. City of Hialeah*, 508 U.S. 520, 547 (1993) (citation omitted). Thus, in *Gonzales v. O’Centro Espirita Beneficiente Uniao do Vegetal*, 546 U.S. 418 (2006), the Supreme Court held that the existence of an exemption from requirements of the Controlled Substances Act for individuals who use peyote for religious purposes undermined the position that denying a similar exemption to those who use hoasca for such purposes was necessary to advance a compelling governmental interest. *Id.* at 433.

Here, that same principle strongly supports the Agencies’ conclusion. Neither the contraceptive-coverage mandate itself nor the accommodation has ever been applied to the tens of thousands of employers that qualify as “churches, their integrated auxiliaries, and conventions or associations of churches,” 26 U.S.C. § 6033(a)(3)(A)(i); *see* 76 Fed. Reg. at 46,623; 83 Fed. Reg. at 57,560. And since 2013, coverage for employees insured through self-insured “church plans”

of church-affiliated not-for-profit organizations—including a number of large religious universities and hospitals—has been effectively voluntary as well. *See* 79 Fed. Reg. at 51,095 n.8. Especially given those longstanding exemptions, the Agencies correctly determined that they could not claim that applying the mandate or accommodation to other religious objectors was necessary to satisfy a compelling governmental interest. *See* 83 Fed. Reg. at 57,546-48.

The Agencies also correctly recognized that any interest in “seamless” contraceptive coverage is not compelling. Women who participate in health plans maintained by objecting organizations can often obtain contraception (if they want it) through other means, including existing federal, state, and local programs that provide free or subsidized contraceptives to low-income women. *See id.* at 57,548. And although utilizing the health plans of objecting employers to provide access to contraception might make such access marginally more convenient, that additional convenience is not the sort of “paramount interest[]” that has been recognized as compelling. *Sherbert v. Verner*, 374 U.S. 398, 406 (1963) (citation omitted).

Federal Defendants acknowledge that this Court previously disagreed with the conclusion that RFRA required the Agencies to issue the Religious Exemption Rule. Second PI Opinion at 46-51. But Federal Defendants respectfully request that the Court reverse its conclusion, especially in light of the Supreme Court’s *Little Sisters* decision. First, this Court concluded that RFRA does not require the Religious Exemption because the Court in *Hobby Lobby* “explained that an exemption akin to the Final Religious Exemption goes beyond RFRA’s requirements.” Second PI Opinion at 48 (citing *Hobby Lobby*, 573 U.S. at 719 n.30). However, Federal Defendants respectfully submit that this conclusion is incorrect. The exemption discussed in the footnote in *Hobby Lobby* was “written so broadly that it would allow any employer to deny any

health service to any American for virtually any reason—not just for religious objections.” 573 U.S. at 719 n.30 (citation and emphasis omitted).

Second, the Court concluded that, under the law of this Circuit—specifically, *Real Alternatives, Inc. v. Sec’y of HHS*, 867 F.3d 338 (3d Cir. 2017) and *Geneva Coll. v. Sec’y of HHS*, 778 F.3d 422 (3d Cir. 2015), *vacated and remanded sub nom. Zubik v. Burwell*, 578 U.S. 403 (2016)—there is no substantial burden on objecting entities. Second PI Opinion at 49-50. But in *Real Alternatives*, the Third Circuit was faced only with the question of whether the accommodation substantially burdened employees, rather than objecting employers or schools. *See Real Alternatives*, 867 F.3d at 355 & n.17 (noting that the relevant question “is distinct from an employer’s RFRA claim objecting to the mandated provision of contraceptive services that was found to be meritorious in [*Hobby Lobby*]”). *Real Alternatives* thus contains no holding on whether the accommodation substantially burdens employers or schools. As for *Geneva College*, it was vacated by the Supreme Court, and for the reasons discussed above, the reasoning in the Supreme Court’s jurisprudence teaches that RFRA does compel the exemption. As the Supreme Court noted in *Little Sisters*, it is “abundantly clear that, under RFRA, the [Agencies] must accept the sincerely held complicity-based objections of religious entities.” 591 U.S. at 681 (citing *Hobby Lobby*, 573 U.S. at 723-24).

Third, this Court held that the Religious Exemption Rule is not required by RFRA because the Rule applies to publicly traded companies. Second PI Op. at 50-51. Although no publicly traded corporation was before the Court in *Hobby Lobby*, the logic of that decision compels the result that, if a publicly held corporation had a sincerely held religious objection, then RFRA would require the Agencies to accommodate it. *Cf. Hobby Lobby*, 573 U.S. at 708 (“No known understanding of the term ‘person’ includes some but not all corporations.”) (emphasis omitted).

Thus, because public companies are covered by RFRA, their inclusion in the Rule does not demonstrate that the Rule goes beyond what RFRA requires.⁸

In sum, because RFRA required the Religious Exemption Rule, the alleged shortcomings in the Agencies' decisionmaking process that Plaintiffs assail as arbitrary and capricious constitute harmless error.

II. The Court Should Enter Summary Judgment on the Claims Addressed by the Supreme Court in *Little Sisters*.

In *Little Sisters*, the Supreme Court rejected Plaintiffs' claims that the Agencies (1) "did not follow the notice and comment procedures as set forth in the APA" before issuing the final rules because they accepted comments only after issuing the IFRs and did not keep an open mind, Am. Compl. ¶¶ 174-76; (2) could not consider RFRA, when enacting the religious exemption, *id.* ¶ 185; and (3) violated the APA by enacting the Religious and Moral Exemption Rules without statutory authority, in contravention of the ACA and the APA, *id.* ¶ 182. *Little Sisters*, 591 U.S. at 675-87. As to the notice-and-comment claim, the Supreme Court concluded that the States "are incorrect[.]" because "[f]ormal labels aside, the rules contained all of the elements of a notice of proposed rulemaking as required by the APA" and satisfied the "APA's objective criteria" for addressing comments. *Id.* at 683, 685. The Supreme Court also concluded that the Agencies properly considered RFRA, *id.* at 680-82, and that the "plain language of the statute clearly allows the Departments to create the . . . religious and moral exemptions," *id.* at 679. Federal Defendants therefore respectfully request that the Court enter summary judgment for Federal Defendants on these claims, a point Plaintiffs do not dispute. *See generally* Pls.' MSJ.

⁸ Moreover, although the Court also held that the Agencies should not have considered *RFRA*, *see* Second PI Opinion at 44-46, the Supreme Court rejected that holding. *Little Sisters*, 591 U.S. at 680-82.

III. Any Relief Should Be Limited to the Parties Before the Court.

As explained above, Federal Defendants have demonstrated that the Court should enter summary judgment in their favor. In any event, should the Court rule in favor of Plaintiffs on the merits, the APA dictates the appropriate remedy: the “set[ting] aside” of the agency action deemed unlawful by the Court. 5 U.S.C. § 706(2)(A), (D). The matter should then be “remand[ed] to the [A]genc[ies] for additional investigation or explanation.” *Fla. Power & Light Co. v. Lorion*, 470 U.S. 729, 744 (1985).

The scope of this “set aside”—or, indeed, any form of relief the Court may enter—must be limited to the parties before this Court. Nothing in the APA expands the Court’s jurisdiction beyond its traditional constitutional and equitable limitations. Rather, the APA preserves all ordinary principles of equity. *See* 5 U.S.C. § 702(1) (“Nothing herein affects ... the power or duty of the court to . . . deny relief on any other appropriate legal or equitable ground[.]”). Although Section 706(2) of the APA authorizes unlawful “agency action” to be “set aside,” it does not provide that such action be set aside facially, as opposed to solely with respect to those applications that actually injure a plaintiff. Accordingly, Section 706(2) is not properly construed to displace the general rule that equitable remedies may go no further than necessary to redress plaintiff’s own injury. *See Weinberger v. Romero-Barcelo*, 456 U.S. 305, 313 (1982) (“[W]e do not lightly assume that Congress has intended to depart from established [equitable] principles.”); *Califano v. Yamasaki*, 442 U.S. 682, 702 (1979) (equitable principles require that a remedy should be “no more burdensome to the defendant than necessary to provide complete relief to the plaintiffs”).

Thus, were the Court to order declaratory or injunctive relief here, any such remedy should be limited to the Plaintiffs that have demonstrated an impending future injury in order to have standing for prospective relief. *See generally Clapper v. Amnesty Int’l USA*, 568 U.S. 398 (2013).

Under Article III, a plaintiff must “demonstrate standing . . . for each form of relief that is sought.” *Town of Chester v. Laroe Estates, Inc.*, 581 U.S. 433, 439 (2017) (citation omitted); *see also Gill v. Whitford*, 585 U.S. 48, 66, 72 (2018) (a “plaintiff’s remedy must be limited to the inadequacy that produced his injury in fact” because “[t]he Court’s constitutionally prescribed role is to vindicate the individual rights of the people appearing before it”) (citation omitted). Nothing in *DHS v. Regents of the University of California*, 591 U.S. 1 (2020), cited by Plaintiffs, suggests to the contrary. Indeed, the Third Circuit has specifically recognized that a plaintiff lacks “standing to seek an injunction” beyond what is necessary to “provide [it] full relief.” *Ameron, Inc. v. U.S. Army Corps of Eng’rs*, 787 F.2d 875, 888 (3d Cir. 1986).

Moreover, nationwide injunctions “take a toll on the federal court system—preventing legal questions from percolating through the federal courts, encouraging forum shopping, and making every case a national emergency for the courts and for the Executive Branch.” *Trump v. Hawaii*, 585 U.S. 667, 713 (2018) (Thomas, J., concurring); *cf. United States v. Mendoza*, 464 U.S. 154, 158-62 (1984) (holding that nonparties to an adverse decision against the federal government may not invoke the decision to preclude the government from continuing to defend the issue in subsequent litigation). The Third Circuit has repeatedly held that nonparty injunctions should not be used as an end-run around the class action procedure. *See Ameron*, 787 F.2d at 888; *Meyer v. CUNA Mut. Ins. Soc’y*, 648 F.3d 154, 170 (3d Cir. 2011).

For all these reasons, the Final Rules should not be vacated in the event that the Court were to rule in favor of Plaintiffs, but rather, the remedy should be tailored only to plaintiffs who have demonstrated standing before the Court. Moreover, based on the severability clause in the Final Rules, *see, e.g.*, 83 Fed. Reg. at 57,589, no relief should be applied except against specific portions of the Rules that injure Plaintiffs (assuming any do). For example, the individual exemption is not

challenged by Plaintiffs, and there is no plausible evidence of injury to Plaintiffs by the religious exemption for churches and religious non-profits (due to the existence of the previous exemptions, the self-insured church plan accommodation, and injunctions protecting religious non-profits), nor of injury from the moral exemption (since the only entities known to claim it hire only persons who share their beliefs).

Additionally, although Plaintiffs raise a facial challenge, they have not met their burden “to show that the Rule[s] are] “inconsistent with the [ACA] on its face.” *Bondi v. VanDerStok*, No. 23-852, 2025 WL 906503, at *5 (U.S. Mar. 26, 2025); *see also Am. Hosp. Ass’n v. NLRB*, 499 U.S. 606, 619 (1991) (“[T]hat petitioner can point to a hypothetical case in which the rule might lead to an arbitrary result does not render the rule ‘arbitrary or capricious.’ This case is a challenge to the validity of the entire rule in all its applications.”). And if the Court were to find that the Religious Exemption Rule was improperly extended to publicly traded companies or to entities whose religious objections are fully addressed by the accommodation, then it should not vacate the entire Religious Exemption Rule but instead only vacate it to the extent it extends to such entities. *See, e.g., Montgomery Cnty., Md. v. FCC*, 863 F.3d 485, 493 (6th Cir. 2017) (vacating FCC rule as arbitrary and capricious “as applied to [certain] incumbent cable operators”).

CONCLUSION

For the reasons stated above, Federal Defendants respectfully request that the Court enter summary judgment in their favor and deny Plaintiffs’ motion for summary judgment.

Dated: April 18, 2025

Respectfully submitted,

YAAKOV M. ROTH
Acting Assistant Attorney General

MICHELLE R. BENNETT
Assistant Director, Federal Programs Branch

/s/ Daniel Riess _____

DANIEL RIESS

MICHAEL GERARDI

Trial Attorneys

U.S. Department of Justice, Civil Division

Federal Programs Branch

1100 L Street, NW

Washington, D.C. 20005

(202) 353-3098

Daniel.Riess@usdoj.gov

Attorneys for Federal Defendants