Nos. 17-3752, 18-1253, 19-1129, 19-1189

United States Court of Appeals for the Third Circuit

COMMONWEALTH OF PENNSYLVANIA, *et al.*,
Plaintiffs-Appellees,

v.

PRESIDENT, UNITED STATES OF AMERICA, *et al.*,
Defendants-Appellants,

and

LITTLE SISTERS OF THE POOR, SAINTS PETER AND PAUL HOME,
Defendant-Intervenor-Appellant.

On Appeal from the U.S District Court for the
Eastern District of Pennsylvania,
No. 2:17-cv-4540

Brief of Defendant-Intervenor-Appellant The Little Sisters of the Poor, Saints Peter and Paul Home

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CORPORATE DISCLOSURE STATEMENT

Pursuant to Federal Rule of Appellate Procedure 26.1, the Little Sisters represent that they do not have any parent entities and do not issue stock.

Dated: February 15, 2019

/s/ Mark Rienzi

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INTRODUCTION

This case concerns the validity of the federal government's latest effort to both provide contraceptive access and protect religious liberty. In 2017, after many years of unsuccessful litigation against religious objectors, the federal government finally admitted that it did not need to hijack the health plans of unwilling religious entities. Instead, the government found it has many less restrictive alternatives to provide contraceptive access.

How good are these alternatives? So good that to date neither of the Plaintiff States can find even a single woman among their 21.8 million residents who stands to lose contraceptive access as a result of the rules at issue here. Nor can the 23 states engaged as plaintiffs or amici in parallel litigation in California.

Accordingly, in issuing new religious exemption rules, the federal government did the only thing it could do: it stopped trying to force religious objectors to comply with the contraceptive mandate. And although the federal government was free (and remains free) to simply revoke the mandate entirely, it instead tailored its response to only the small class of employers with religious or moral objections. The federal government

also ensured that other programs to provide free and low-cost contraceptives will remain in place. It has even sought to expand Title X to create additional access in case any employee of a religious or moral objector seeks coverage.

That should have been the end of the long and unseemly culture-war battle over whether the federal government is *permitted* to force nuns to participate in the distribution of contraception. But the Plaintiff States sued to advance a more radical claim: that the federal government is *required* to force nuns to participate in the distribution of contraception.

That position is so extreme it was never advanced in the five years of litigation over the contraceptive mandate from 2011-2016. To the contrary, the Obama Administration—like the Trump Administration—believed that the agencies had discretion to avoid burdening religious employers. *See* 76 Fed. Reg. 46,621, 46,623 (Aug. 3, 2011). And lest the regulators had any doubt about their obligation to avoid such burdens, federal judges have entered more than 50 injunctions forbidding applying the mandate against religious objectors. Those injunctions from Article III courts remain in place and continue to bind the agencies.

Despite all this, the district court issued two separate nationwide injunctions that purport to require the federal government to apply the contraceptive mandate to religious objectors. Those injunctions cannot stand, both because the district court lacked jurisdiction, and because the rules at issue are both procedurally and substantively valid. Simply put, the agencies were obeying Congress (which enacted RFRA) and the courts (dozens of which found that the mandate violated RFRA) in issuing the rules. The agencies were given discretion about what to include in the preventive services mandate and what "guidelines" should apply to it, but they were not given discretion about whether to obey RFRA. The court's contrary injunction thus orders the agencies to violate federal law.

But the strangest aspect of the district court's injunction—what it called "the elephant in the room"—is that the very analysis the court used to invalidate the religious exemption rules would also invalidate the contraceptive mandate for *all* employers. For example, if issuing final rules after interim final rules violates the Administrative Procedure Act, Appx.85-91, then the *entire contraceptive mandate is unlawful*. Likewise, if the agency lacks authority to change the mandate to ac-

count for religious burdens, Appx.93-100, then the agency also lacked the authority to create the prior exemptions on which the district court relied. Any legal theory that would invalidate the religious exemption rules would simultaneously invalidate the old version of the contraceptive mandate-plus-exemptions that the district court reinstated.

The district court was well aware of this problem. The court called the legality of the prior regime "puzzling," "an important question," and "the elephant in the room." Appx.703, 705, 736. And when the States insisted that the court could enter the injunction anyway because "this case is not about those prior exemptions," the district court candidly responded "Well, that wouldn't really help me." Appx.704.

Nevertheless, the district court ultimately issued the nationwide injunction without explaining how its legal reasoning did not simultaneously invalidate the version of the mandate-plus-exemptions it reinstated. Instead, the court simply claimed, as the States had at argument, that the legality of the prior exemptions was "not before this court." Appx.93 n.20.

But this Court cannot affirm an injunction that would render invalid the very relief the States seek. Under RFRA, the prior version of the re-

ligious accommodation must go, or the entire contraceptive mandate must go. Either way, the Little Sisters are entitled to protection, and the decisions below must be reversed.

JURISDICTIONAL STATEMENT

The States asserted jurisdiction in the district court under 28 U.S.C. § 1331. Nonetheless, that court was without jurisdiction because the States lack Article III standing. *See infra* Part I. The district court entered a preliminary injunction on December 15, 2017, Appx.51, and a second preliminary injunction on January 14, 2019, Appx.124. This Court's appellate jurisdiction rests on 28 U.S.C. § 1292(a)(1).

STATEMENT OF THE ISSUES

The Little Sisters' appeal presents four main issues:

Standing. Was the district court correct that the States have standing, despite the fact that they identified no employers who plan to drop contraceptive coverage, nor any citizens who stand to lose such coverage, nor any citizens who would then qualify for and turn to the government for coverage? Dkt.108 at 10-15; Appx.14-23; Appx.71-78.

Success on the merits. Have the States demonstrated a likelihood of success on the merits of their claims that the government lacked good cause to issue the interim final rule, that the interim final rule was con-

trary to law, and that the final rule was contrary to law? Dkt.108 at 16-32; Appx.19-37; 82-110.

Remedy. Can the Court reinstate the underlying mandate that predated the interim final rule and final rule if that underlying mandate violates the Administrative Procedure Act, the Affordable Care Act, and the Religious Freedom Restoration Act? Dkt.108 at 20-24; Appx.91.

Preliminary injunction. Do the remaining injunction factors justify the district court's decision to issue nationwide injunctions against the interim final rule and the final rule? Dkt.108 at 43-44; Appx.43-49; 110-23.

STATEMENT OF RELATED CASES

This case has been before this Court previously in the related appeal No. 17-3679, resulting in the decision reported at 888 F.3d 52.

All of the actions listed below are related to this action. These actions include claims or defenses that overlap with the States' claims here and are either pending, involve decisions of this Court at issue in this case, or resulted in permanent injunctions against former versions of the mandate. Unless otherwise noted, the dates listed are the dates the permanent injunction was issued.

Pending cases challenging the rules at issue here:

1. *Massachusetts v. HHS*, No. 1:17-cv-11930 (D. Mass.) (defendants' Mot. for Summary Judgment granted April 4, 2018; on appeal to 1st Cir. No. 18-1514)

2. *California v. Azar*, No. 4:17-cv-05783 (N.D. Cal.) (preliminary injunction issued Jan. 13, 2019; on appeal to 9th Cir. No. 19-15072, Jan. 14, 2019)

Pending cases challenging prior versions of the rules:

3. *Bindon v. Azar*, No. No. 1:13-cv-01207 (D.D.C.)

4. *DeOtte v. Azar*, No. 4:18-cv-00825 (N.D. Tex.)

5. *Dobson v. Azar*, No. 1:13-cv-03326 (D. Colo.)

6. *E. Tex. Baptist Univ. v. Azar*, No. 4:12-cv-03009 (S.D. Tex.)

7. *La. Coll. v. Azar*, No. 1:12-cv-00463 (W.D. La.)

8. *Triune Health Group, Inc. v. HHS*, No. 1:12-cv-06756 (N.D. Ill.)

Cases resulting in permanent injunctions issued prior to October 2017 against prior versions of the rules:

9. *Am. Pulverizer Co. v. HHS*, No. 6:12-cv-03459 (W.D. Mo.) (Oct. 30, 2014)

10. *Annex Medical, Inc., v. Solis*, No. 0:12-cv-02804 (D. Minn.) (Aug. 19, 2015)

11. *Armstrong v. Sebelius*, No. 1:13-cv-00563 (D. Colo.) (Oct. 7, 2014)

12. *Autocam Corp. v. Sebelius*, No. 1:12-cv-01096 (W.D. Mich.) (Jan. 5, 2015)

13. *Barron Indus., Inc. v. Sebelius*, No. 1:13-cv-01330 (D.D.C.) (Oct. 27, 2014)

14. *Bick Holdings, Inc. v. HHS*, No. 4:13-cv-00462 (E.D. Mo.) (Nov. 18, 2014)

15. *Brandt, Bishop of the Roman Catholic Diocese of Greensburg v. Sebelius*, No. 2:14-cv-00681 (W.D. Pa.) (Aug. 20, 2014)

16. *Briscoe v. Sebelius*, No. 1:13-cv-00285 (D. Colo.) (Jan. 27, 2015)

17. *Catholic Diocese of Beaumont v. Sebelius*, No. 1:13-cv-00709 (E.D. Tex.) (Jan. 2, 2014)

18. *C.W. Zumbiel Co. v. HHS*, No. 1:13-cv-01611 (D.D.C.) (Nov. 3, 2014)

19. *Conestoga Wood Specialties Corp. v. Sebelius*, No. 5:12-cv-06744 (E.D. Pa.) (Oct. 2, 2014)

20. *Daniel Medford v. Sebelius*, No. 0:13-cv-01726 (D. Minn.) (Nov. 20, 2014)

21. *Doboszenski & Sons, Inc. v. Sebelius*, No. 0:13-cv-03148 (D. Minn.) (Nov. 18, 2014)

22. *Domino's Farms Corp. v. Sebelius*, No. 2:12-cv-15488 (E.D. Mich.) (Dec. 3, 2014)

23. *Eden Foods, Inc. v. Sebelius*, No. 2:13-cv-11229 (E.D. Mich.) (Feb. 12, 2015)

24. *Feltl & Co. v. Sebelius*, No. 0:13-cv-02635 (D. Minn.) (Nov. 26, 2014)

25. *Gilardi v. HHS*, No. 1:13-cv-00104 (D.D.C.) (Oct. 20, 2014)

26. *Grote Indus., LLC v. Sebelius*, No. 4:12-cv-00134 (S.D. Ind.) (Apr. 30, 2015)

27. *Hall v. Sebelius*, No. 0:13-cv-00295 (D. Minn.) (Nov. 26, 2014)

28. *Hartenbower v. U.S. Dep't of Health & Human Servs.*, No. 1:13-cv-02253 (N.D. Ill.) (Nov. 3, 2014)

29. *Hastings Chrysler Center, Inc. v. Sebelius*, No. 0:14-cv-00265 (D. Minn.) (Dec. 11, 2014)

30. *Hobby Lobby Stores, Inc. v. Sebelius*, No. 5:12-cv-01000 (W.D. Okla.) (Nov. 19, 2014)

31. *Holland v. U.S. Dep't of Health & Human Servs.*, No. 2:13-cv-15487 (S.D. W. Va.) (May 29, 2015)

32. *Johnson Welded Products, Inc. v. Sebelius*, No. 1:13-cv-00609 (D.D.C.) (Oct. 24, 2014)

33. *Korte v. HHS*, No. 3:12-cv-1072 (S.D. Ill.) (Nov. 7, 2014)

34. *Lindsay v. U.S. Dep't of Health & Human Servs.*, No. 1:13-cv-01210 (N.D. Ill.) (Dec. 3, 2014)

35. *M&N Plastics, Inc. v. Sebelius*, No. 5:13-cv-14754 (E.D. Mich.) (Nov. 17, 2015)

36. *March for Life v. Azar*, No. 1:14-cv-01149 (D.D.C.) (Aug. 31, 2015)

37. *Mersino Dewatering Inc. v. Sebelius*, No. 2:13-cv-15079 (E.D. Mich.) (Feb. 27, 2015)

38. *Mersino Mgmt. Co. v. Sebelius*, No. 2:13-cv-11296 (E.D. Mich.) (Feb. 4, 2015)

39. *Midwest Fastener Corp. v. Sebelius*, No. 1:13-cv-01337 (D.D.C.) (Oct. 24, 2014)

40. *MK Chambers Co. v. U.S. Dep't of Health & Human Servs.*, No. 2:13-cv-11379 (E.D. Mich.) (Nov. 21, 2014)

41. *Newland v. Sebelius*, No. 1:12-cv-01123 (D. Colo.) (Mar. 17, 2015)

42. *O'Brien v. HHS*, No. 4:12-cv-00476 (E.D. Mo.) (Nov. 12, 2014)

43. *Randy Reed Auto., Inc. v. Sebelius*, No. 5:13-cv-06117 (W.D. Mo.) (Nov. 12, 2014)

44. *Roman Catholic Archdiocese of N.Y. v. Sebelius*, No. 1:12-cv-02542 (E.D.N.Y.) (Dec. 16, 2013)

45. *Sioux Chief MFG. Co. v. Sebelius*, No. 4:13-cv-00036 (W.D. Mo.) (Nov. 12, 2014)

46. *SMA, LLC v. Sebelius*, No. 0:13-cv-01375 (D. Minn.) (Nov. 20, 2014)

47. *Stewart v. Sebelius*, No. 1:13-cv-01879 (D.D.C.) (Feb. 2, 2015)

48. *Stinson Electric, Inc. v. Sebelius*, No. 0:14-cv-00830 (D. Minn.) (Nov. 18, 2014)

49. *Tonn and Blank Constr. LLC v. Sebelius*, No. 1:12-cv-00325 (N.D. Ind.) (Nov. 6, 2014)

50. *Tyndale House Publishers, Inc. v. Sebelius*, No. 1:12-cv-01635 (D.D.C.) (Jul. 15, 2015)

51. *Weingartz Supply Co. v. Sebelius*, No. 2:12-cv-12061 (E.D. Mich.) (Dec. 31, 2014)

52. *Wieland v. U.S. Dep't of Health & Human Servs.*, No. 4:13-cv-01577 (E.D. Mo.) (Jul 21, 2016)

53. *Williams v. Sebelius*, No. 1:13-cv-01699 (D.D.C.) (Nov. 5, 2014)

54. *Willis and Willis PLC v. Sebelius*, No. 1:13-cv-01124 (D.D.C.) (Oct. 31, 2014)

55. *Zubik v. Sebelius*, No. 2:13-cv-01459 (W.D. Pa.) (Dec. 20, 2013) (appeal dismissed Oct. 20, 2017)

Cases resulting in permanent injunctions issued since October 2017 against prior versions of the rules:

1. *Ass'n of Christian Sch. v. Azar*, No. 1:14-cv-02966 (D. Colo.) (Dec. 10, 2018)

2. *Ave Maria Sch. of Law v. Sebelius*, No. 2:13-cv-00795 (M.D. Fla.) (Jul. 11, 2018)

3. *Ave Maria Univ. v. Sebelius*, No. 2:13-cv-00630 (M.D. Fla.) (Jul. 11, 2018)

4. *Catholic Benefits Ass'n LCA v. Sebelius*, No. 5:14-cv-00240 (W.D. Okla.) (Mar. 7, 2018)

5. *Colorado Christian Univ. v. HHS*, No. 1:13-cv-02105 (D. Colo.) (Jul. 11, 2018)

6. *Dordt Coll. v. Sebelius*, No. 5:13-cv-04100 (N.D. Iowa) (June 12, 2018)

7. *Geneva Coll. v. Sebelius*, No. 2:12-cv-00207 (W.D. Pa.) (Jul. 5, 2018)

8. *Grace Sch. v. Sebelius*, No. 3:12-cv-00459 (N.D. Ind.) (June 1, 2018)

9. *Little Sisters of the Poor v. Hargan*, No. 1:13-cv-02611 (May 16, 2018)

10. *Reaching Souls Int'l Inc. v. Sebelius*, No. 5:13-cv-01092 (W.D. Okla.) (Mar. 15, 2018)

11. *Sharpe Holdings, Inc. v. HHS*, No. 2:12-cv-00092 (E.D. Mo.) (Mar. 28, 2018)

12. *S. Nazarene Univ. v. Hargan*, No. 5:13-cv-01015 (W.D. Okla.) (May 15, 2018)

13. *Wheaton Coll. v. Burwell*, No. 1:13-cv-08910 (N.D. Ill.) (Feb. 22, 2018)

Case challenging the prior rules resulting in judgment against plaintiff:

14. *Real Alternatives, Inc. v. Sec'y, Dep't of Health & Human Servs.*, 867 F.3d 338 (3d Cir. 2017)

STATEMENT OF THE CASE

A. The mandate and its exceptions

This case originates with the Patient Protection and Affordable Care Act of 2010 (ACA).[1] The ACA requires certain employers to offer "health insurance coverage" that includes "preventive care and screenings" for women without "any cost sharing requirements." 42 U.S.C. § 300gg-13(a)(4); 26 U.S.C. § 9815; 29 U.S.C. § 1185d.

Congress did not specify what "preventive care and screenings" should be included. Instead, it delegated that task to the agencies, deferring to whatever "comprehensive guidelines" are "supported" by the Health Resources and Services Administration (HRSA), which is within the Department of Health and Human Services (HHS). 42 U.S.C. § 300gg-13(a)(4). HHS asked for recommendations from the Institute of Medicine (IOM), 77 Fed. Reg. 8,725, 8,726 (Feb. 15, 2012), which pro-

[1] Pub. L. No. 111-148, 124 Stat. 119, amended by the Health Care and Education Reconciliation Act of 2010, Pub. L. No. 111-152, 124 Stat. 1029.

posed including, *inter alia*, all FDA-approved contraceptives and sterilization methods.[2]

The agencies then adopted IOM's recommendations as the "comprehensive guidelines." HRSA, *Women's Preventive Services Guidelines*, U.S. Department of Health & Human Services (Aug. 2011) https://www.hrsa.gov/womens-guidelines/index.html. The penalty for offering a plan that excludes coverage for even one of the FDA-approved contraceptive methods is $100 per day for each affected individual. 26 U.S.C. § 4980D(a)-(b). If an employer larger than 50 employees fails to offer a plan at all, the employer owes $2,000 per year for each of its full-time employees. 26 U.S.C. § 4980H(a), (c)(1).

The mandate includes many exemptions. For example, plans that have not made certain changes since March 2010 are grandfathered and exempted indefinitely. 42 U.S.C. § 18011. In 2018, approximately one fifth of employers offered grandfathered plans.[3]

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[2] Institute of Medicine, *Clinical Preventive Services for Women: Closing the Gaps*, The National Academies Press 3 (2011), https://bit.ly/2QOysgH.

[3] *See* Kaiser Family Found., *Employer Health Benefits 2018 Annual Survey* 209 (2018), https://bit.ly/2T4qwbQ.

Additionally, employers with fewer than 50 full-time employees are not required to provide health coverage at all. *See* 26 U.S.C. § 4980H(c)(2). In 2014, 34 million Americans—more than a quarter of the private-sector workforce—worked for such employers. *Burwell v. Hobby Lobby Stores, Inc.*, 573 U.S. 682, 699 (2014). The statute also does not cover government plans such as Medicare and some Medicaid programs, which may impose cost-sharing or exclude some forms of contraception.[4]

B. The First IFR

The preventive services mandate was first implemented by invoking the good cause exception from the APA's notice and comment requirement in an interim final rule (IFR) on July 19, 2010, published by HHS, DOL, and Treasury (the agencies). 75 Fed. Reg. 41,726, 41,728 (July 19,

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[4] *See* Congressional Research Service, *Federal Support for Reproductive Health Services: Frequently Asked Questions* 13 (2016), https://fas.org/sgp/crs/misc/R44130.pdf ("There is no explicit statutory requirement for Medicare to cover contraceptive services . . . . Sterilization is not covered as an elective procedure or for the sole purpose of preventing any effects of a future pregnancy"); *id.* at 7 ("States have discretion in identifying the specific services and supplies (including emergency contraception) covered under the traditional Medicaid state plan.").

2010) (First IFR). The First IFR stated that HRSA would produce guidelines and provided further guidance concerning cost sharing. *Id.* This IFR went into effect on the day that comments were due. The agencies reasoned that "it would be impracticable and contrary to the public interest to delay putting the provisions in these [IFRs] in place until a full public notice and comment process was completed." *Id.* at 41,730.

C. The Second IFR

In July 2011, IOM issued a recommendation including coverage of all FDA-approved contraceptives. Appx.1009. Thirteen days later, the agencies promulgated the next IFR. 76 Fed. Reg. 46,621 (Second IFR). That same day, HRSA published guidelines on its website adopting the IOM recommendations in full.[5] The Second IFR granted HRSA "discretion to exempt certain religious employers from the Guidelines." 76 Fed. Reg. at 46,623. But it defined the term "religious employer" so narrowly

[5] 77 Fed. Reg. 8,725 & n.1; *see also* HRSA, *Women's Preventive Services Guidelines*, U.S. Department of Health & Human Services (Aug. 2011) https://bit.ly/2OHsmgH.

that it excluded religious non-profits that, like the Little Sisters, serve people of all faiths. *Id.* at 46,626.

The Second IFR was effective immediately without prior notice or public comment. The agencies stated that they had "good cause" because public comment was "impracticable, unnecessary, or contrary to the public interest." *Id.* at 46,624.

The agencies received "over 200,000" comments on the Second IFR. 77 Fed. Reg. at 8,726. Many of the comments explained the need for a broader religious exemption. However, on February 15, 2012, the agencies adopted a rule that "finaliz[ed], without change," the Second IFR. *Id.* at 8,725.

The agencies then published an Advance Notice of Proposed Rulemaking (ANPRM), 77 Fed. Reg. 16,501 (Mar. 21, 2012), and a Notice of Proposed Rulemaking (NPRM), 78 Fed. Reg. 8,456 (Feb. 6, 2013), which were later adopted in a final rule making further changes to the mandate, 78 Fed. Reg. 39,870 (July 2, 2013). The agencies received over 600,000 comments on those proposals, many of which explained how the

mandate would violate the conscience of religious believers who objected to the contraceptives at issue.[6]

In the final rules, the agencies amended the definition of religious employer but continued to limit that definition to churches and the "exclusively religious" activities of religious orders, not including religious nonprofits like the homes run by the Little Sisters. 78 Fed. Reg. at 39,874. The final rules did not finalize the list of recommended preventive services; those remain on HRSA's website and have never been subject to notice and comment. *See supra* note 5.

Also in the final rules, the agencies adopted an arrangement—termed an "accommodation"—by which religious objectors could offer the objected-to coverage on their health plans by executing a self-certification and delivering it to the organization's insurer or third-party administrator (TPA). The self-certification would trigger the insurer or TPA's obligation to "provide[] payments for contraceptive services." 78 Fed. Reg. at 39,876 (insurers); *id.* at 39,879 (TPAs).

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[6] 78 Fed. Reg. 8,456, 8,459 (Feb. 6, 2013); 78 Fed. Reg. at 39,871; *see also, e.g.*, Christian Medical Association, Comment Letter on NPRM (Mar. 21, 2013), https://bit.ly/2O28k3p (NPRM "fails to avoid moral compromise for faith-based objectors").

D. RFRA litigation and the Third IFR

The "accommodation" did not address the concerns of all religious organizations, and some filed lawsuits under the Religious Freedom Restoration Act (RFRA).[7] The Little Sisters were part of a class action filed on September 24, 2013. Complaint, *Little Sisters of the Poor Home for the Aged v. Sebelius*, 6 F. Supp. 3d 1225 (D. Colo. 2013) (No. 13-2611). In August 2014, the agencies published a third IFR "in light of the Supreme Court's interim order" in *Wheaton College v. Burwell*, again without notice and comment. 79 Fed. Reg. 51,092 (Aug. 27, 2014) (Third IFR); *Wheaton Coll. v. Burwell*, 134 S. Ct. 2806 (2014).

This Third IFR amended the "accommodation" to allow a religious objector to "notify HHS in writing of its religious objection" instead of notifying its insurer or TPA. 79 Fed. Reg. at 51,094. The Third IFR received over 13,000 comments.[8]

To justify bypassing notice and comment, the agencies said that they must "provide other eligible organizations with an option equivalent to

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[7] *See* Becket, *HHS Case Database*, https://bit.ly/2zlzvOs (last accessed Feb. 15, 2019).

[8] *See* EBSA, *Coverage of Certain Services Under the Affordable Care Act* (Aug. 27, 2014), https://bit.ly/2Nv8Kjh.

the one the Supreme Court provided to Wheaton College . . . as soon as possible." 79 Fed. Reg. at 51,095. The Third IFR was ultimately finalized on July 14, 2015. 80 Fed. Reg. 41,318 (July 14, 2015).

E. Supreme Court litigation

The Third IFR did not accommodate the Little Sisters' religious beliefs. It continued to require the Little Sisters to authorize the provision of objectionable drugs and services on their health plan. The Little Sisters' case proceeded to the Tenth Circuit Court of Appeals, which ruled against them. *Little Sisters of the Poor v. Burwell*, 794 F.3d 1151 (10th Cir. 2015), *vacated and remanded sub nom. Zubik v. Burwell*, 136 S. Ct. 1557 (2016).

The Little Sisters' appeal to the Supreme Court was consolidated with similar cases from the Fifth and D.C. Circuits and this Circuit. *See Zubik v. Burwell*, 136 S. Ct. 1557 (2016). At the Supreme Court, the agencies abandoned the arguments and factual findings upon which they had relied below. First, the government admitted for the first time that the accommodation required contraceptive coverage to be "part of the same plan as the coverage provided by the employer," Br. for the Resp'ts at 38, *Zubik*, 136 S. Ct. 1557 (No. 14-1418) (quotations omitted),

https://bit.ly/2DiCj32.[9] The government thus removed any basis for the lower courts' prior holding that the mandate did not impose a substantial burden on the religious exercise of objecting employers because the provision of contraceptives was separate from their plans.[10]

Next, the agencies admitted to the Supreme Court that women who do not receive contraceptive coverage from their employer can "ordinarily" get it from "a family member's employer," "an Exchange," or "another government program." Br. for the Resp'ts at 65, *Zubik*, 136 S. Ct. 1557, https://bit.ly/2DiCj32. The government also acknowledged that the mandate "could be modified" to be more protective of religious liberty, Suppl. Br. for the Resp'ts at 14-15, *Zubik v. Burwell*, 136 S. Ct. 1557, https://bit.ly/2O0oUAJ, thus admitting the mandate was not the least restrictive means of achieving the government's interests.

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[9] *See also* Tr. of Oral Arg. at 60-61, *Zubik v. Burwell*, 136 S. Ct. 1557 (Chief Justice Roberts: "You want the coverage for contraceptive services to be provided, I think as you said, seamlessly. You want it to be in one insurance package. . . . Is that a fair understanding of the case?"; Solicitor General Verrilli: "I think it is one fair understanding of the case.").

[10] *See* Tr. of Oral Arg. at 61, *Zubik v. Burwell*, 136 S. Ct. 1557 (2016) (No. 14-1418) (Solicitor General Verrilli "would be content" if Court would "assume a substantial burden" and rule only on the government's strict scrutiny defense).

The Supreme Court unanimously vacated the decisions of the Courts of Appeals of the Third, Fifth, Tenth, and D.C. Circuits. *Zubik*, 136 S. Ct. at 1560. It ordered the government not to impose taxes or penalties on petitioners for failure to comply with the mandate and remanded the cases so that the parties could be "afforded an opportunity to arrive at an approach going forward" that would resolve the dispute. *Id.*

The Little Sisters' case was stayed while the government reconsidered the exemptions to the mandate. *See, e.g.*, Order, *Little Sisters of the Poor v. Hargan*, No. 13-1540 (10th Cir. June 27, 2016) (ordering parties to file periodic status reports). In May 2018, after failing to reach a settlement with the government, the Little Sisters sought and obtained a permanent injunction from the district court. *Little Sisters of the Poor v. Azar*, No. 1:13-cv-02611 (D. Colo. May 29, 2018), Dkt.82.

F. The Fourth and Fifth IFRs

After making the concessions that prompted the Supreme Court's order in *Zubik*, the agencies issued a "Request for Information" in July 2016 to seek input on "whether there are modifications to the accommodation that would be available under current law and that could resolve the RFRA claims raised by organizations that object to the existing ac-

commodation on religious grounds." 81 Fed. Reg. 47,741, 47,743 (July 22, 2016). The agencies received "over 54,000 public comments." 82 Fed. Reg. 47,792, 47,814 (Oct. 13, 2017). The agencies concluded, in a set of FAQs published only on the Department of Labor's website, that they were unable to modify the accommodation in a way that respected both the agencies' goals and the religious objectors' concerns.[11]

In October 2017, the agencies engaged in another round of rulemaking and issued the IFRs at issue in this lawsuit. 82 Fed. Reg. 47,792 (Fourth IFR).[12] The Fourth IFR protected those with religious objections, referring to the litigation as the impetus for the regulatory change: "Consistent with . . . the Government's desire to resolve the pending litigation and prevent future litigation from similar plaintiffs, the Departments have concluded that it is appropriate to reexamine the exemption and accommodation scheme currently in place for the Man-

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[11] U.S. Dep't of Labor, *FAQs About Affordable Care Act Implementation Part* 36 at 4 (Jan. 9, 2017), https://bit.ly/2O7yJNr.

[12] The agencies issued another IFR on the same day, addressing a "moral exemption." 82 Fed. Reg. 47,838, 47,849 (Oct. 13, 2017) (Fifth IFR). The States also challenge the Fifth IFR, but the Little Sisters' arguments focus on the Fourth IFR. Likewise, the Little Sisters focus on the final rule that grants a religious exemption.

date." *Id.* at 47,799. The agencies reasoned that they had good cause to issue the exemptions "in order to cure such violations [of RFRA] (whether among litigants or among similarly situated parties that have not litigated), to help settle or resolve cases, and to ensure, moving forward, that our regulations are consistent with any approach we have taken in resolving certain litigation matters." *Id.* at 47,814. The Fourth IFR set a sixty-day period for comments, which ended on December 5, 2017.

Pennsylvania filed a complaint less than a week after the Fourth IFR was issued, seeking an injunction against the religious exemption that protected the Little Sisters and other religious objectors. Appx.164-97. This was the first time Pennsylvania involved itself in any mandate case, despite six years of litigation in which dozens of religious objectors received preliminary and permanent injunctions against the mandate. *See* Statement of Related Cases. Pennsylvania also, for the first time in six notice and comment periods, filed comments on the Fourth IFR in December 2017. *See* State Attorneys General, Comment Letter on Fourth IFR (Dec. 5, 2017), https://www.regulations.gov/document?D=CMS-2014-0115-58168.

Pennsylvania moved for a preliminary injunction against the Fourth and Fifth IFRs, asking the court to instead reinstate the rules established by the first three IFRs. Dkt.8. On November 22, the Little Sisters moved to intervene. On appeal, this Court reversed the district court's denial of intervention. *Pennsylvania v. President*, 888 F.3d 52 (3d Cir. 2018). The district court granted Pennsylvania's motion for a preliminary injunction on December 15, 2017. The Little Sisters and the agencies appealed and filed opening briefs on September 21, 2018.

While the Fourth IFR was enjoined and this appeal was pending, other courts enjoined the federal government from enforcing the mandate against religious objectors, including the Little Sisters of the Poor. Some of those injunctions were in open-ended class actions or associational standing cases that allow new members to join. *See, e.g.*, *Reaching Souls Int'l, Inc. v. Azar*, No. CIV-13-1092-D, 2018 WL 1352186, at *2 (W.D. Okla. Mar. 15, 2018); *Catholic Benefits Ass'n LCA v. Hargan*, No. 5:14-cv-00240-R, Order, Dkt.184 (W.D. Okla. Mar. 7, 2018) (granting permanent injunction of Mandate to current and future nonprofit members of Catholic Benefits Association). These injunctions were in

addition to the over 50 injunctions that were already in place following the *Zubik* decision. *See* Statement of Related Cases.

G. The Final Rule

While the appeal was pending, the agencies received comments and reviewed them over a period of several months. They then finalized the religious exemption in a final rule that took effect on January 14, 2019. 83 Fed. Reg. 57,536 (Nov. 15, 2018) (Final Rule). Pennsylvania amended its complaint and the State of New Jersey joined as a plaintiff. Searches of public documents reveal no comments from New Jersey during any of the comment periods. The States then sought a preliminary injunction of the final rules on December 17, 2018. The district court granted the second preliminary injunction on January 14, 2019 without modifying or dissolving its prior injunction.

H. The decisions below

In granting the first injunction, the district court ruled that Pennsylvania had Article III standing to challenge the exemption because it "seeks to protect a quasi-sovereign interest—the health of its women residents," and because the exemption "will likely inflict a direct injury upon the Commonwealth by imposing substantial financial burdens on State coffers." Appx.19-20. The district court held that Pennsylvania

can assert "a procedural right under the APA . . . without meeting all the normal standards for redressability and immediacy." Appx.23.

The district court then ruled that Pennsylvania was likely to succeed on the merits because the agencies did not have good cause to forgo notice and comment, and because the exemption "contradict[s] the text of the [ACA]" by creating "sweeping exemptions" to the ACA's requirements. Appx.35, 40.

In granting the second injunction, the district court held that the States have standing even in the context of non-procedural claims. The court held that the States have "special solicitude" in standing when protecting the "quasi-sovereign interests" in the "health and wellbeing" of their residents. Appx.19. The district court also held that the States have shown a "causal connection" between the final rules and financial injury. Appx.22.

On the merits of the injunction, the district court held that the States are likely to succeed on their procedural APA claim because the lack of notice and comment in promulgating the IFRs "fatally tainted the issuance of the Final Rules." Appx.91. The district court held that the States are likely to succeed on their substantive APA claim because the

final rules "exceed the scope of the Agencies' authority under the ACA, and, further, cannot be justified under RFRA." Appx.93. Though the district court recognized at the hearing that the question of how the agencies had authority to issue the exemptions in the prior mandate regulations but did not have the authority to issue the Final Rule was "the elephant in the room," Appx.736, the district court opinion did not address that question, noting only that "the 2011 religious exemption is not before this Court," Appx.93 n.20. In invalidating the Final Rule, the district court essentially reinstated the initial mandate and its initial exemptions.

STANDARD OF REVIEW

Legal conclusions regarding standing are reviewed *de novo*. *Edmonson v. Lincoln Nat'l Life Ins. Co.*, 725 F.3d 406, 414 (3d Cir. 2013). This Court reviews the district court's decision to enjoin the United States for an abuse of discretion, but a district court necessarily abuses its discretion if it bases its ruling on legal errors, which are reviewed *de novo*. *See Dam Things from Denmark v. Russ Berrie & Co.*, 290 F.3d 548, 556 (3d Cir. 2002). With regard to factual determinations, "Where, as here, First Amendment rights are at issue . . . [courts of appeal] have a con-

stitutional duty to conduct an independent examination of the record as a whole[.]" *Brown v. City of Pittsburgh*, 586 F.3d 263, 268-69 (3d Cir. 2009) (internal quotation omitted). Finally, as suggested by *Reynolds*, an agency's assertion of good cause to bypass notice and comment in rulemaking calls for deference to agency factual findings (unless they are arbitrary and capricious) and *de novo* review on matters of law. *See United States v. Reynolds*, 710 F.3d 498, 508-09 (3d Cir. 2013); 5 U.S.C. § 706(2).

SUMMARY OF THE ARGUMENT

The two injunctions should never have issued because the States lack standing. They have suffered no harm and have no concrete interest at stake. Their constitutional claims are foreclosed as a matter of law. And any injuries they allege are not redressable. Any harm they allege is a result of their own voluntary programs, not the Final Rule; the injunctions cannot stop religious objectors from receiving protection in other ways; and the regime they ask the district court to implement is unlawful and foreclosed by their very arguments against the Final Rule.

Even assuming standing, the States are not likely to succeed on the merits. The district court held that the agencies do not have the authority to create religious exemptions, but did not explain how it could reimplement a scheme that has assumed that same authority in prior iterations going back to 2011. Moreover, the agencies have statutory authority—indeed, an express statutory *obligation*—to comply with RFRA in offering a religious exemption.

The States' arguments that the Final Rule violates the Establishment Clause and the Equal Protection Clause cannot be reconciled with a long tradition of providing religious exemptions to prevent burdening consciences. And the States' arguments that the Final Rule violates Title VII and the Pregnancy Discrimination Act has been rejected by the only court to consider that contention.

The States' procedural arguments fare no better. The Fourth IFR never violated the APA because the agencies had good cause to issue a rule that complied with pressing court orders and ameliorated an infringement on fundamental civil rights. Moreover, any procedural defect in the IFRs cannot prevent the agencies from issuing a new rule following full notice and comment.

At bottom, the district court abused its discretion by reimplementing regulations that violate RFRA and are themselves illegal under the district court's own reasoning.

ARGUMENT

I. The States lack standing.

"To seek injunctive relief," the States must show that they are "under threat of suffering 'injury in fact' that is concrete and particularized; the threat must be actual and imminent, not conjectural or hypothetical; it must be fairly traceable to the challenged action of the defendant; and it must be likely that a favorable judicial decision will prevent or redress the injury." *Summers v. Earth Island Inst.*, 555 U.S. 488, 493 (2009). And they must "demonstrate standing for each claim [they] seek[] to press and for each form of relief that is sought." *Town of Chester v. Laroe Estates, Inc.*, 137 S. Ct. 1645, 1650 (2017) (quoting *Davis v. FEC*, 554 U.S. 724, 734 (2008) (internal quotation marks omitted)). The States fail every part of this test.

A. The States cannot bring Establishment Clause, Equal Protection, or Title VII claims.

The States cite no authority for the idea that states can bring Establishment Clause claims against the federal government to challenge a

religious accommodation. Since the States challenge a federal exemption rather than an expenditure, they cannot have offended observer or taxpayer standing in relation to the federal government.

Similarly, states are not "person[s]" under the Fifth Amendment capable of asserting an equal protection claim. *Pennsylvania v. Riley*, 84 F.3d 125, 130 n.2 (3d Cir. 1996) ("A State . . . is not entitled to due process protection") (citing *South Carolina v. Katzenbach*, 383 U.S. 301 (1966)).

The States also lack standing to bring their Title VII claim, as they are not employees, and the federal government is not their employer.

B. The States lack injury in fact.

1. The States' purported injuries are generalized and speculative.

The States ask this Court to set national policy through litigation, based upon vague assertions of harm. Most of the injuries that the States do assert are to unnamed citizens. *See, e.g.*, Appx.168, 189-91; Appx.314-18. The only alleged harms specific to the States are the lack of opportunity to comment—an argument their own actions foreclose—and downstream financial burdens on state-funded health programs.

See Appx.185, 189-91. The district court found standing on this basis. Appx.20-23.

The States' claims of injury are no more than a "chain of contingencies" that "amount[] to mere speculation" about the actions of third parties. *Sheller, P.C. v. HHS*, 663 F. App'x 150, 156 (3d Cir. 2016). The States have not identified a single employer in their borders that plans to drop contraceptive coverage because of the IFRs or the Final Rule. Many employers in the States are already exempt from the federal mandate, either through grandfathering (a fifth of employers have grandfathered plans),[13] the prior religious exemption that the district court reinstated, or because they are small employers and are not required to provide insurance at all.[14] And many religious objectors have had opportunities to seek and receive injunctions from the mandate in court. *See* Statement of Related Cases. These employers are not obligat-

[13] *See* Kaiser Family Found., *supra* note 3, at 204; *Hobby Lobby*, 573 U.S. at 698-700 (grandfathered plans are exempt from the preventive services mandate).

ed to provide contraceptive coverage, regardless of the Final Rule, and their decisions therefore cannot cause injury via the Final Rule.

If the States could locate even one employer who plans to drop coverage because of the Final Rule, it must next speculate as to the religious beliefs and choices of employees. For example, women working for religious employers may share their employers' religious beliefs. *See* 82 Fed. Reg. at 47,802. They might prefer a contraceptive method still covered by their employer, since many objectors object to only 4 out of 20 FDA-approved methods. *See Hobby Lobby*, 573 U.S. at 696-98. Or they may "obtain coverage through a family member's employer, through an individual insurance policy purchased on an Exchange or directly from an insurer, or through Medicaid or another government program." Br. for the Resp'ts at 65, *Zubik v. Burwell*, 136 S. Ct. 1557 (2016) (No. 14-1418), https://bit.ly/2DiCj32. That is what the Obama Administration told the Supreme Court in 2016, and it remains true today. Given the alternatives available—and their apparent efficacy in preventing the States from feeling any effects from the prior and much larger exemp-

[14] *Hobby Lobby*, 573 U.S. at 698-700 (discussing small employer exemption).

tions—the States have no reason to believe that the mere fact that this case concerns a *religious* exemption will mean that women will suddenly begin generating costs for state programs.

Nor is there any reason to believe the States would bear the cost of the feared unintended pregnancies. This would only happen if women with health insurance did not obtain contraceptives in some other way *and* did not use their health insurance for their medical expenses related to pregnancy *and* qualified for state aid. The States offer no reason to think that even a single state resident will thread this needle, or that a single state resident ever threaded it before, despite the absence of a federal mandate until 2012 or the much larger exemptions (such as grandfathering) in place since 2012. If the States' suppositions were correct, the States would surely have been harmed prior to the Fourth IFR. But the States never intervened in lawsuits challenging the mandate and never sought a nationwide injunction (or any other relief) against these far more sweeping exemptions.

A judicial decision based upon the supposition that this might theoretically occur now, and only now, is advisory.

2. The States cannot sue as parens patriae.

Most of the injuries claimed in the amended complaint are to unnamed citizens. But the States are barred from asserting the rights of their citizens as *parens patriae* against the federal government. *See Massachusetts v. Mellon*, 262 U.S. 447 (1923). Even if the claimed injuries to their citizens existed, "it is the United States, and not the state, which represents them as *parens patriae*, when such representation becomes appropriate." *Id.* at 485-86. The States seek to avoid the application of RFRA for their citizens, but that is precisely "what *Mellon* prohibits," namely a suit by a State "to protect her citizens from the operation of federal statutes." *Massachusetts v. EPA*, 549 U.S. 497, 520, n.17 (2007) (citation omitted).

3. The States cannot overcome these deficiencies with "special solicitude."

Any "special solicitude" the States claim does not overcome their lack of injury in fact. The district court analogized to *Texas v. United States*, 809 F.3d 134, 151 (5th Cir. 2015) and *Massachusetts v. EPA*, 549 U.S. 497 (2007). In *Massachusetts*, however, the Clean Air Act's unique "procedural right" to challenge an EPA denial of a petition for rulemaking on emission standards was "critical[ly] importan[t]" to standing. *Id.* at

516, 518 (citing 42 U.S.C. § 7607(b)(1)). The district court recognized that "a procedural right under the relevant statute" is a necessary component for special solicitude. Appx.73. But it did not address the procedural right afforded the States in this case. Appx.75. Nothing in the ACA, the mandate, or the Final Rule provides such a procedural right to the States.

And in *Texas*, the Fifth Circuit was careful not to substitute special solicitude for injury or for a legally protected interest. There, Texas was able to show 500,000 people who would automatically be eligible for a $130 subsidy benefit under the challenged federal program. "Even a modest estimate would put the loss at several million dollars." *Texas*, 809 F.3d at 155 (internal quotation marks omitted). Here, the States have not identified even one person who would become eligible for state benefits.

C. The States' purported harms are neither traceable to the Final Rule nor redressable by enjoining it.

The States' claims fail because the alleged injuries are neither traceable to the Final Rule nor redressable by order of this Court.

1. Any injury to the States is self-inflicted.

Any increase in contraceptive-related costs is a result of the States' decision to subsidize contraceptive access for its citizens. Thus, the States' alleged pocketbook injury is not "fairly . . . traceable" to the Final Rule. *See Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560 (1992) (citation omitted). The agencies' decision to exempt religious entities from providing certain contraceptives to their employees only increases the States' costs because of a voluntary choice the States made, and "[n]o State can be heard to complain about damage inflicted by its own hand." *Pennsylvania v. New Jersey*, 426 U.S. 660, 664 (1976) (per curiam). As in *Pennsylvania v. New Jersey*, "nothing prevent[s] [the States] from withdrawing" their subsidies for contraceptives. *Id.* at 664. The States are free to adjust their policies, but they should not be permitted to subsidize a service and then sue the federal government whenever a federal action supposedly means more people may claim that service.

2. The Court cannot redress the alleged harm.

An order enjoining the Final Rule would not redress the claimed harm. Religious objectors can bring their own RFRA lawsuits and obtain injunctions, given that the government has admitted that it has no compelling interest in enforcing the underlying mandate. Or they can

join existing classes that already have injunctions against the mandate. *See supra* at 24. Or, since many religious employers have fewer than fifty employees, they can simply drop health insurance altogether. 26 U.S.C. § 4980H(c)(2). The district court addressed none of these eventualities. *See* Appx.76-77.

Furthermore, the district court's injunction also fails to redress the claimed harm because the federal defendants remain free to eliminate contraceptive coverage from the mandate, since Congress granted discretion to HRSA to decide which services should be covered.

3. The Court cannot reinstate rules that are subject to the same alleged APA problems.

Before the Fourth IFR and the Final Rule were issued, the regulations contained variations from the mandate in the form of an exemption for churches and integrated auxiliaries and a separate "accommodation" for other religious employers. That accommodation is central to the district court's RFRA holding. Yet—according to the district court and the States' reasoning—the earlier exemption and accommodation violate the APA.

The district court held that the agencies exceeded their authority in promulgating the Final Rule because the ACA authorized the agencies

to determine only "*what* must be covered," not "who must provide the coverage," Appx.99. The States likewise argued that the agencies do not have statutory authority to create exemptions to the preventive services mandate. Appx.703; Dkt.91-2 at 20 ("Nothing in the ACA[] . . . suggests that employers may avoid their legal obligations for religious or moral reasons"). But the States also request that the Court replace the Final Rule with the mandate *as it existed before the IFRs*, Appx.791.

That relief—the revival of the prior mandate regime, complete with the "accommodation" and religious employer exemption—cannot be entered consistent with the court's order. If HRSA has no authority to decide "who must provide the coverage," then it surely has no authority to exempt some employers, "accommodate" others, and impose new obligations on insurers and TPAs to comply in their place. Yet that is precisely the regime the district court reimposed.[15]

[15] If the district court was correct that RFRA compels the government to exempt churches, Appx.42, it can only be for one reason: that an exemption, rather than the accommodation, is compelled by RFRA. Under that reasoning, either the accommodation is illegal, or the religious exemption is.

The same is true for the States' procedural claims. The underlying mandate was created by the same IFR procedures that the States object to and that the district court invalidated. The contraceptive mandate itself was implemented only by a list of services on HRSA's website and has never been subjected to notice and comment. *See supra* note 5. And the regulations were themselves implemented via a series of IFRs followed by final rules. *See supra* at 14-19. To accept the States' argument is to admit that both the mandate itself and the accommodation system upon which the district court's RFRA analysis relies violate the APA. The district court sidestepped this problem by claiming that the prior regulations were "not before this Court," but that ignores the fact that the prior regulations are the very system the district court was asked to reinstate. *See* Appx.114 (explaining that a "preliminary injunction will maintain the status quo," including the "exemptions or accommodations prior to October 6, 2017"). Simply put, because the States' arguments would ultimately prove the mandate itself is invalid, they are self-defeating, and the States' claimed harms cannot be redressed by the order they seek.

For all these reasons, the States lack standing, and the case must be dismissed.

II. The States cannot succeed on the merits.

Even if the Court were to determine that the States had standing, the injunction should still be vacated because they have failed to establish likelihood of success on the merits. A preliminary injunction—particularly one that prohibits enforcing a federal regulation against nonparties—is an "extraordinary remedy never awarded as of right." *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 24 (2008).

A. The States are not likely to succeed on their claim that the Final Rule is contrary to law.

1. The agencies may make exemptions from a mandate they were never obligated to create in the first place.

The district court enjoined the Final Rule and the Fourth IFR as contrary to law, reasoning that the agencies lacked authority to create exemptions from the mandate. But the States face an uphill battle challenging an exemption to a contraceptive mandate that the ACA did not require in the first place. The ACA merely requires certain employers to offer "a group health plan" that provides coverage for "preventive care"

for women. 42 U.S.C. § 300gg-13(a)(4); 26 U.S.C. § 9815; 29 U.S.C. § 1185d.[16] Congress did not specify what "preventive care" means, but instead delegated that task to HRSA. Congress directed HRSA to create a set of "guidelines," rather than a bare list of mandated items. HRSA was under no obligation to include contraceptives on that list at all, much less all FDA-approved contraceptives. It could have limited itself to other preventive services such as domestic violence screening and well-woman visits, made no mention of contraceptives, and still been well within its statutory mandate. *See* 42 U.S.C. § 300gg-13(a)(4); HRSA *Women's Preventive Services Guidelines*, U.S. Department of Health & Human Services (Aug. 2011), https://bit.ly/2OHsmgH; Appx.9 (noting that "which preventive care and screenings should be covered by the ACA [is] up to HRSA").

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[16] Although it has not been raised in this case, the Little Sisters note that one court has held that the individual mandate, as amended by the Tax Cuts and Jobs Act of 2017, Pub. L. No. 115-97, 131 Stat. 2054 (2017), is unconstitutional. *See Texas v. United States*, No. 4:18-CV-00167-O, 2018 WL 6589412 (N.D. Tex. Dec. 14, 2018). Because the mandate is part of the "minimum essential coverage" required to satisfy the insurance mandate, there is strong reason to believe that the women's preventive services provisions are not severable from the individual mandate. *See id.* at *18-29 (striking the remainder of the law as non-severable).

The district court held that the statutory delegation of authority did not include authority to create exemptions from the preventive care mandate. In making this determination, the court ignored the most relevant statutory term, "guidelines." Appx.38-41; 42 U.S.C. § 300gg-13(4). The dictionary definition of guideline is an "indication of policy or procedure by which to determine a course of action."[17] Had Congress meant for HRSA to simply create a list of covered items from which there could be no deviation, it could have said so. It did just this for subsections (1) and (2) of § 300gg-13:

> (1) evidence-based items or services that have in effect a rating of "A" or "B" in the current recommendations of the United States Preventive Services Task Force;
>
> (2) immunizations that have in effect a recommendation from the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention with respect to the individual involved;

42 U.S.C. § 300gg-13. These provisions require coverage of all "items or services" on a particular list, or all immunizations, if recommended "with respect to the individual involved." *Id.* The language used in (4) is markedly different: "such additional preventive care and screenings . . .

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[17] *The American Heritage Dictionary* (3d ed. 1992).

(1) as provided for in comprehensive guidelines" from HRSA. 42 U.S.C. § 300gg-13(4). Since "it is presumed that Congress expresses its intent through the ordinary meaning of its language," *Idahoan Fresh v. Advantage Produce, Inc.*, 157 F.3d 197, 202 (3d Cir. 1998), the distinction between these provisions indicates a broader grant of discretion to HRSA in crafting the regulations.

HHS has used that discretion, and not just on contraceptives. For example, in average-risk women, HPV screenings are only covered for those over 30, and mammograms are only covered for those over 40. *Women's Preventive Services Guidelines*, U.S. Department of Health & Human Services (Oct. 2017), https://bit.ly/2irrzlT. For all preventive services, HRSA has exercised discretion to "specify the frequency, method, treatment, or setting for the provision of that service," and has directed that if such information is not specified, "the plan or issuer can use reasonable medical management techniques to determine any coverage limitations." Centers for Consumer Information & Insurance Oversight, *Affordable Care Act Implementation FAQs – Set 12*, Centers for Medicare & Medicaid Services, https://go.cms.gov/2I54sZV. HRSA has been exercising its statutory discretion to frame coverage require-

ments for years, and the States have not claimed that it is in excess of the mandate to limit preventive services by age (a limitation not found in § 300gg-13(a)(4)), nor that it is improper to utilize "reasonable medical management techniques" to determine exclusions from coverage.

The upshot is that HRSA could have required coverage of some contraceptives and not others, or permitted employers to exclude coverage of some due to cost considerations (which it in fact does),[18] or determined that a contraception mandate was unnecessary due to widespread coverage pre-dating the ACA. Indeed, HRSA could edit its website tomorrow to eliminate some or all contraceptives from the list, and the States would have no recourse, since the listing of contraceptives itself is not in the Code of Federal Regulations and has never been subject to formal rulemaking. To claim that the agencies have no authority to create exemptions from the mandate in these circumstances is weaving new administrative law from whole cloth.

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[18] Employers may exclude more expensive contraceptives if they cover a cheaper contraceptive in the same category. *See* Centers for Consumer Information & Insurance Oversight, *Affordable Care Act Implementation FAQs*, *Set 12*, Centers for Medicare & Medicaid Services, https://go.cms.gov/2I54sZV (last visited Feb. 14, 2019).

2. The States' reasoning would also invalidate the preexisting religious exemptions and accommodation.

The States' APA argument fails for another reason. If it is true, as the district court held, that the agencies had authority only to determine "*what* must be provided under the ACA's 'preventive care' requirement" and not "*who* must provide it," the agencies lacked the authority to issue the 2011 religious exemption, or even the accommodation upon which the district court relied for its RFRA analysis. Appx.93-94; 76 Fed. Reg. at 46,626. At the preliminary injunction hearing, the States could not explain this disparity. Appx.705. The judge seemed troubled by this, admitting that this question was "the elephant in the room," Appx.736, but did not answer the question in her opinion, noting only that "the 2011 religious exemption is not before this Court." Appx.93 n.20. As a result, the court has enjoined one regulation and in so doing left the government to enforce an underlying regulation that suffers from the same purported flaws.

3. The agencies are permitted to issue the Final Rule to comply with RFRA.

The district court correctly acknowledged in its first injunction—and the States nowhere dispute—that "any exception to the ACA required by RFRA is permissible." Appx.37; *see also* Appx.42-52. A religious ex-

emption required by a federal civil rights statute cannot be "arbitrary [and] capricious" or "not in accordance with law." 5 U.S.C. § 706(2)(A). Thus, if the agencies are correct that the Final Rule was mandated by RFRA, the entire basis for the district court's injunctions falls away.

The lower court misunderstood both RFRA and this Court's precedents, holding that the agencies' view of RFRA had been "foreclosed" by this Court "twice now." Appx.42; *see also* Appx.49-50. That misreading of precedent led the district court to reimpose a version of the mandate that is currently forbidden by RFRA-based injunctions from dozens of federal courts.

Properly understood, RFRA makes it illegal for the agencies to impose the contraceptive mandate without a religious exemption, and nothing in this Court's precedents is to the contrary. Accordingly, the district court's order must be reversed.

a. RFRA applies broadly to federal laws, federal agencies, and religious exercises.

RFRA requires that the federal government "shall not substantially burden a person's exercise of religion" unless doing so is the "least restrictive means" of advancing a "compelling governmental interest." 42 U.S.C. § 2000bb-1(a)-(b). RFRA is not just a judicial remedy, as the dis-

trict court stated, Appx.103, but applies to any "agency" and "to all Federal law, and the implementation of that law, whether statutory or otherwise," including to the agencies' actions under the ACA. 42 U.S.C. § 2000bb-2, bb-3.

Congress also made clear that "religious exercise" under RFRA is a broad term, encompassing "any exercise of religion." 42 U.S.C. § 2000cc-5. Religious exercise includes "'not only belief and profession but the performance of (or abstention from) physical acts' that are 'engaged in for religious reasons.'" *Hobby Lobby*, 573 U.S. at 710 (quoting *Emp't Div. v. Smith*, 494 U.S. 872, 877 (1990)).

b. The mandate as it existed before the Fourth IFR violates RFRA.

The Little Sisters and other religious groups exercise religion by providing health insurance that complies with their religious beliefs. *See* Appx.340-41. It is undisputed that these groups have a sincere religious objection to complying with the "accommodation." *Id.* ¶¶35-38. That failure to comply would result in large fines under 26 U.S.C. § 4980D ($100/day per person); 26 U.S.C. § 4980H(c)(1) ($2000 per employee, per year)—the same fines that constituted an obvious substantial burden in *Hobby Lobby*. 573 U.S. at 691 ("If these consequences do

not amount to a substantial burden, it is hard to see what would."). Indeed, the agencies themselves concede that forcing religious groups to comply with the accommodation "constituted a substantial burden" on religious exercise. 82 Fed. Reg. at 47,806.

Under RFRA, Congress permitted agencies to impose such burdens on religion only where they could prove that imposing the burden on a particular person was the least restrictive means of advancing a compelling government interest. 42 U.S.C. § 2000bb-1. Here, the government cannot carry that burden (and, to its credit, has finally stopped trying). The mandate fails strict scrutiny for many reasons, including:

- The government's interest in requiring employers to provide contraceptives cannot be "compelling" since small businesses, grandfathered plans, churches, and government-sponsored plans are exempt.
- The States here either have no contraceptive mandate (Pennsylvania) or a narrower mandate that includes cost-sharing (New Jersey) and a religious exemption broader than that in the federal mandate. Appx.461; Appx.552-53. The States cannot seriously contend there is a compelling interest in prohibiting actions they themselves never prohibited.
- As the Obama Administration acknowledged to the Supreme Court, women have many other avenues to obtain coverage.

This concession is part of why the Supreme Court remanded *Zubik* and why the government subsequently lost every case.[19]

- A range of state programs provide contraceptives. Indeed, the States' entire case is premised on such programs. The very existence of those programs proves that a plan run by nuns is not the least restrictive means of distributing contraceptives.

- As the Supreme Court explained in *Hobby Lobby*, "[t]he most straightforward way of [providing contraceptive coverage] would be for the Government to assume the cost of providing the four contraceptives at issue to any women who are unable to obtain them under their health-insurance policies due to their employers' religious objections." *Hobby Lobby*, 573 U.S. at 728.

- The federal government is prepared to pay directly via Title X, foreclosing any argument that the forced involvement of the Little Sisters is necessary.[20]

- The agencies have publicly acknowledged that the mandate fails strict scrutiny, 82 Fed. Reg. at 47,792, 47,806; they therefore cannot carry their statutory burden in this or any other court.

Accordingly, the mandate cannot pass strict scrutiny, and exemptions to that mandate are compelled by RFRA.

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[19] S*ee* Mark L. Rienzi, *Fool Me Twice:* Zubik v. Burwell *and the Perils of Judicial Faith in Government Claims*, 2016 Cato Sup. Ct. Rev. 123 (2015-2016) (detailing concessions leading to the *Zubik* remand).

[20] *See* 83 Fed. Reg. 25,502, 25,514 (June 1, 2018) ("[T]his proposed rule would amend the definition of 'low income family' to include women who are unable to obtain certain family planning services under their employer-sponsored health insurance policies due to their employers' religious beliefs or moral convictions.").

c. After Zubik, *courts have unanimously found the mandate as applied to religious employers violated RFRA.*

Since the Supreme Court's *Zubik* order, every single religious employer case that has been litigated to conclusion has resulted in a permanent injunction. Those injunctions find a RFRA violation and forbid the agencies from enforcing the mandate. For example:

- *Wheaton Coll. v. Azar*, No. 1:13-cv-8910 (N.D. Ill. Feb. 22, 2018), Dkt.119 at 3 ("enforcement of the contraceptive mandate against Wheaton would violate Wheaton's rights under" RFRA);
- *Little Sisters v. Azar*, No. 1:13-cv-02611 (D. Colo. May 29, 2018), Dkt.82 at 1-2 ("enforcement of the mandate against Plaintiffs, either through the accommodation or other regulatory means . . . violated and would violate the Religious Freedom Restoration Act");
- *Reaching Souls Int'l, Inc. v. Azar*, No. 13-cv-01092 (W.D. Okla. Mar. 15, 2018), Dkt.95 at 3-4 ("enforcement of the contraceptive mandate against Plaintiffs . . . violated and would violate RFRA").

These post-*Zubik* injunctions join pre-*Zubik* injunctions. All told, more than 50 RFRA-based injunctions continue to bind the federal agencies.

d. Neither Geneva College *nor* Real Alternatives *forecloses a RFRA finding.*

The district court mistakenly thought *Geneva College* and *Real Alternatives* precluded a finding of a RFRA violation. Appx.41-42; Appx.107. But neither does.

First, *Geneva College* was one of the decisions vacated by the Supreme Court in *Zubik*. 136 S. Ct. at 1561. It thus "carries no precedential force" in this Circuit. *1621 Route 22 W. Operating Co., LLC v. NLRB*, 825 F.3d 128, 141 n.6 (3d Cir. 2016). Indeed, in *Geneva College* itself, the district court subsequently entered a permanent injunction on RFRA grounds. *Geneva Coll. v. Azar*, No. 2:12-cv-00207 (W.D. Pa. July 5, 2018), Dkt.153. The panel decision in *Geneva College* thus is not even the law of the *case* in *Geneva College*; it is certainly not the law of the *Circuit*.

Second, the vacated opinion in *Geneva College* was procured on incorrect facts, which the government later admitted. In particular, in *Geneva College*, the agencies repeatedly told this Court that contraceptive coverage under the "accommodation" was *not* part of the religious organization's health plan. For example:

- "in all cases" contraceptive coverage "is provided separately from [the religious employer's] health coverage" (Br. for the Appellants, *Geneva Coll. v. Sebelius*, No. 14-1376, 2014 WL 2812346, at *1-2 (3d Cir. June 10, 2014), *vacated and remanded by Zubik*, 137 S. Ct. 1557);
- "separate payments" (*id.* at *8, 9, 17, 18, 22, 28, 35, 38);
- "through alternative mechanisms" (*id.* at *8);
- "through other means" (*id.* at *38).

The *Geneva College* panel accepted these representations as true and relied on them in making its substantial burden holding. *See Geneva Coll. v. Sec'y Dep't Health & Human Servs.*, 778 F.3d 422, 439 (3d Cir. 2015) (coverage is "separate and apart from" religious employer's plan) (citation omitted).

At the Supreme Court, however, the agencies admitted that the accommodation "coverage" actually *is* "part of the same plan as the coverage provided by the employer." Br. for the Resp'ts at 38, *Zubik*, 136 S. Ct. 1557 (quotations omitted), https://bit.ly/2DiCj32; *see also* Tr. of Oral Arg. at 60-61, *Zubik*, 136 S. Ct. 1557 (admitting it is "one fair understanding of the case" that all services are "in the one insurance package").

Finally, nothing in *Real Alternatives* revived *Geneva College*. The only RFRA claim in *Real Alternatives* concerned whether an *employee*

might have a RFRA claim based on participation in a health plan that offers objectionable benefits. *Real Alternatives v. Sec'y Dep't Health & Human Servs.*, 867 F.3d 338, 354-55 (3d Cir. 2017). That claim is fundamentally different from the claim in *Geneva College* and here—that it violates RFRA to force *employers* to authorize and facilitate the provision of objectionable products on the plans they sponsor. *Id.* (calling employee claim "a question of first impression" and "distinct from an employer's RFRA claim objecting to the mandated provision" of coverage). Indeed, the majority in *Real Alternatives* specifically disclaimed treating *Geneva College* as precedential, *id.* at 356 n.18 ("*Geneva* is no longer controlling"), and specifically distinguished the RFRA claim of the employees from that of an employer. *Id.* at 362 ("There is a material difference between employers arranging or providing an insurance plan that includes contraception coverage" and an employee's act of signing up for the plan).

For these reasons, nothing in *Geneva College* or *Real Alternatives* alters the analysis above: RFRA requires exemptions from the mandate.

e. Where courts are divided, government has discretion to err on the side of not violating civil rights.

Since federal agencies have to implement national policy for all 50 states, it was at least a reasonable act of discretion for the agencies to comply with multiple injunctions and err on the side of not burdening religious liberty. RFRA is more than a judicial remedy; it "applies to all Federal law." 42 U.S.C. § 2000bb-3. RFRA "intru[des] at every level of government, displacing laws"—and therefore the regulations—of "every [federal] agency." *See Mack v. Warden Loretto FCI*, 839 F.3d 286, 301 (3d Cir. 2016) (quotations omitted). When agencies implement federal law, they are necessarily implementing RFRA, and they are duty-bound to obey it. Accordingly, the Office of Legal Counsel has advised agencies that they can accommodate persons who they have reason to believe will face a substantial burden on religious exercise. *See, e.g.*, *Application of the Religious Freedom Restoration Act to the Award of a Grant Pursuant to the Juvenile Justice and Delinquency Prevention Act*, 31 Op. O.L.C. 162, 176-77 (2007); *cf. Charitable Choice Regulations Applicable to States Receiving Substance Abuse Prevention and Treatment Block Grants*, 68 Fed. Reg. 56,430, 56,435 (Sept. 30, 2003).

So too, here, the agencies were correct to the extent they erred on the side of protecting religious exercise under RFRA. This is particularly true because more than 50 federal courts have entered RFRA-based injunctions. That is why Congress made the Establishment Clause—not judicial pronouncements on the substantial burden test—the outer limit on exemptions: "Granting . . . exemptions, to the extent permissible under the Establishment Clause, shall not constitute a violation of this chapter." 42 U.S.C. § 2000bb-4. RFRA thereby expresses Congress's intent that federal agencies be allowed some leeway when accommodating religious exercise. Thus, both the Fourth IFR and the Final Rule are well within the discretion committed to HHS under the ACA and RFRA.

f. The Fourth IFR and Final Rule do not violate the Establishment or Equal Protection Clauses.

In Pennsylvania's first motion for a preliminary injunction, the Commonwealth went so far as to argue that the Fourth IFR (and thus, the Final Rule) violate the Establishment and Equal Protection Clauses. Dkt.8-2 at 32-37; Dkt.91-2 at 11 n.15 (incorporating arguments by reference). Even if the States had standing for such claims, they would be frivolous. Over six years of hard-fought litigation, neither the Obama Administration, nor the lower federal courts, nor any Supreme Court

Justice took the view that granting relief to religious organizations would violate the Establishment Clause. And with good reason: the Final Rule easily passes Establishment Clause muster under any test.

First, "the Establishment Clause *must* be interpreted 'by reference to historical practices and understandings.'" *Town of Greece v. Galloway*, 134 S. Ct. 1811, 1819 (2014) (quoting *County of Allegheny v. ACLU Greater Pittsburgh Chapter*, 492 U.S. 573, 670 (1989)) (emphasis added). There is no historical evidence supporting the notion that the Final Rule establishes religion. To the contrary, religious accommodations "fit[] within the tradition long followed" in our nation's history, even when they are broader than necessary to comply with the Free Exercise Clause. *Id.* at 1820.[21] Indeed, avoiding what would historically have been understood as an "establishment" in some cases *requires* broad exemptions for religious entities. *See, e.g.*, *Hosanna-Tabor Evangelical Lutheran Church & Sch. v. EEOC*, 565 U.S. 171 (2012) (Establishment Clause forbids government from interfering in the selection of ministers).

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[21] *See also* Michael W. McConnell, *The Origins and Historical Understanding of Free Exercise of Religion*, 103 Harv. L. Rev. 1409 (1990).

Even under the *Lemon* test, the Supreme Court has long recognized that accommodation of religion is a permissible secular purpose which does not advance or endorse religion, and which avoids, rather than creates, entanglement with religion. The leading case is *Amos*. There, the Supreme Court *unanimously* upheld Title VII's religious exemption, concluding that the "government acts with [a] proper purpose" when it "lift[s] a regulation that burdens the exercise of religion." *Corp. of the Presiding Bishop v. Amos*, 483 U.S. 327, 338 (1987). The same is true here. Such religious accommodations are not just permissible under the Establishment Clause, they "follow[] the best of our traditions." *Zorach v. Clauson*, 343 U.S. 306, 314 (1952).

The States' equal protection argument also fails. The IFRs make no sex classification. It is the underlying mandate, which the States wish to *enforce*, that creates differential rights based on sex. The Little Sisters and other religious groups cannot participate in (for example) the sterilization of either men or women. But they only need a religious exemption from the latter because that is all the States are seeking to force them to provide. The States' theory would mean that the Supreme

Court violated equal protection when it granted exemptions to the same mandate in *Hobby Lobby*. That cannot be the case.

g. The Final Rule does not violate Title VII or the Pregnancy Discrimination Act.

The States asked the district court to create a backdoor, nationwide contraceptive coverage mandate through Title VII. Dkt.8-2 at 28-32; Dkt.91-2 at 11 n.15. The only appeals court to have reached the question ruled that Title VII does not mandate contraceptive coverage. *See In re Union Pac. R.R. Employment Practices Litigation*, 479 F.3d 936, 942 (8th Cir. 2007). If the States were correct that failure to cover contraceptives violates Title VII, then how can they explain their own choice not to mandate contraceptive coverage for all employers, or to require it only in limited circumstances? Indeed, the States' argument would invalidate the grandfathering exemption and New Jersey's own exemption from its contraceptive coverage law. Appx.321-22. Such a sweeping conclusion would upend the orderly regulation of insurance coverage and state-level contraceptive mandates. The States cannot show a likelihood of success on such an overbroad and previously rejected legal theory.

B. The States are not likely to establish that the Final Rule is procedurally invalid.

After numerous courts held that the mandate violated RFRA and entered injunctions, the agencies issued a Fourth IFR that complied with the injunctions and with the agencies' admissions at the Supreme Court. Then, after carefully reviewing some 56,000 comments, the agencies adopted the Final Rule. The agencies' decision to use the IFR as a stopgap to prevent further litigation falls directly within the APA's good cause exception to prior notice and comment. 5 U.S.C. § 553. And even if the IFR were somehow procedurally deficient, the Final Rule—which issued *after* notice and comment—is procedurally valid.

1. The agencies had good cause to issue the Fourth IFR.

IFRs are either permissible modes of rulemaking to impose and modify the mandate or they are not. But under no circumstance could the law be as the district court and the States envision it: that the government can use IFRs three times to impose a mandate, create a religious exemption, and modify that exemption—but the fourth time, they violate the APA. To the contrary, the case for proceeding by IFR is more compelling now than it was in 2010, 2011, and 2014 because the D.C. Circuit sustained the prior IFRs under the good cause exception. *See*

Priests For Life v. HHS, 772 F.3d 229, 276-77 (D.C. Cir. 2014), *vacated on other grounds*, *Zubik v. Burwell*, 136 S. Ct. 1557 (2016).

IFRs are procedurally valid "when the agency for good cause finds" that notice and comment "are impracticable, unnecessary, or contrary to the public interest." 5 U.S.C. § 553(b). Review of good cause will be "inevitably fact- or context-dependent." *Mid-Tex Elec. Co-op., Inc. v. FERC*, 822 F.2d 1123, 1132 (D.C. Cir. 1987) (Ruth Bader Ginsburg, J.). Here, the agencies "determined" that notice and comment rulemaking "would be impracticable and contrary to the public interest." 82 Fed. Reg. at 47,813. Either ground establishes good cause.

Impracticable. Under the APA, notice and opportunity to comment need only be "sufficient to fairly apprise interested parties of all significant subjects and issues involved." *NVE, Inc. v. HHS*, 436 F.3d 182, 191 (3d Cir. 2006). "Interested parties" had at least six opportunities to comment "about whether and by what extent to expand" the existing religious exemption," and hundreds of thousands of them did—just not Pennsylvania or New Jersey. 82 Fed. Reg. at 47,814.

The agencies justifiably concluded that "[d]elaying the availability of the expanded exemption" was impracticable. *Id.* To start, "courts ha[d]

issued orders setting . . . pressing deadlines," *id.*, for the agency to resolve "outstanding issues" with religious objectors, *Zubik*, 136 S. Ct. at 1560; *see also* 82 Fed. Reg. at 47,814 (noting that the IFRs "provide a specific policy resolution that courts have been waiting to receive from the [agencies] for more than a year"). The agencies could have "reasonably interpreted" that cascade of injunctions and court orders across the country as a mandate "to take action to further alleviate any burden on the religious liberty of objecting religious organizations." *Priests for Life*, 772 F.3d at 276; *see also Am. Fed'n of Gov't Emps., AFL-CIO v. Block*, 655 F.2d 1153, 1157 (D.C. Cir. 1981) (upholding an IFR issued in response to an injunction, even though the trial court emphasized that it "was not mandating the action to be taken by the Department to comply with [the] injunction").

The agencies also found that delay would "increase the costs of health insurance" for religious objectors with grandfathered plans who have forestalled cost-saving changes in order to preserve their grandfa-

thered status and avoid the mandate.[22] 82 Fed. Reg. at 47,815. The district court dismissed this finding out of hand because agencies' examples were several years old—an irrelevant distinction both because grandfathering remains common and because arbitrary and capricious review precludes the court from "substitut[ing] its judgment for that of the agency." *Motor Vehicle Manufacturers Ass'n v. State Farm Auto Mutual Ins. Co.*, 463 U.S. 29, 43 (1983).

Given the need for action and the marginal utility in additional public comment, the agencies had good cause to implement the Fourth IFR.

Contrary to public interest. The agencies also had good cause because they correctly concluded that the mandate infringed fundamental rights and a broader exemption was necessary to "to cure such violations." *See* 82 Fed. Reg. at 47,814. The Fourth IFR was issued in the face of dozens of lawsuits and injunctions. *See* Statement of Related Cases. Leaving an illegal mandate in place with the expectation that it

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[22] The agencies supported this proposition with two legal opinions. *See Roman Catholic Archdiocese of Atlanta v. Sebelius*, No. 1:12-CV03489-WSD, 2104 WL 1256373 (N.D. Ga. Mar. 26, 2014); *Diocese of Fort Wayne-S. Bend, Inc. v. Sebelius*, 988 F. Supp. 2d 958 (N.D. Ind. 2013). These legal opinions are judicially noticeable as public records. *See* Fed. R. Evid. 201(b).

will violate federal civil rights is "contrary to the public interest." The agencies were thus "obligat[ed]" to "alleviate any burden on religious liberty" by IFR. *See Priests for Life*, 772 F.3d at 276.

The district court decided that litigation "uncertainty" does not justify bypassing notice and comment. Appx.31. But dozens of injunctions are certainty, not uncertainty. This reasoning also ignores that the agencies have independently concluded that the mandate and prior accommodation violated RFRA. Federal agencies invoking RFRA as a basis to stop burdening religion when implementing federal law is hardly new. *See supra* Part II.A.3.e. The agencies correctly concluded that allowing ongoing civil rights violations was contrary to the public interest and warranted yet another IFR.

2. If the States' procedural arguments are correct, the underlying mandate and "accommodation" are equally invalid.

The mandate has included a religious exemption from day one, when the agencies saw that "it is appropriate that HRSA, in issuing these Guidelines, takes into account the effect on the religious beliefs of certain religious employers" and gave HRSA "discretion to exempt certain religious employers from the Guidelines where contraceptive services

are concerned." 76 Fed. Reg. at 46,623. If the States are correct that the agencies have no delegated authority to create exemptions from the mandate, then each subsequent version of the exemptions must be invalid too.

In its first preliminary injunction, the district court reinstated these exemptions by invalidating the Fourth IFR and leaving the prior version of the mandate in force instead. Appx.52. The district court justified this decision by claiming that the old religious employer exemption is mandated by RFRA and the Constitution, but that further exemptions are not. Appx.42 (citing *Hobby Lobby*, 573 U.S. at 751-52 & n.14). The court did not attempt to explain why the Constitution exempts some religious orders, but not the Little Sisters.

The Second IFR created the nation's first nationwide contraceptive coverage mandate without any preliminary opportunity for public comment. It did not solicit prior comments on the anticipated guidelines, nor issue any prior notice even mentioning contraceptives, let alone the question of conscience protections. 77 Fed. Reg. at 8,726 (noting that "comments on the anticipated guidelines were not requested in the interim final regulations"). Nevertheless, the agencies argued that "an

additional opportunity for public comment is unnecessary" because "the amendments made in these interim final rules in fact are based on . . . public comments" received on the First IFR—an IFR that never specifically mentioned contraceptives or a religious exemption. 76 Fed. Reg. at 46,624; *see also* 75 Fed. Reg. 41,726. If the Second IFR could be issued based on the public comments that had already been received, the Fourth IFR is even more warranted after seven years of vigorous debate and hundreds of thousands of comments.

If the Fourth IFR is invalid for failure to have pre-IFR notice-and-comment, then so too is the rest of the IFR-based regime that the district court reinstated. Perhaps troubled by this "elephant in the room," the district court was notably silent on the question of reinstating the prior rules in its second preliminary injunction. Appx.736. But the only conceivable purpose of that injunction is to restore the status quo ante—the old version of the rules. *See* Appx.114.

3. Any procedural defect in the interim rules is harmless.

Even if the Fourth IFR contained a procedural defect, it would not, in this circumstance, constitute "prejudicial error." *See* 5 U.S.C. § 706; *see also Shinseki v. Sanders*, 556 U.S. 396, 406 (2009) (holding that § 706 is

an administrative law "harmless error rule") (internal quotation marks and citation omitted). The district court's conclusion that post-IFR notice and comment is categorically unable to cure a procedurally defective interim rule overreads this Court's precedents and, if sustained, would have destabilizing consequences. If the States were correct that lack of prior opportunity for comment on an IFR necessarily invalidates the resulting final rule, then HHS would have no choice but to go back to the drawing board, eliminating the mandate and reconsidering the entirety of the women's preventive services regulations.

The States, of course, must carry the "burden" to "explain why" the IFR "caused harm." *Sanders*, 556 U.S. at 410. A procedural error is harmless if "the outcome of the administrative proceedings will be the same absent [the agency]'s error." *Green Island Power Auth. v. FERC*, 577 F.3d 148, 165 (2d Cir. 2009); *see also PDK Labs. Inc. v. U.S. Drug Enf't Admin.*, 362 F.3d 786, 799 (D.C. Cir. 2004) ("If the agency's mistake did not affect the outcome, if it did not prejudice the petitioner, it would be senseless to vacate and remand for reconsideration."). The States cannot show prejudice because, even if the IFRs do not qualify for the good cause exception, any error could not have affected the out-

come: the Final Rules were issued *after* notice and comment, and on top of a regulatory regime that was itself implemented by interim rulemaking and which had garnered hundreds of thousands of comments.

This Circuit's precedent does not support a categorical rule that post-IFR notice and comment is meaningless. One round of procedurally invalid rulemaking does not taint all subsequent rulemaking. Rather, this Circuit's cases rely on unique circumstances, absent here, to establish prejudice. In *Sharon Steel Corp. v. EPA*, the EPA administrator changed Pennsylvania's Clean Air Act implementation plan without prior notice and comment. 597 F.2d 377, 379 (3d Cir. 1979). In that context, prior notice and comment with States was essential to fulfill the Clean Air Act's commitment to "cooperative federalism." *Cf. GenOn REMA, LLC v. EPA*, 722 F.3d 513, 516 (3d Cir. 2013). Here, no such state implementation plan is at issue: the mandate regulates employers directly, not via state intermediaries.

Moreover, *Sharon Steel* was only focused on the validity of the original rule issued without notice and comment. The Third Circuit did not suggest that what the agencies have done here—issued a subsequent final rule after notice and an opportunity to comment—was also im-

permissible. To the contrary, the Third Circuit ordered the agency to "forbear" from enforcing the procedurally invalid rule and then *provide* the type of notice and comment opportunity that has already been provided here with respect to the (enjoined) IFRs. *Id.* at 381-82. *Sharon Steel* not only permitted but mandated the development a new final rule after notice and comment.

The district court's extensive reliance on *NRDC v. EPA* is also misplaced. 683 F.2d 752 (3d Cir. 1982). *NRDC* arose after the Reagan administration's EPA issued an IFR to "effectively repeal" a rule that had been the product "of a lengthy and intensive development process" during the Carter administration. *Id.* at 758, 762. Given the asymmetry between using an interim rule to repeal a rule promulgated with prior notice and comment, and suspicious of the "sharp changes" in EPA policy, *id.* at 760, the Third Circuit held that postpromulgation comment did not "cure" the EPA's original procedurally invalid action. *Id.* at 767-68.

Here, the underlying mandate and prior exemptions were created by the same mechanism as the Fourth IFR and the Final Rule. *Cf. AFGE, Local 3090 v. FLRE*, 777 F.2d 751, 759 (D.C. Cir. 1985) (explaining that

an agency "seeking to . . . modify" a rule should "undertake similar procedures to accomplish such modification").

Moreover, in marked contrast to *NRDC*, the Final Rule is not an abrupt change in federal policy. HHS is not rescinding anything close to the entire mandate, leaving it in place for the vast majority of employers who were subject to it before. And the narrow modifications are consistent with the previous administration's concessions regarding the mandate. *See* Suppl. Br. for the Resp'ts at 14-15, *Zubik*, 136 S. Ct. 1557 (No. 14-1418) (mandate "could be modified" to be more protective of religious liberty). Given the previous administration's concessions regarding both the mechanism of the mandate and the availability of alternatives, *see supra*, as well as their post-comment conclusion that they could not adequately modify the existing accommodation scheme, narrow modifications to the exemption scheme were necessary. *See* U.S. Dep't of Labor, *FAQs About Affordable Care Act Implementation Part 36* at 4-5 (Jan. 09, 2017), https://bit.ly/2iaSoHW; 83 Fed. Reg. at 57,544 & n.14 (explaining that this conclusion necessitated a different approach).

Thus the agencies had no choice but to admit that the mandate and accommodation as they stood violated RFRA. *See* 83 Fed. Reg. at 57,544

(mandate "imposes a substantial burden on the exercise of religion under RFRA"); *see also Reynolds*, 710 F.3d at 518 (noting that failure to provide notice and comment is harmless when "an agency's substantive rule is 'the only reasonable one' that the court 'would reverse' [had the agency] 'c[o]me out the other way.'") (quoting *Sheppard v. Sullivan*, 906 F.2d 756, 762 (D.C. Cir. 1990)). All of that makes this case readily distinguishable from *NRDC*. Here, the agencies used an interim rule to save a regulatory regime (itself issued via IFRs), creating targeted exemptions consistent with concessions made by the prior administration and in response to injunctions.

The district court also derived the categorical bar against post-IFR comment from *Reynolds*—an inapposite case addressing the Attorney General's authority to impose, via an interim rule, the Sex Offender Registration and Notification Act (SORNA)'s requirements on pre-Act offenders. The Third Circuit held the rule invalid and determined post-IFR comment was not harmless since the government issued the interim rule to "eliminate any dispute" about the statute's retroactive application—"the very subject matter about which [the government] was to keep an open mind." 710 F.3d at 519 (internal quotation marks and ci-

tation omitted). Critically, *Reynolds* only addressed whether post-IFR comment could remove the prejudice from the earlier interim rule (the basis of the challenged conviction). It does not support the States' far broader claim that an invalid interim rule "fatally infect[s]" the Final Rule *despite* post-IFR comments that *precede* the Final Rule. Dkt.91-2 at 12.

Any suggestion that *Reynolds* precludes the government from utilizing subsequent comment is refuted by the fact that this Circuit has repeatedly upheld SORNA convictions obtained after the Justice Department finalized the interim rule that *Reynolds* invalidated. *See* 73 Fed. Reg. 38,030, 38,046-47 (July 2, 2008) (promulgating through notice and comment the "SMART" guidelines to implement SORNA and reaffirming the interim rule applying SORNA retroactively); 75 Fed. Reg. 81,849 (Dec. 29, 2010) (finalizing the interim retroactivity rule); *e.g.*, *United States v. Cooper*, 750 F.3d 263, 265 (3d Cir. 2014) (affirming the Attorney General's authority to issue the SMART guidelines); *United States v. Dimpfl*, 523 F. App'x 865, 866 (3d Cir. 2013). The district court's judgment, then, could be used to upend SORNA convictions be-

cause the Justice Department finalized the procedurally invalid interim rule with post-IFR comment.

That result is as implausible as it sounds. Extending *Sharon*, *NRDC*, and *Reynolds* to cover all circumstances in which an allegedly procedurally invalid interim rule is finalized after subsequent comment would cast a pall on thousands of regulations. According to the GAO, 35% of all major rules were finalized with post-IFR notice and comment. *See* U.S. Gov't Accountability Office, GAO-13-21, *Federal Rulemaking: Agencies Could Take Additional Steps to Respond to Public Comments*, 3 n.6, 8 (Dec. 2012), http://www.gao.gov/assets/660/651052.pdf. Moreover, since the States' position gives agencies zero credit for undertaking post-IFR notice and comment, agencies issuing interim rules and confident they have good cause will forgo notice and comment altogether—an outcome that is inconsistent with the purpose of section 553. *See, e.g.*, *Levesque v. Block*, 723 F.2d 175, 188 (1st Cir. 1983) ("[C]omment after the fact is better than none at all.").

The better understanding of the law is that post-IFR notice and comment—which of course *precedes* issuance of a final rule—is proper, in many cases, to create a finalized rule. *See, e.g.*, *United States v.*

Johnson, 632 F.3d 912, 930, 932 (5th Cir. 2011) (sex offender not prejudiced by post-IFR notice and comment "because the Attorney General nevertheless considered the arguments Johnson has asserted and responded to those arguments during the interim rulemaking."); *Friends of Iwo Jima v. Nat'l Capital Planning Comm'n*, 176 F.3d 768, 774 (4th Cir. 1999) (Wilkinson, J.) (holding harmless deficient notice because the "identical substantive claims" to that of plaintiffs was "the main focus of each stage in the approval process," it "simply did not prevail").[23] Case-specific factors can render the error prejudicial, but no such factors exist here. The Fourth IFR was consistent with the procedures used for prior versions of the rule, and the exemptions were forced by in-court factual concessions and court orders requiring compliance with federal civil rights laws.

[23] *See also, e.g.*, *Advocates for Highway & Auto Safety v. Fed. Highway Admin.*, 28 F.3d 1288, 1292 (D.C. Cir. 1994) (explaining that "tardy request for public comment, however, is not necessarily fatal" where the agency "displayed an open mind when considering the comments").

III. Ordering the agencies to enforce the same supposed violations of law used to justify the preliminary injunctions is an abuse of discretion.

The district court justified the preliminary injunctions by holding the agencies could not impose "sweeping" changes to healthcare policy by IFR, Dkt. 59 at 34, nor add exceptions to the preventive services provision, Dkt.136 at 42. But invalidating the IFR and later the Final Rule "necessarily reinstated" the prior contraceptive mandate regime. *See Georgetown Univ. Hosp. v. Bowen*, 821 F.2d 750, 757 (D.C. Cir. 1987); *see also* Appx.114 (a "preliminary injunction will maintain the status quo," including the "exemptions or accommodations prior to October 6, 2017"). And, as explained above, that regime was imposed by multiple IFRs and *itself* created exceptions to the preventive services regime.

Reinstating the mandate and religious exemption is tantamount to ordering the agencies to carry out the *same* violation of law used to justify the injunction. Such an injunction is an abuse of discretion. *See Rappa v. New Castle Cty.*, 18 F.3d 1043, 1074 (3d Cir. 1994) (vacating an injunction because "the district court's injunction in this case itself perpetuates the constitutional infirmity of the statute by leaving in place" other unconstitutional restrictions on speech).

The district court's broad ruling does not merely lay the groundwork for a different lawsuit; it commits reversible error in *this* case. By its own reasoning, the court saws off the branch on which it sits.

IV. The States cannot satisfy the remaining injunction factors.

A. The States are not suffering irreparable harm.

The States also must show a preliminary injunction is necessary to prevent "irreparable harm" before the merits decision, that is, "harm that cannot adequately be compensated after the fact by monetary damages." *Adams v. Freedom Forge Corp.*, 204 F.3d 475, 484-85 (3d Cir. 2000). The risk of "irreparable harm" must be "significant," not "speculative." *Id.* at 484-85, 488. "This is not an easy burden." *Id.* at 485. Because the States cannot establish any cognizable injury, *see supra* Part I, they necessarily cannot establish an irreparable harm.

The States have not identified even one employer which will drop contraceptive coverage due to the IFR, nor have they identified any women who would fall into the exceedingly narrow category of women who would choose to forego their employer's insurance coverage and qualify for and seek state assistance for contraceptive services.

Nor can the States rely upon wholly speculative predictions of harm to establish entitlement to an injunction. The district court relied upon

hypotheticals about denial of coverage and warned of the dire consequences that would result from the IFRs going into effect. Appx.36-37, 43-48, 111-13. The court ignores the seven-year history of the mandate and its legal battles. The slippery slope argument has been advanced against every challenge to the mandate and has proven false every time.

Most notably, the Supreme Court rejected this claim in *Hobby Lobby*. 573 U.S. at 733 ("Nor has HHS provided evidence that any significant number of employers sought exemption, on religious grounds, from any of ACA's coverage requirements other than the contraceptive mandate."). There, the dissent predicted a number of consequences, raising the specter of exemption claims by "employers with religiously grounded objections to . . . [1] blood transfusions (Jehovah's Witnesses); [2] antidepressants (Scientologists); [3] medications derived from pigs, including anesthesia, intravenous fluids, and pills coated with gelatin (certain Muslims, Jews, and Hindus); and [4] vaccinations (Christian Scientists, among others)." *Id.* at 2805. But those claims never materialized.

Searches of post-*Hobby Lobby* cases underscore this fact. A search for federal and state decisions involving employers seeking to avoid cover-

ing blood transfusions turns up no such cases. A search for federal and state decisions involving employers seeking to avoid covering antidepressants likewise turns up no such cases. A search for federal and state decisions involving employers seeking to avoid covering pork-derived products turns up no such cases. And finally, a search of federal and state decisions involving employers seeking to avoid covering vaccines turns up no such cases. In fact, each search turns up two kinds of results: (1) cases which have nothing to do with employer health coverage, and (2) other contraceptive mandate cases discussing these dire predictions.

It has been four years since *Hobby Lobby*, and the horribles have not paraded. It is incumbent upon plaintiffs seeking a nationwide injunction to demonstrate that their fears of endless religious objection claims will in fact come true. The States cannot.

Even fears about lack of contraceptive coverage are overblown. Contraceptive coverage was widespread prior to the mandate, as the IOM acknowledged. The IOM found that "the vast majority"—89%—"of health plans cover contraceptives." Institute of Medicine, *supra* n.2, at 49. If 89% of plans covered contraceptives *before* the mandate, where is

the States' proof that many employers will choose to fake objections—thus risking fines—due to the IFRs? Indeed, the IFRs had already been in effect for two months before the first preliminary injunction was granted, and yet the record is devoid of evidence of any employer, other than those like the Little Sisters who had already challenged the mandate, who had taken advantage of it. A Guttmacher study performed in 2017 actually found that contraceptive use among sexually active women had remained constant—not increased—after the mandate went into effect.[24] This is unsurprising given the many exceptions to the mandate and the widespread availability of contraceptive coverage prior to the mandate.

B. The public interest and the balance of the equities favor broad protection of religious exercise.

Unlike the speculative harms asserted by the States, enjoining the accommodation will impinge the religious freedom of religious objectors like the Little Sisters. "The loss of First Amendment freedoms, for even

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[24] Jonathan Bearak & Rachel K. Jones, *Did Contraceptive Use Patterns Change After the Affordable Care Act? A Descriptive Analysis*, Guttmacher Institute (Mar. 13, 2017), https://bit.ly/2NyhHIR ("We observed no changes in contraceptive use patterns among sexually active women.").

minimal periods of time, unquestionably constitutes irreparable injury." *Elrod v. Burns*, 427 U.S. 347, 373 (1976). The same is true of violations of RFRA. *See, e.g.*, *Kikumura v. Hurley*, 242 F.3d 950, 963 (10th Cir. 2001) ("[A] plaintiff satisfies the irreparable harm analysis by alleging a violation of RFRA."). This is why so many courts enjoined the prior versions of the mandate, and why a regulatory fix is appropriate.

This strong interest in fundamental freedoms, coupled with the lack of demonstrated harm if the IFR goes into effect, shows that the balance favors the IFR and religious objectors like the Little Sisters. The arguments here are similar to those in *Hobby Lobby*, where the Supreme Court found that it was actually the government's position that would lead to "intolerable consequences": 'Under HHS's view, RFRA would permit the Government to require all employers to provide coverage for any medical procedure allowed by law in the jurisdiction in question—for instance, third-trimester abortions or assisted suicide." *Hobby Lobby*, 573 U.S. at 733. Indeed, given the district court's construction of substantial burden, the government could impose a third-trimester abortion "accommodation" or an assisted suicide "accommodation," and the Little Sisters would be powerless to fight it, since the accommoda-

tion would defeat any RFRA claim. *See* Appx.41-42 (no substantial burden).

The danger in this case arises not from a sensible religious accommodation, but from judicial decisions which tie the government's hands when it attempts to comply with civil rights laws and stop burdening religion. After seven years, the government arrived at a win-win solution in which most employers provide contraceptive coverage, but the burden is lifted from religious employers, and employees may choose from a broad range of alternatives. This Court should reject the States' belated attempt to dictate federal policy via nationwide injunction.

CONCLUSION

The States lack standing, so the decisions below should be vacated and the case remanded with instructions to dismiss. If the Court reaches the merits, it should hold that the States have not met any of the criteria to justify a preliminary injunction, and reverse both the decisions below.

Dated: February 15, 2019

Respectfully submitted,

/s/ Mark Rienzi

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CERTIFICATE OF BAR MEMBERSHIP

I hereby certify that I am a member in good standing of the bar of the United States Court of Appeals for the Third Circuit.

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CERTIFICATE OF COMPLIANCE WITH FEDERAL RULE OF APPELLATE PROCEDURE 32(A) AND LOCAL RULE 31.1

I hereby certify that the following statements are true:

1. This brief complies with the type-volume limitations imposed by Federal Rules of Appellate procedure 29(d) and 32(a)(7)(B). It contains 15,741 words, excluding the parts of the brief exempted by Federal Rule 32(a)(7)(B)(iii) and by Local Rule 29.1(b).
2. This brief complies with the typeface and typestyle requirements of Federal Rule 32(a)(5) and 32(a)(6). It has been prepared in a proportionally-spaced typeface using Microsoft Office Word 2016 in 14-point Century Schoolbook font.
3. This brief complies with the electronic filing requirements of Local Rule 31.1(c). The text of this electronic brief is identical to the text of the paper copies, and the latest version of Windows Defender has been run on the file containing the electronic version of this brief and no virus has been detected.

Executed this 15th day of February 2019.

/s/ Mark Rienzi
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CERTIFICATE OF SERVICE

I certify that on the date indicated below, I filed the foregoing document with the Clerk of the Court, using the CM/ECF system, which will automatically send notification and a copy of the brief to the counsel of record for the parties. I further certify that all parties to this case are represented by counsel of record who are CM/ECF participants.

Executed this 15th day of February, 2019.

/s/ Mark Rienzi
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