PRECEDENTIAL

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

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

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COMMONWEALTH OF PENNSYLVANIA; STATE OF NEW JERSEY

v.

PRESIDENT UNITED STATES OF AMERICA; SECRETARY UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; SECRETARY UNITED STATES DEPARTMENT OF TREASURY; UNITED STATES DEPARTMENT OF TREASURY; SECRETARY UNITED STATES DEPARTMENT OF LABOR; UNITED STATES DEPARTMENT OF LABOR; UNITED STATES OF AMERICA

Little Sisters of the Poor Saints Peter and Paul Home
(Intervenor in D.C.),
Appellant in 17-3752, 19-1129

President United States of America, Secretary United States of Department of Health and Human Services, United States Department of Health and Human Services, Secretary United

States Department of Treasury, United States Department of Treasury, Secretary United States Department of Labor, United States Department of Labor,

Appellants in 18-1253,
19-1189 (Except President United States of America)

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ON APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF PENNSYLVANIA
(E.D. Pa. No. 2:17-cv-04540)
District Judge: Hon. Wendy Beetlestone

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Argued May 21, 2019

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Before: McKEE, SHWARTZ, and FUENTES, Circuit Judges.

(Filed July 12, 2019)

Michael J. Fischer [ARGUED]
Aimee D. Thompson
Office of Attorney General of Pennsylvania
1600 Arch Street, Suite 300
Philadelphia, PA 19103

Glenn J. Moramarco
Office of Attorney General of New Jersey
Department of Law & Public Safety, Division of Law

Richard J. Hughes Justice Complex
25 Market Street, P.O. Box 112
Trenton, NJ 08625

Counsel for Appellees Commonwealth of Pennsylvania and State of New Jersey

Lowell V. Sturgill, Jr.
United States Department of Justice, Civil Division
950 Pennsylvania Avenue, N.W., Room 7241
Washington, DC 20530

Hashim M. Moopan [ARGUED]
United States Department of Justice
Civil Division, Appellate Staff
950 Pennsylvania Avenue, N.W.
Washington, DC 20530

Karen Schoen
United States Department of Justice
Civil Division, Appellate Section
950 Pennsylvania Avenue, N.W. Room 7533
Washington, DC 20530

Counsel for Appellants President United States of America, Secretary United States Department of Health & Human Services, United States Department of Health & Human Services, United States Department of Treasury, Secretary United States Department of Treasury, United States Department of Labor, Secretary United States Department of

Labor, and United States of America

Mark L. Rienzi [ARGUED]
Lori H. Windham
Becket Fund for Religious Liberty
1200 New Hampshire Avenue, N.W., Suite 700
Washington, DC 20036

Nicholas M. Centrella
Conrad O'Brien
1500 Market Street
West Tower, Suite 3900
Philadelphia, PA 19102

Counsel for Appellee-Intervenor Little Sisters of the Poor Saints Peter and Paul Home

Jason R. LaFond
Office of Attorney General of Texas
209 West 14th Street, 7th Floor
Austin, TX 78711

Counsel for Amici Curiae in Support of Appellants States of Texas, Alabama, Arkansas, Georgia, Idaho, Louisiana, Missouri, Nebraska, Oklahoma, South Carolina, and West Virginia

Elizabeth N. Dewar
Office of Attorney General of Massachusetts
20th Floor, One Ashburton Place
McCormack Building

Boston, MA 02108

Counsel for Amici Curiae States of Massachusetts, California, Colorado, Connecticut, Delaware, Hawaii, Illinois, Iowa, Maine, Maryland, Michigan, Minnesota, Nevada, New Mexico, New York, North Carolina, Oregon, Rhode Island, Vermont, Virginia, Washington and the District of Columbia

Dariely Rodriguez
Lawyers' Committee for Civil Rights Under Law
1500 K Street, N.W., Suite 900
Washington, DC 20005

Counsel for Amici Curiae Center for Reproductive Rights, Lawyers Committee for Civil Rights Under Law, California Womens Law Center, GLBTQ Legal Advocates and Defenders, LatinoJustice PRLDEF, Lawyers for Civil Rights, Legal Momentum, Legal Voice, Mississippi Center for Justice, National Center for Lesbian Rights, and Women's Law Project

Sara J. Rose
American Civil Liberties Union
313 Atwood Street
Pittsburgh, PA 15213

Counsel for Amici Curiae American

Civil Liberties Union, Anti Defamation League, Leadership Conference on Civil and Human Rights, and National Urban League

Thomas W. Hazlett
Stephen J. Kastenberg
Ballard Spahr
1735 Market Street, 51st Floor
Philadelphia, PA 19103

Counsel for Amici Curiae Public Interest Law Center of Philadelphia, Washington Lawyers Committee for Civil Rights and Urban Affairs, Chicago Lawyers Committee for Civil Rights, Lawyers Committee for Civil Rights of the San Francisco Bay Area, and Public Counsel

Jeffrey Blumenfeld
Lowenstein Sandler
2200 Pennsylvania Avenue, N.W., Suite 5
Washington, DC 20037

Counsel for Amici Curiae National Womens Law Center, National Latina Institute for Reproductive Health, Sisterlove Inc., and National Asian Pacific American Women Forum

Robert Dunn
Gibson Dunn & Crutcher
1881 Page Mill Road

Palo Alto, CA 94304

Counsel for Amicus Curiae Religious Sisters of Mercy

Miles Coleman
Nelson Mullins Riley & Scarborough
104 South Main Street, Suite 900
Greenville, SC 29601

Counsel for Amici Curiae Ronald J. Colombo, Richard Epstein, Carl H. Esbeck, David F. Forte, Richard W. Garnett, Esq., Professor Robert P. George, Mary Ann Glendon, Michael P. Moreland, Stacy Scaldo, and Michael Uhlmann

Bruce H. Schneider
Stroock Stroock & Lavan
180 Maiden Lane, 38th Floor
New York, NY 10038

Counsel for Amici Curiae American Nurses Association, American College of Obstetricians and Gynecologists, American Academy of Nursing, American Academy of Pediatrics, and Physicians for Reproductive Choice and Health

Allan J. Arffa

Melina M. Meneguin-Layerenza
Sierra Robart
Paul Weiss Rifkind Wharton & Garrison
1285 Avenue of the Americas
New York, NY 10019

Counsel for Amici Curiae Planned Parenthood Federation of America, National Health Law Program, and National Family Planning & Reproductive Health Association

Priscilla J. Smith
Yale Law School RRJP Clinic
319 Sterling Place
Brooklyn, NY 11328

Counsel for Amicus Curiae Program for the Study of Reproductive Justice

Leah Bruno
Dentons US
233 South Wacker Drive, Suite 5900
Chicago, IL 60606

Jeffrey S. Feldman
The Feldman Firm
600 West Germantown Pike, Suite 400
Plymouth Meeting, PA 19462

Counsel for Amici Curiae United States Women's Chamber of Commerce and National Association for Female

Executives

Joshua A. Matz
Kaplan Hecker & Fink
350 Fifth Avenue, Suite 7110
New York, NY 10118

Counsel for Amicus Curiae Church State Scholars

Rhiannon N. Batchelder
Jamie A. Levitt
Morrison & Foerster
250 West 55th Street
New York, NY 10019

Counsel for Amici Curiae American Association of University Women and Service Employees International Union

Richard B. Katskee
Americans United for Separation of Church & State
1310 L Street, N.W., Suite 200
Washington, DC 20005

Counsel for Amicus Curiae Americans United for Separation of Church and State

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OPINION OF THE COURT

SHWARTZ, Circuit Judge.

The Women's Health Amendment to the Affordable Care Act ("ACA") mandated that women's health insurance include coverage for preventive health care. Through the Amendment, Congress directed the Health Resources and Services Administration ("HRSA"), a component of the Department of Health and Human Services ("HHS"), to issue guidelines setting forth the preventive health care services that women should be provided. Among the services HRSA identified was contraceptive care. Nowhere in the enabling statute did Congress grant the agency the authority to exempt entities from providing insurance coverage for such services nor did Congress allow federal agencies to issue regulations concerning this coverage without complying with the Administrative Procedure Act.

Notwithstanding Congress's directives, in 2017, HHS and the Departments of Labor and Treasury (collectively, "the Agencies") promulgated regulations that expanded the entities that could invoke an exemption to the requirement that group health insurance plans cover contraceptive services as a form of women's preventive health care. Because the state plaintiffs are likely to succeed in proving that the Agencies did not follow the APA and that the regulations are not authorized under the ACA or required by the Religious Freedom Restoration Act ("RFRA"), we will affirm the District Court's order preliminarily enjoining the rules' enforcement nationwide.

I

A

Enacted as a part of the ACA, Pub. L. No. 111-148, 124 Stat. 119 (2010), the Women's Health Amendment mandates that "[a] group health plan[1] and a health insurance issuer offering group or individual health insurance coverage shall, at a minimum provide coverage for and shall not impose any cost sharing requirements for . . . preventive care and screenings [for women] . . . as provided for in comprehensive guidelines supported by the [HRSA]."[2] 42 U.S.C. § 300gg-13(a), (a)(4). HRSA commissioned an expert panel from the Institute of Medicine to recommend covered services. In 2011, HRSA adopted the Institute's recommendations and issued guidelines defining preventive care to include all "Food and Drug Administration approved contraceptive methods, sterilization procedures, and patient education and counseling for all women with reproductive capacity," "as prescribed" by a woman's health care provider. HRSA, Women's Preventive Services Guidelines, https://www.hrsa.gov/womens-guidelines/index.html (last visited May 8, 2019). This

[1] Pursuant to 42 U.S.C. § 300bb-8(1), the term "group health plan" has the meaning set forth in 26 U.S.C. § 5000(b)(1), which defines a "group health plan" as "a plan (including a self-insured plan) of, or contributed to by, an employer . . . to provide health care (directly or otherwise) to the employees."

[2] Congress expressly exempted two sets of actors from various ACA requirements, including the Women's Health Amendment: grandfathered health plans, 42 U.S.C. § 18011, and employers with fewer than 50 employees, 26 U.S.C. § 4980H(c)(2).

statutory and regulatory scheme was deemed the "Contraceptive Mandate." Several regulations and litigation followed.

1

The same day that the Guidelines were issued, the Agencies promulgated an interim final rule ("IFR"), followed by a final rule in 2013, to exempt certain religious employers—namely, churches and similar entities—from the Contraceptive Mandate. Group Health Plans and Health Insurance Issuers Relating to Coverage of Preventive Services Under the Patient Protection Affordable Care Act, 77 Fed. Reg. 8,725 (Feb. 15, 2012) (the "Church Exemption"); Group Health Plans and Health Insurance Issuers Relating to Coverage of Preventive Services Under the Patient Protection and Affordable Care Act, 76 Fed. Reg. 46,621 (Aug. 3, 2011).[3] As the Agencies later

[3] After a notice-and-comment rulemaking process, which included consideration of comments concerning whether coverage may conflict with the religious beliefs of some employers, Group Health Plans and Health Insurance Issuers Relating to Coverage of Preventive Services Under the Patient Protection and Affordable Care Act, 76 Fed. Reg. 46,621, 46,623 (August 3, 2011), the Agencies defined "religious employer[s]" in the Church Exemption as entities "that [are] organized and operate[] as . . . nonprofit entit[ies] and [are] referred to" as such in the internal revenue code provision applying to "churches, their integrated auxiliaries, and conventions or associations of churches, as well as to the exclusively religious activities of any religious order," Coverage of Certain Preventive Services Under the

explained, the "exemption for churches and houses of worship is consistent with their special status under longstanding tradition in our society and under federal law." Coverage of Certain Preventive Services Under the Affordable Care Act, 80 Fed. Reg. 41,318, 41,325 (July 14, 2015).

The 2013 final rule also separately provided that a nonprofit religious employer who "(1) [o]pposes providing coverage for some or all of the contraceptive services required to be covered . . . on account of religious objections; (2) is organized and operates as a nonprofit entity; (3) holds itself out as a religious organization; and (4) self-certifies that it satisfies the first three criteria," 78 Fed. Reg. at 39,874, is entitled to an accommodation to avoid "contracting, arranging, paying, or referring for contraceptive coverage," id. at 39,875. This accommodation process (the "Accommodation") permits an employer to send a self-certification form to its insurance issuer, which then excludes contraceptive coverage, either in full or in part, from the group health plan and in turn "provide[s] payments for contraceptive services for plan participants and beneficiaries, separate from the group health plan, without the imposition of cost sharing, premium, fee, or other charge on plan participants or beneficiaries or on the eligible organization or its plan." Id. at 39,876. A third party administrator ("TPA") may also be used as a claims or plan administrator "solely for the purpose of providing payments for contraceptive services for participants and beneficiaries in a self-insured plan of an eligible organization at no cost to plan participants or beneficiaries or to the eligible organization." Id. at 39,879. By invoking the Accommodation, the employer was

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Affordable Care Act, 78 Fed. Reg. 39,870, 39,871, 39,889 (July 2, 2013); see 45 C.F.R. § 147.132.

no longer responsible for providing coverage for contraceptive care.

2

Various legal challenges followed. First, in Burwell v. Hobby Lobby Stores, Inc., 573 U.S. 682 (2014), the Supreme Court held that the Accommodation must be extended to closely-held for-profit corporations with sincere religious objections to the provision of contraceptive coverage so that their religious beliefs were not substantially burdened under RFRA, 42 U.S.C. § 2000bb-1. Id. at 724-26. The Court observed that use of the Accommodation process was a less restrictive means to ensure access to cost-free contraceptives. Id. at 730-31. Days later, in Wheaton College v. Burwell, 573 U.S. 958 (2014), the Court concluded that Wheaton College, who also lodged a religious objection to providing insurance for services covered by the Contraceptive Mandate, did not have to use the Accommodation self-certification form, known as the ESBA Form 700, but could instead rely on its notification to HHS to satisfy the Accommodation's prerequisites. Id. at 959.

To ensure compliance with these rulings, the Agencies promulgated another IFR and final rule.[4] Coverage of Certain Preventive Services Under the Affordable Care Act, 80 Fed. Reg. 41,318 (July 14, 2015). The rule "extend[ed] the [A]ccommodation to a for-profit entity that is not publicly

[4] The final rule implementing Hobby Lobby was preceded by notice of proposed rulemaking. Coverage of Certain Preventive Services Under the Affordable Care Act, 79 Fed. Reg. 51,118 (Aug. 27, 2014).

traded, is majority-owned by a relatively small number of individuals, and objects to providing contraceptive coverage based on its owners' religious beliefs." Id. at 41,324. The rule also "allow[ed] eligible organizations to choose between using [the] ESBA Form 700 or the alternative process [of notifying HHS in writing of a religious objection to covering contraceptive services] consistent with the Wheaton interim order." Id. at 41,323.

In Zubik v. Burwell, 136 S. Ct. 1557 (2016) (per curiam), the Supreme Court addressed the petitioners' assertions that "submitting [the Accommodation] notice substantially burden[ed] the exercise of their religion, in violation of [RFRA]." Id. at 1559. The Court did not reach the merits of this claim but rather remanded to afford the parties "an opportunity to arrive at an approach going forward that accommodates petitioners' religious exercise while at the same time ensuring that women covered by petitioners' health plans receive full . . . contraceptive coverage." Id. at 1560 (internal quotation marks and citation omitted).

In response to the Court's direction in Zubik, the Agencies solicited comments regarding the current procedure and possible alternatives to the Accommodation. Coverage for Contraceptive Services, 81 Fed. Reg. 47,741 (July 22, 2016). The Agencies reviewed the comments and found that "no feasible approach has been identified at this time that would resolve the concerns of religious objectors while still ensuring that the affected women receive full and equal health coverage, including contraceptive coverage." Dep't of Labor, FAQs About Affordable Care Act Implementation Part 36, at 4 (Jan. 9, 2017), available at https://www.dol.gov/sites/default/files/ebsa/about-ebsa/our-

activities/resource-center/faqs/aca-part-36.pdf. As a result, the Accommodation remained unchanged.

3

In May 2017, President Donald Trump issued an executive order directing the Agencies to "consider issuing amended regulations, consistent with applicable law, to address conscience-based objections to the preventive-care mandate promulgated under [42 U.S.C. § 300gg-13(a)(4)]." Exec. Order No. 13,798 § 3, 82 Fed. Reg. 21,675 (May 9, 2017). In response, and without issuing a notice of proposed rulemaking or soliciting public comment, the Agencies issued two new IFRs: the Religious IFR and the Moral IFR. These IFRs expanded the existing exemption and Accommodation framework, made the Accommodation process voluntary, and offered similar protections to organizations with moral objections to contraceptives. See Religious Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act, 82 Fed. Reg. 47,792 (Oct. 13, 2017); Moral Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act, 82 Fed. Reg. 47,838 (Oct. 13, 2017). This litigation followed.

B

1

The Commonwealth of Pennsylvania filed suit against various governmental entities[5] and sought to enjoin the enforcement of the IFRs. Little Sisters of the Poor Saints Peter and Paul Home ("Little Sisters") intervened.[6] The District

[5] These entities include the President, the Agencies and their Secretaries, and the United States of America (collectively, "the Government").

[6] Little Sisters, a religious nonprofit operating a home in Pittsburgh, moved to intervene, the District Court denied its motion, and our Court reversed, concluding, at that time, intervention was appropriate because the litigation posed a threat to Little Sisters' interest in an exemption, and that its interests are not adequately represented by the Government. See generally Pennsylvania v. President of the United States of Am., 888 F.3d 52 (3d Cir. 2018). Since then, however, the United States District Court for the District of Colorado permanently enjoined enforcement of the Contraceptive Mandate for benefit plans in which Little Sisters participates. Pennsylvania v. Trump, 351 F. Supp. 3d 791, 829 n.27 (E.D. Pa. 2019) ("Defendant-Intervenor has secured a permanent injunction, preventing enforcement of the Contraceptive Mandate against it."); Little Sisters of the Poor v. Azar, No. 1:13-cv-02611, Dkt. No. 82 at 2-3 (D. Colo. May 29, 2018); Accordingly, Little Sisters is no longer aggrieved by the District Court's ruling, its need for relief is moot, and thus they lack appellate standing. See Ass'n of Banks in Ins. v. Duryee, 270 F.3d 397, 403 (6th Cir. 2001) ("[T]he intervenor-defendants face the threat of economic injury should the Ohio

Court granted Pennsylvania's request to preliminarily enjoin the IFRs. See generally Pennsylvania v. Trump, 281 F. Supp. 3d 553 (E.D. Pa. 2017). The Court held that Pennsylvania was likely to succeed on its procedural and substantive challenges under the APA. Id. at 576, 581. The Government appealed, and the District Court granted a stay pending appeal.

While the appeal of the order preliminarily enjoining the IFRs was pending, the Agencies promulgated two Final Rules, which are virtually identical to the Religious and Moral IFRs. See Religious Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act, 83 Fed. Reg. 57,536 (Nov. 15, 2018); 45 C.F.R. § 147.132 ("Religious Rule" or "Religious Exemption"); Moral Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act, 83 Fed. Reg. 57,592 (Nov. 15, 2018); 45 C.F.R. § 147.133 ("Moral Rule" or "Moral Exemption") (collectively, "the Rules" or "the Exemptions"). Like the Religious IFR, the Final Rule creating the Religious Exemption expanded the categories of employers who are permitted to invoke the exemption from the Contraceptive Mandate to include all nonprofit, for-profit, and publicly-held companies. The Religious Exemption also made participation in the

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statutory provisions not be enforced. Such threatened injury is sufficient to confer appellate standing on the intervenor-defendants and allows them to challenge the merits of the district court's decision."); cf. In re Grand Jury, 111 F.3d 1066, 1071 (3d Cir. 1997) ("Since both intervenors remain aggrieved after the district court's disposition, the constitutional requirements for standing to appeal as well as standing to sue are satisfied.").

Accommodation process completely voluntarily, relieving employers from the need to "file notices or certifications of their exemption."[7] 83 Fed. Reg. at 57,558; see also id. at 57,537, 57,562. The Final Rule creating the Moral Exemption offered the same exemption and voluntary accommodation process to nonprofit organizations and non-publicly traded organizations "with sincerely held moral convictions opposed to coverage of some or all contraceptive or sterilization methods." Id. at 57,593.

At Pennsylvania's request, the District Court lifted the stay, and Pennsylvania filed an amended complaint, joined New Jersey as a plaintiff,[8] added challenges to the Final Rules and moved to enjoin them.[9]

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[7] The Agencies assert that under ERISA, employees will at least receive notice that their plans no longer cover certain contraceptives because, "with respect to plans subject to ERISA, a plan document must include a comprehensive summary of the benefits covered by the plan," which will "serve to help provide notice to participants and beneficiaries" of what services are covered. 83 Fed. Reg. at 57,558. Even if this is true, this would apply only to certain employers.

[8] Pennsylvania and New Jersey are referred to herein collectively as the "the States."

[9] The States' amended complaint for declaratory and injunctive relief pleads five counts: (I) violation of Equal Protection of the laws under the Fifth Amendment; (II) violation of Title VII of the Civil Rights Act and the Pregnancy Discrimination Act; (III) violation of the procedural requirements of the APA; (IV) violation of the

The District Court held hearings and received evidence regarding the Rules. Specifically, the States submitted evidence from health care professionals and state insurance regulators about the Rules' impact. The evidence addressed the relationship between costs and contraceptive use and the impact the Rules would have on state-funded healthcare services.

Cost is a significant barrier to contraceptive use and access. The most effective forms of contraceptives are the most expensive. After the ACA removed cost barriers, women switched to the more effective and expensive methods of contraception.[10] Because the Rules allow employers to opt out of providing coverage for contraceptive services, some women may no longer have insurance to help offset the cost for these and other contraceptives.

Pennsylvania and New Jersey have state-funded programs that provide family planning and contraceptive services for eligible individuals. For example, Pennsylvania

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substantive requirements of the APA; and (V) violation of the Establishment Clause of the First Amendment.

[10] Before the ACA, women spent between 30 and 40% of their total out-of-pocket health costs on contraceptives, and 55% of women experienced a time where they could not afford contraceptives. Amicus Curiae Women's Law Ctr. Br. at 15-17; id. at 17 (describing that the ACA dropped out-of-pocket contraceptive expenditures by 70%).

Medicaid and New Jersey's FamilyCare[11] cover all health care for childless adults, pregnant women, and parents with incomes up to 138% and up to 215% of the federal poverty level, respectively. Pennsylvania's Family Planning Services Program also covers all family planning-related services, including contraceptives, for individuals with incomes up to 215% of the federal poverty level even if they have private insurance, and New Jersey's Plan First program offers the same for individuals with incomes up to 205% of the federal poverty level.

Women who lack contraceptive coverage and who meet certain income levels may also turn to Title X family planning clinics which "provide access to contraceptive services, supplies, and information to all who want and need them" with priority to low-income persons. Office of Population Affairs, Funding History, HHS, https://www.hhs.gov/opa/title-x-family-planning/about-title-x-grants/funding-history/index.html (last visited May 12, 2019). State and federal governments fund Title X clinics, but recently, federal funding has decreased.

The States expect that when women lose contraceptive insurance coverage from their employers, they will seek out these state-funded programs and services. The States further assert that women who do not seek or qualify for state-funded contraceptives may have unintended pregnancies. Public funds are used to cover the costs of many unintended

[11] NJ FamilyCare is New Jersey's state and federally-funded Medicaid.

pregnancies.[12] Accordingly, the States expect to spend more money due to the Rules.

In addition to this evidence, the Agencies presented spread sheets that listed the organizations and companies that were previously involved in ACA Contraceptive Mandate litigation. The Agencies offered this evidence to demonstrate the likely universe of employers whom they contend may seek to invoke the Rules and opt out of covering contraceptive care.

3

The day the Final Rules were set to go into effect, January 14, 2019, the District Court issued a nationwide injunction enjoining their enforcement. Pennsylvania v. Trump, 351 F. Supp. 3d 791 (E.D. Pa. 2019). The Court found that the States had standing to challenge the Final Rules and established a likelihood of success on the merits of their APA claims. First, the Court held that the States are likely to succeed on their procedural APA claims because the Agencies failed to comply with the notice-and-comment requirement and this defect tainted the Final Rules. Id. at 813. Second, the Court held that the States were likely to succeed on their substantive APA challenges because neither the ACA nor RFRA authorized the Agencies to create exemptions. Specifically, the unambiguous language of the ACA's Women's Health Amendment only authorized the Agencies to decide what services would be covered, not who provides

[12] Nationally, a publicly-funded birth in 2010 cost $12,770, and that year, New Jersey spent an estimated $186.1 million on unintended pregnancies and Pennsylvania an estimated $248.2 million.

them, id. at 821, and RFRA did not require or authorize such broad exemptions, particularly given RFRA's remedial function that places the responsibility for adjudicating religious burdens on the courts, not the Agencies, id. at 822-23. The Court concluded that the balance of equities and public interest favored an injunction, id. at 829-30, and that a nationwide injunction was appropriate to ensure complete relief for the States, id. at 834-35. The Government appeals.

II[13]

We first address whether the States have standing.[14] Article III limits the scope of federal judicial review to "cases" or "controversies." U.S. Const. art. III § 2. A fundamental safeguard of this limitation is the doctrine of standing. Spokeo, Inc. v. Robins, 136 S. Ct. 1540, 1547 (2016). Put simply, only parties with standing "can invoke the jurisdiction of the federal courts." Constitution Party of Pa. v. Aichele, 757 F.3d 347, 357 (3d Cir. 2014). To have standing to sue, "[t]he plaintiff must have (1) suffered an injury in fact, (2) that is fairly traceable to the challenged conduct of the defendant, and (3) that is likely to be redressed by a favorable judicial decision." Spokeo, 136 S. Ct. at 1547 (citing Lujan v. Defenders of Wildlife, 504 U.S. 555, 560-61 (1992)). We will examine each element in turn.

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[13] The District Court had jurisdiction under 28 U.S.C. § 1331. We have jurisdiction under 28 U.S.C. § 1292(a)(1).

[14] "We review the legal conclusions related to standing de novo, but review for clear error the factual elements underlying the District Court's determination of standing." Edmonson v. Lincoln Nat'l Life Ins. Co., 725 F.3d 406, 414 (3d Cir. 2013) (internal quotation marks and citation omitted).

A

To establish injury in fact, the alleged injury must be "concrete and particularized" and "actual or imminent, not conjectural or hypothetical." Id. at 1548 (quoting Lujan, 504 U.S. at 560). An injury is concrete if it "actually exist[s]" and is not abstract. Id. "For an injury to be particularized, it must affect the plaintiff in a personal and individualized way." Id. (internal quotation marks and citations omitted). Plaintiffs need not "demonstrate that it is literally certain that the harms they identify will come about." Clapper v. Amnesty Int'l USA, 568 U.S. 398, 414 n.5 (2013). Instead, "[a]n allegation of future injury may suffice if . . . there is a substantial risk that the harm will occur." Susan B. Anthony List v. Driehaus, 573 U.S. 149, 158 (2014) (internal quotation marks and citation omitted); see also Clapper, 568 U.S. at 410 (rejecting lower court's use of an "objectively reasonable likelihood" standard to assess injury).

1

The States have established that they will suffer a concrete and particularized injury. The States describe that (1) employers will take advantage of the exemptions and women covered by their plans will lose contraceptive coverage; and (2) financially- eligible women will turn to state-funded services for their contraceptive needs and for the unintended pregnancies that may result from the loss of coverage. As a result, the States will suffer a concrete financial injury from the increased use of state-funded services. See Cottrell v. Alcon Labs., 874 F.3d 154, 163 (3d Cir. 2017) ("Typically, a plaintiff's allegations of financial harm will easily satisfy each of these components, as financial harm is a

classic and paradigmatic form[ ] of injury in fact." (alteration in original) (internal quotation marks and citations omitted)). The States will suffer this injury in a particularized manner, as each State's coffers will be depleted by the expenditure of funds to meet the increased demand for state services. Having concluded that the States have identified a concrete and particular injury, we next examine whether the injury at issue is not conjectural and is actual or imminent.

The record shows that the injury the States expect to sustain is not conjectural. First, the Agencies' regulatory impact analysis acknowledges that between 70,500 and 126,400 women nationwide will lose contraceptive coverage as a result of their employers' invocation of the Religious Exemption, 83 Fed. Reg. at 57,578, 57,581, and fifteen women will lose coverage as a result of their employers' use of the Moral Exemption, 83 Fed. Reg. at 57,627. See California v. Azar ("California II"), 911 F.3d 558, 572 (9th Cir. 2018) (noting that the Agencies' own regulatory impact analysis estimates loss of coverage, and therefore "it is reasonably probable that women in the plaintiff states will lose some or all employer-sponsored contraceptive coverage due to the IFRs"), cert. denied Little Sisters of the Poor v. California, No. 18-1192, -- S. Ct. --, 2019 WL 1207008 (June 17, 2019) (Mem.). Second, based on the Agencies' list of entities who challenged the Contraceptive Mandate, eight employers, not including Little Sisters, between New Jersey and Pennsylvania would likely take advantage of the Exemptions. Massachusetts v. U.S. Dep't of Health & Human Servs., 923 F.3d 209, 224 (1st Cir. 2019) (relying on spreadsheet of litigating entities to find "it is highly likely that at least three employers in the Commonwealth with self-insured health plans . . . will use the expanded exemptions"). Accordingly, it is not conjecture to

conclude that employers in Pennsylvania and New Jersey will take advantage of the Exemptions and, as a result, women will lose coverage. Id. at 224 n.12 (stating that "it is improbable based on the evidence that no women in the [States] would lose contraceptive coverage" (emphasis omitted)).

2

The record also supports the District Court's conclusion that the injury is imminent. The States have provided evidence showing that the Exemption will result in the expenditure of state funds because some women who lose coverage will inevitably seek out state-sponsored programs providing contraceptive services; and some women will forego contraceptive use, causing the States to shoulder the costs of unintended pregnancies.

With the ACA, many patients "switch[ed] from a cheaper, less effective [contraceptive] method to a more effective, expensive method that was better for their medical health and personal needs." App. 272. Contraceptives are not only used for pregnancy prevention. They are the "standard first-line of care for a number of hormonal, and other, disorders, including poly-cystic ovarian syndrome, primary ovarian insufficiency/premature ovarian failure, amenorrhea, dysmenorrhea/chronic pelvic pain, and abnormal uterine bleeding." App. 292. A "vast majority" of women use inter-uterine devices ("IUDs")—a treatment religious objectors are particularly focused on, App. 350-83—"for purposes other than birth control." App. 293 (describing 90-95% of patients using IUDs for non-birth control purposes). Contraceptive use "carries long-term health benefits for women[,]" including reducing the risk of ovarian and uterine cancer. App. 294.

"Contraception also helps protect the health of those women for whom pregnancy can be hazardous, or even life-threatening." Amici Curiae Health Prof'l Orgs. Br. at 16. Thus, removing cost free contraceptive coverage can have ramifications on women's health beyond birth control and unplanned pregnancies.

Without insurance to defray or eliminate the cost for the more-effective contraceptive methods, women will use "less expensive and less effective methods," App. 245, and both Pennsylvania and New Jersey "anticipate[] that women who lose contraceptive coverage through employer plans—whether the plan of their own employer or that of another family member—may seek contraception from other sources, including state-funded programs."[15] App. 299; App. 317. Thus, the State-funded programs will be tapped to provide coverage for financially eligible women whose employers invoke the Exemptions.

Furthermore, some women who lose contraceptive coverage may either fail to qualify for state services or elect to forego the use of contraceptives altogether. "Women who stop using contraception are more likely to have unplanned pregnancies and to require additional medical attention." App. 312. The costs of such unintended pregnancies are often

[15] The Agencies "theorize" that some women may be able to pay out of pocket or obtain coverage through a spouse or family member's plan. Massachusetts, 923 F.3d at 227. While "[s]uch a hypothetical woman may exist, . . . the number of women with incomes that make them eligible for state-assisted contraceptive coverage but who still fit in that category would, logically, be very small." Id.

shouldered by states, costing hundreds of millions of dollars. Therefore, the evidence supports the conclusion that the loss of contraceptive coverage may also result in unintended pregnancies for which the States will bear associated health care costs.

For these reasons, "[t]he expanded exemptions are expected to result in greater financial expenditures" by the States on contraceptive services. App. 318. This anticipated substantial impact on state finances presents an imminent injury. Thus, the District Court properly found that the States showed an imminent injury in fact.

The Government faults the States for failing to identify a specific woman who will be affected by the Final Rules, but the States need not define injury with such a demanding level of particularity to establish standing. Massachusetts v. EPA, 549 U.S. 497, 523 n.21 (2007); see Massachusetts, 923 F.3d at 225; California II, 911 F.3d at 572. The likelihood that employers will invoke the Exemptions and leave women without contraceptive coverage, and that women will turn to the States for coverage, is sufficient to demonstrate imminent injury. This likelihood "has nothing to do with whether petitioners have determined [a] precise" woman who will seek such funding. Massachusetts, 549 U.S. at 523 n.21.[16]

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[16] In the context of an environmental case and a claim that the plaintiff-state Massachusetts lacked standing because it failed to identify land that would be impacted by federal regulators' inaction, the Supreme Court observed that

> the likelihood that Massachusetts' coastline will recede has nothing to do with whether petitioners

B

The States' imminent injury is causally connected and fairly traceable to the Exemptions. The States will suffer financial injury when employers in Pennsylvania and New Jersey take advantage of the Exemptions, leaving female employees without contraceptive coverage and prompting financially eligible women to turn to state-funded services. See Texas v. United States, 809 F.3d 134, 159 (5th Cir. 2015) ("For Texas to incur injury, DAPA beneficiaries would have to apply for driver's licenses as a consequence of DHS's action, and it is apparent that many would do so."), aff'd by an equally divided court, United States v. Texas, 136 S. Ct. 2271 (2016) (Mem.) (per curiam). In other words, the States will not experience an increased demand for services and the resulting financial burden unless the new Exemptions, which create a void in contraceptive coverage, go into effect. See id. at 160 ("Far from playing an insignificant role, DAPA would be the

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> have determined the precise metes and bounds of their soon-to-be-flooded land. Petitioners maintain that the seas are rising and will continue to rise, and have alleged that such a rise will lead to the loss of Massachusetts' sovereign territory. . . . Our cases require nothing more.

Massachusetts, 549 U.S. at 523 n.21. Just as it was unnecessary for Massachusetts to identify specific coastline that would be flooded by the agencies' inaction, it is unnecessary for the States to identify a specific woman who would be impacted by the Government's action where in both instances, the record provided a basis to infer specific imminent injury.

primary cause and likely the only one. Without the program, there would be little risk of a dramatic increase in the costs of the driver's-license program."). Thus, there is a link between the Exemptions and the impact on the States' fiscs.

C

The District Court also correctly concluded that an injunction would redress the financial injury the States face from the Rules. Enjoining the Final Rules until their legality is adjudicated on the merits will avoid the imminent financial burden the States face if they are not enjoined. Massachusetts, 923 F.3d at 228 ("[A]n injunction preventing the application of these exemptions would stop the alleged fiscal injury from occurring, making it not only 'likely,' Spokeo, 136 S. Ct. at 1547, but certain that this injury would not occur for as long as the exemptions are enjoined."); see Massachusetts, 549 U.S. at 526 ("The risk of catastrophic harm, though remote, is nevertheless real. That risk would be reduced to some extent if petitioners received the relief they seek.").

For these reasons, the States have standing to bring this suit.[17]

III

Having determined that the States have standing, we now address whether they are entitled to a preliminary injunction. The decision to grant or deny a preliminary

[17] Based upon of the foregoing discussion, we need not decide whether the States also have standing under the special solicitude or parens patriae doctrines.

injunction is within the sound discretion of the district court.[18] Winter v. Nat. Res. Def. Council, Inc., 555 U.S. 7, 24, 33 (2008). To obtain a preliminary injunction, the movants must:

> demonstrate (1) that they are reasonably likely to prevail eventually in the litigation and (2) that they are likely to suffer irreparable injury without relief. If these two threshold showings are made the District Court then considers, to the extent relevant, (3) whether an injunction would harm the [defendants] more than denying relief would harm the plaintiffs and (4) whether granting relief would serve the public interest.

K.A. ex rel. Ayers v. Pocono Mountain Sch. Dist., 710 F.3d 99, 105 (3d Cir. 2013) (alteration in original) (quoting Tenafly Eruv Ass'n v. Borough of Tenafly, 309 F.3d 144, 157 (3d Cir. 2002)); accord Fed. R. Civ. P. 65. To establish a likelihood of success, "a sufficient degree of success for a strong showing exists if there is 'a reasonable chance, or probability, of winning.'" In re Revel AC, Inc., 802 F.3d 558, 568 (3d Cir. 2015) (quoting Singer Mgmt. Consultants, Inc. v. Milgram, 650 F.3d 223, 229 (3d Cir. 2011) (en banc)).

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[18] "We employ a tripartite standard of review for . . . preliminary injunctions. We review the District Court's findings of fact for clear error. Legal conclusions are assessed de novo. The ultimate decision to grant or deny the injunction is reviewed for abuse of discretion." K.A. ex rel. Ayers v. Pocono Mountain Sch. Dist., 710 F.3d 99, 105 (3d Cir. 2013) (omission in original) (internal quotation marks and citations omitted).

Here, we must decide whether the District Court correctly concluded that the States have a reasonable probability of showing that the Final Rules violate the APA, and if so, whether the equitable factors warrant a nationwide injunction.

A[19]

To promulgate binding regulations, agencies engage in what is known as notice-and-comment rulemaking. 5 U.S.C. § 553. This requires an agency to publish notice of the proposed rule in the Federal Register, collect and consider public comments, and issue a concise statement of purpose upon finalizing the new rule. Id. § 553(b)-(c). Deviation from these procedures is only permitted where expressly authorized by statute, id. § 559, or when the agency has "good cause" to dispense with them, id. § 553(b)(3)(B). The Agencies assert that both grounds justify their decision to forego notice-and-comment procedures here. They are mistaken.

1

The Government first argues that provisions within the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") grant the Agencies discretion to proceed by IFR in lieu of notice-and-comment rulemaking. The provisions upon which the Government relies provide:

[19] Quite appropriately, the Agencies do not challenge the States' statutory standing to sue under the APA. 5 U.S.C. § 702; Massachusetts, 549 U.S. at 520 (recognizing states' "procedural right to challenge the rejection of its rulemaking petition as arbitrary and capricious" under the EPA).

> The Secretary, consistent with section 104 of [HIPAA], may promulgate such regulations as may be necessary or appropriate to carry out the provisions of this [subchapter]. The Secretary may promulgate any interim final rules as the Secretary determines are appropriate to carry out this [subchapter].

26 U.S.C. § 9833; 29 U.S.C. § 1191c; 42 U.S.C. § 300gg-92 [hereinafter "Regulation Provision"]. This language does not eliminate the need for notice and comment.

First, the APA only allows a subsequent statute to modify or supersede its procedural requirements "to the extent [the statute] does so expressly." 5 U.S.C. § 559. The Regulation Provision contains no express language supplanting APA procedures, and the sole reference to "interim final rules" does not confer a license to ignore APA requirements. Indeed, in contrast to statutory authorizations to forego APA procedures, the Regulation Provision is "permissive ('The Secretary may promulgate any interim final rules as the Secretary determines are appropriate . . .'), wide-ranging (applying to any regulatory proceeding relating to group health insurance plans), and do[es] not contain any specific deadlines for agency action." Coal. for Parity, Inc. v. Sebelius, 709 F. Supp. 2d 10, 18-19 (D.D.C. 2010) (omissions in original and emphasis omitted); see also California II, 911 F.3d at 578-80. In short, because the Regulation Provision "neither contain[s] express language exempting agencies from the APA nor provide[s] alternative procedures that could reasonably be understood as departing from the APA," it does

not authorize the Agencies to disregard the notice-and-comment requirements. California II, 911 F.3d at 579.

Second, the statutory reference within the Regulation Provision sheds light on the scope and purpose of its IFR sentence. As the Court of Appeals for the Ninth Circuit points out, § 104 of HIPAA aims to assure regulatory coordination between the Agencies' Secretaries for matters over which they share responsibility. See California II, 911 F.3d at 579-80 (citing Pub. L. No. 104-191, 110 Stat. 1936 (1996) (codified at 42 U.S.C. § 300gg-92)). The first sentence of the Regulation Provision authorizes each Secretary to promulgate regulations "consistent with" the HIPAA section on coordination. The second sentence is identical but for two differences: it discusses IFRs instead of final regulations, and it omits any mention of HIPAA's coordination section. Read in light of the first sentence, the second ensures that each Agency can proceed by IFR where a Secretary "need[s] to regulate within his or her own domain temporarily while sorting out . . . inter-agency conflict." Id. at 579. Thus, "we need not give the second sentence the [A]gencies' expansive interpretation in order for the second sentence to retain independent effect." Id. at 579-80. In sum, the Regulation Provision does not expressly excuse the Agencies from complying with APA procedures and therefore does not provide a basis for issuing the IFRs without notice and comment.[20]

[20] Congress knows how to excuse an agency from complying with the APA. For example, one HIPAA provision expressly permits the Agencies to promulgate a rule prior to notice and comment. 42 U.S.C. § 1320a-7b note. That provision requires the Secretary of Health and Human Services to publish a rule prescribing penalties for

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The Agencies also lacked good cause for dispensing with notice of and comment to the IFRs. An agency has "good cause" to forego APA procedures where following them would be "impracticable, unnecessary, or contrary to the public interest."[21] 5 U.S.C. § 553(b)(3)(B). "[C]ircumstances justifying reliance on [the good cause] exception are indeed rare and will be accepted only after the court has examine[d] closely proffered rationales justifying the elimination of public procedures." Nat. Res. Def. Council, Inc. v. EPA ("NRDC"),

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kickbacks by January 1, 1997, then less than four months away. It provides that "[s]uch rule shall be effective and final immediately on an interim basis, but is subject to change and revision after public notice and opportunity for . . . public comment." Unlike the Regulation Provision, § 1320a-7b expressly provides for notice and comment after the promulgation of an IFR. Congress's omission of that procedure from the Regulation Provision demonstrates that it did not provide the Agencies authority to promulgate IFRs without notice and comment.

[21] 5 U.S.C. § 553(b)(3) provides

> [e]xcept when notice or hearing is required by statute, this subsection does not apply—
> . . .
> (B) when the agency for good cause finds (and incorporates the finding and a brief statement of reasons therefor in the rules issued) that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest.

683 F.2d 752, 764 (3d Cir. 1982) (alterations in original) (internal quotation marks and citation omitted). Thus, we construe the "good cause" exception to the notice-and-comment requirement narrowly.[22] Id.

When they issued the IFRs, the Agencies claimed good cause to waive notice and comment based on (1) the urgent need to alleviate harm to those with religious objections to the current regulations; (2) the need to address "continued uncertainty, inconsistency, and cost" arising from "litigation challenging the previous rules"; and (3) the fact that the Agencies had already collected comments on prior Mandate-related regulations. 82 Fed. Reg. at 47,813-15; see also 82 Fed. Reg. at 47,855-59. None of these assertions meet the standard for good cause.

First, the Agencies' desire to address the purported harm to religious objections does not ameliorate the need to follow appropriate procedures. All regulations are directed toward reducing harm in some manner.[23] See United States v.

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[22] Though the review standard for agency assertions of good cause remains an open question in our circuit, see United States v. Reynolds, 710 F.3d 498, 509 (3d Cir. 2013), we need not answer that question here. Even applying the most deferential of the potential standards—reviewing the agency's good cause determination to see if it is arbitrary and capricious—the IFRs cannot stand.

[23] As we observed in Reynolds,

> [m]ost, if not all, laws passed by Congress requiring agencies to promulgate new rules are designed to eliminate some real or perceived

Reynolds, 710 F.3d 498, 512-13 (3d Cir. 2013). Thus, "[a] need to regulate affected parties does not create the urgency necessary to establish good cause." Id. at 511. "As with any other administrative agency conclusion, we require some statement of facts or circumstances that justifies the existence of good cause (e.g., an imminent, externally imposed deadline or the existence of an emergency)." Id. at 512. The Agencies fail to cite any facts or impending deadlines sufficient to raise "good cause" here.

Second, the need to address uncertainty is likewise insufficient to establish good cause. Uncertainty precedes every regulation, and to allow uncertainty to excuse compliance with notice-and-comment procedures "would have the effect of writing [those] requirements out of the statute." Id. at 510. Furthermore, our precedent forecloses the acceptance of uncertainty as a basis for good cause. Id. ("An agency's intention to provide clarity, without more, cannot amount to good cause.").

Third, the Agencies' previous solicitation and collection of comments regarding other rules concerning the

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> harm. If the mere assertion that such harm will continue while an agency gives notice and receives comments were enough to establish good cause, then notice and comment would always have to give way. An agency will invariably be able to point to some continuing harm during the notice and comment period antecedent to the promulgation of a rule.

710 F.3d at 512-13.

Contraceptive Mandate cannot substitute for notice and comment here. If the APA permitted agencies to forego notice-and-comment concerning a proposed regulation simply because they already regulated similar matters, then the good cause exception could largely obviate the notice-and-comment requirement. Furthermore, the IFRs did not make a minor change. The IFRs create exemptions from the Contraceptive Mandate with unprecedented scope and make the Accommodation wholly voluntary. Such a dramatic overhaul of the Contraceptive Mandate regulations required notice-and-comment under the APA.

For these reasons, the Agencies did not have good cause to ignore the APA's notice and comment requirement.

B

The Government also contends that, even if the IFRs were procedurally deficient, the Agencies' subsequent use of notice-and-comment rulemaking to finalize the Rules cured any procedural defects. Under our precedent, however, "post-promulgation notice and comment procedures cannot cure the failure to provide such procedures prior to the promulgation of the rule at issue." NRDC, 683 F.2d at 768; see Reynolds, 710 F.3d at 519 ("Any suggestion that the postpromulgation comments to the Interim Rule can satisfy [the purposes of notice-and-comment rulemaking] misses the point." (internal citation omitted)); Sharon Steel Corp. v. EPA, 597 F.2d 377, 381 (3d Cir. 1979) ("We hold that the period for comments after promulgation cannot substitute for the prior notice and comment required by the APA.").

APA notice-and-comment procedures serve several goals, including "(1) to ensure that agency regulations are tested via exposure to diverse public comment, (2) to ensure fairness to affected parties, and (3) to give affected parties an opportunity to develop evidence in the record to support their objections to the rule and thereby enhance the quality of judicial review." Prometheus Radio Project v. FCC, 652 F.3d 431, 449 (3d Cir. 2011) (quoting Int'l Union, United Mine Workers of Am. v. Mine Safety & Health Admin., 407 F.3d 1250, 1259 (D.C. Cir. 2005)). The comment process also allows each agency to "maintain[] a flexible and open-minded attitude towards its own rules," Reynolds, 710 F.3d at 511 (alteration in original and citation omitted) (quoting Prometheus Radio, 652 F.3d at 449); see also Azar v. Allina Health Servs., 139 S. Ct. 1804, 1816 (2019) ("Notice and comment . . .affords the agency a chance to avoid errors and make a more informed decision." (internal citation omitted)). To preserve the integrity of this process, "[t]he opportunity for comment must be a meaningful opportunity," Prometheus Radio, 652 F.3d at 450 (alteration in original), to have interested parties share their views, and to have the agency consider them with an "open mind," Reynolds, 710 F.3d at 517-19.

The notice and comment exercise surrounding the Final Rules does not reflect any real open-mindedness toward the position set forth in the IFRs.[24] First, as the Government admits, the minor changes to the Final Rules do not "alter the

[24] We express no opinion on whether the Agencies appropriately responded to comments collected during this process, see Trump, 351 F. Supp. 3d at 811-12, as this issue is not before us.

fundamental substance of the exemptions set forth in the IFRs." Dkt. 107-1 at 8. Second, the reasons the Agencies supplied for promulgating the Final Rules simply echoed those provided for issuing the IFRs. See 83 Fed. Reg. at 57,552, 57,609. These rationales do not show the "flexible and open-minded attitude" the notice-and-comment process requires. Reynolds, 710 F.3d at 511. Together, the Agencies' justifications for avoiding notice and comment to the IFRs, and the fact that the IFRs and the Final Rules are virtually identical, suggest that the opportunity for comment was not a "meaningful" one in the way the APA requires. Prometheus Radio, 652 F.3d at 450.

Lastly, even setting aside the Agencies' lack of open-mindedness, the IFRs also impaired the rulemaking process by altering the Agencies' starting point in considering the Final Rules. In NRDC, our Court rejected the EPA's argument that the opportunity for post-promulgation comment remedied the EPA's initial failure to promulgate a rule through notice-and-comment rulemaking:

> [t]o allow the APA procedures in connection with the [new rule] to substitute for APA procedures in connection with [the initial, procedurally defective rule] would allow [the] EPA to substitute post-promulgation notice and comment procedures for pre-promulgation notice and comment procedures at any time by taking an action without complying with the APA, and then establishing a notice and comment procedure on the question of whether that action should be continued. This would

> allow agencies to circumvent [our case law] and the APA. We cannot countenance such a result.

683 F.2d at 768 (citation omitted). This reasoning applies with equal force here. By first promulgating the IFRs that granted the expanded exemptions without notice and comment, the Agencies changed the question presented concerning the Final Rules from whether they should create the exemptions to whether they should depart from them. This starting position is impermissible under the APA. Id.; see also Sharon Steel, 597 F.2d at 381 ("Provision of prior notice and comment allows effective participation in the rulemaking process while the decisionmaker is still receptive to information and argument. After the final rule is issued, the petitioner must come hat-in-hand and run the risk that the decisionmaker is likely to resist change." (citation omitted)).

In sum, because deficits in the promulgation of the IFRs compromised the procedural integrity of the Final Rules, the States have demonstrated a likelihood of success in showing that the Final Rules are procedurally defective, and in turn, violate the APA.

C

There are also serious substantive problems with the Final Rules. More specifically, neither of the statutes upon which the Agencies rely, the ACA and RFRA, authorize or require the Final Rules. Thus, they were enacted "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right," making them "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A), (C).

1

The Agencies argue that their authority under the ACA to issue preventive care guidelines includes the power to promulgate the Exemptions. This assertion is without textual support. The Women's Health Amendment to the ACA, 42 U.S.C. § 300gg-13(a)(4), provides:

> A group health plan and a health insurance issuer offering group or individual health insurance coverage shall, at a minimum provide coverage for and shall not impose any cost sharing requirements for— . . .
>
> (3) with respect to infants, children, and adolescents, evidence-informed preventive care and screenings provided for in the comprehensive guidelines supported by the [HRSA].
>
> (4) with respect to women, such additional preventive care and screenings not described in paragraph (1)[25] as provided for in comprehensive guidelines supported by the [HRSA] for purposes of this paragraph.

42 U.S.C. § 300gg-13(a). The authority to issue "comprehensive guidelines" concerns the type of services that are to be provided and does not provide authority to undermine

[25] Paragraph (1) refers to "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." 42 U.S.C. § 300gg-13(a)(1).

Congress's directive concerning who must provide coverage for these services. Section 300gg-13(a) unambiguously dictates that group health plans and health insurance issuers "shall provide" the preventive care services set forth in the HRSA-supported comprehensive guidelines, and "shall" not impose cost sharing. The term "shall" denotes a requirement, Prometheus Radio Proj. v. FCC, 824 F.3d 33, 50 (3d Cir. 2016) ("Th[e] repeated use of 'shall' creates 'an obligation impervious to . . . discretion.'" (omission in original) (quoting Lexecon Inc. v. Milberg Weiss Bershad Hynes & Lerach, 523 U.S. 26, 35 (1998)), and HRSA's authority to issue the guidelines does not empower it to ignore that requirement. Nothing from § 300gg-13(a) gives HRSA the discretion to wholly exempt actors of its choosing from providing the guidelines services. On the contrary, the mandate articulated in § 300gg-13(a) forecloses such exemptions.[26]

[26] The Government argues that if the ACA does not grant the authority to issue the Exemptions, then HRSA was equally without authority to issue the Church Exemption and the Accommodation. This argument fails. Though the Church Exemption may seem facially at odds with § 300gg-13(a), Supreme Court precedent dictates a narrow form of exemption for houses of worship. See 80 Fed. Reg. at 41,325 (describing the exemption for churches and houses of worship as "consistent with their special status under longstanding tradition in our society and under federal law"); see, e.g., Hosanna-Tabor Evangelical Lutheran Church & Sch. v. EEOC, 565 U.S. 171 (2012) (discussing the existence of a ministerial exception precluding application of employment legislation to a religious institution to respect churches' internal autonomy). The Accommodation likewise does not plainly run afoul of the ACA. Instead, it provides a process

The Agencies' reliance on the language that directed HRSA to create the guidelines concerning women's preventive health care and the use of the phrase "as provided for in" such guidelines does not advance their position. The Agencies contrast § 300gg-13(a)(4)'s use of the phrase "as provided for in" comprehensive guidelines with a neighboring sub-section's provision addressing preventive care for infants, children, and adolescents, which is "provided for in the" comprehensive guidelines for those services. Compare 42 U.S.C. § 300gg-13(a)(3) (describing "preventive care and screenings provided for in the comprehensive guidelines"), with id. § 300gg-13(a)(4) (describing "preventive care and screenings as provided for in comprehensive guidelines"). They assert that the use of the word "as" in § 300gg-13(a)(4) gives HRSA authority to dictate the preventive services to be provided and who must provide them. This argument overlooks the clear explanation for the different language. When the ACA was passed, the comprehensive guidelines for children's preventive care already existed, but guidelines for women's preventive care were not yet written. Congress used the definite article "the" in § 300gg-13(a)(3) to refer to those existing children's preventive care guidelines. In § 300gg-13(a)(4), Congress addressed the women's preventive care guidelines that were yet to be promulgated by stating "as provided for in the comprehensive guidelines."

The Agencies' interpretation of "comprehensive" as authorizing them to issue guidelines that exempt entities from

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through which a statutorily identified actor "shall provide" the mandated coverage. In any event, the Agencies' authority to issue the Church Exemption and Accommodation is not before us.

complying with the Mandate likewise fails. Put simply, the discretion the statute grants HRSA to issue comprehensive guidelines concerning services to be provided does not include the power to exempt actors from the statute itself. This is borne out by the fact that the word "comprehensive" is also used to describe the children's preventive care guidelines, and those guidelines do not exempt any statutorily required party from providing services. See HHS, Preventive Care Benefits for Children, https://www.healthcare.gov/preventive-care-children (last visited May 8, 2019). Congress was obviously aware of the existing children's guidelines when it drafted the Women's Health Amendment, and Congress's use of "comprehensive" to describe both sets of guidelines conveys that it intended them to cover the same type of subject matter, namely health care services for the identified groups. See F.A.A. v. Cooper, 566 U.S. 284, 292 (2012) ("[W]hen Congress employs a term of art, it presumably knows and adopts the cluster of ideas that were attached to each borrowed word in the body of learning from which it was taken." (internal quotation marks and citation omitted)).

Other portions of the ACA also show that Congress retained the authority to exempt certain employers from providing contraceptive coverage. In passing the ACA, Congress explicitly exempted grandfathered plans from the Contraceptive Mandate and other ACA requirements. 42 U.S.C. § 18011(a), (e). Congress also considered and rejected a statutory conscience amendment that would have operated similarly to the challenged Exemptions. 158 Cong. Rec. S1162, 1173-74 (2012). Between the substantially analogous exemption Congress rejected, and the one it decided to keep, Congress demonstrated that exempting specific actors from the ACA's mandatory requirements is its job, not the Agencies.

See United States v. Johnson, 529 U.S. 53, 58 (2000) ("When Congress provides exceptions in a statute," we may infer "that Congress considered the issue of exceptions and, in the end, limited the statute to the ones set forth."). Relatedly, by promulgating the Moral Exemption, which sought to do what Congress refused to do with the conscience amendment, the Agencies contravened Congress's intent. See Food & Drug Admin. v. Brown & Williamson Tobacco Corp., 529 U.S. 120, 147 (2000) (considering Congress's prior refusal to pass laws as material to whether an agency's interpretation of its statute is entitled to deference).

Because § 300gg-13(a) does not authorize the Agencies to exempt plans from providing the required coverage, the Agencies' authority under the ACA to enact the Final Rules is without merit.

2[27]

The Agencies' effort to cast RFRA as requiring the Religious Exemption is also incorrect. Even assuming that RFRA provides statutory authority for the Agencies to issue regulations to address religious burdens the Contraceptive Mandate may impose on certain individuals, RFRA does not require the enactment of the Religious Exemption to address this burden.

RFRA provides that the federal government "[s]hall not substantially burden a person's exercise of religion even if the burden results from a rule of general applicability," 42 U.S.C.

[27] No party argues that RFRA authorizes or requires the Moral Exemption.

§ 2000bb-1(a), unless "that application of the burden to the person—(1) is in furtherance of a compelling governmental interest; and (2) is the least restrictive means of furthering that compelling governmental interest," id. § 2000bb-1(b). "[A] person whose religious exercise has been burdened in violation of this section" may seek relief in a judicial proceeding. Id. § 2000bb-1(c). Thus, RFRA authorizes a cause of action for government actions that impose a substantial burden on a person's sincerely-held religious beliefs, and provides a judicial remedy via individualized adjudication. See 42 U.S.C. § 2000bb-3(a); City of Boerne v. Flores, 521 U.S. 507, 529 (1997) ("[RFRA] prevents and remedies laws which are enacted with the unconstitutional object of targeting religious beliefs and practices."). Because Congress has deemed the courts the adjudicator of private rights of actions under RFRA, Gonzales v. O Centro Espirita Beneficente Uniao do Vegetal, 546 U.S. 418, 434 (2006) (holding RFRA "plainly contemplates that courts would . . . consider whether exceptions are required under the test set forth by Congress" (emphasis omitted)), we owe the Agencies no deference when reviewing determinations based upon RFRA, see Adams Fruit Co., Inc. v. Barrett, 494 U.S. 638, 649 (1990) (declining to defer to an agency's statutory interpretation where Congress "expressly established the Judiciary and not the [agency] as the adjudicator of private rights of action arising under the statute").

A prima facie RFRA case requires a plaintiff to prove that the government imposed a substantial burden on religious exercise. Mack v. Warden Loretto FCI, 839 F.3d 286, 304 (3d Cir. 2016). A substantial burden exists if

> (1) a follower is forced to choose between following the precepts of his religion and forfeiting benefits otherwise generally available to other [persons] versus abandoning one of the precepts of his religion in order to receive a benefit; or (2) the government puts substantial pressure on an adherent to substantially modify his behavior and to violate his beliefs.[28]

Real Alternatives, Inc. v. Sec'y Dep't of Health & Human Servs., 867 F.3d 338, 371 (3d Cir. 2017) (alteration in original) (internal quotation marks and citation omitted). The Supreme Court has directed that, when considering a requested accommodation to address the burden, "courts must take adequate account of the burdens a requested accommodation may impose on nonbeneficiaries." Cutter v. Wilkinson, 544 U.S. 709, 720 (2005) (referring to third parties who may face collateral consequences from accommodating an observer's burden).[29] The Accommodation fulfills this directive as it

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[28] Although we "defer to the reasonableness" of an objector's religious beliefs, "this does not bar our objective evaluation of the nature of the claimed burden and the substantiality of that burden on [the objector's] religious exercise." Real Alternatives, Inc. v. Sec'y Dep't of Health & Human Servs., 867 F.3d 338, 356 (3d Cir. 2017) (emphasis omitted) (citation omitted).

[29] Although Cutter v. Wilkinson, 544 U.S. 709 (2005), dealt with an application of the Religious Land Use and Institutionalized Persons Act ("RLUIPA"), we have said that RLUIPA and RFRA "are analogous for the purpose of the substantial burden test," and we may therefore may apply

provides a means for an observer to adhere to religious precepts and simultaneously allows women to receive statutorily-mandated health care coverage.

RFRA does not require the broad exemption embodied in the Final Rule nor to make voluntary a notice of the employer's decision not to provide such coverage to avoid burdening those beliefs. As our Court has explained,

> the self-certification form does not trigger or facilitate the provision of contraceptive coverage because coverage is mandated to be otherwise provided by federal law. Federal law, rather than any involvement by the [employers] in filling out or submitting the self-certification form, creates the obligation of the insurance issuers and third-party administrators to provide coverage for contraceptive services. . . .
>
> [And] the submission of the self-certification form does not make the [employers] "complicit" in the provision of contraceptive coverage.

Geneva Coll. v. Sec'y of U.S. Dep't of Health & Human Servs., 778 F.3d 422, 437-38 (3d Cir. 2015) (emphasis omitted), vacated and remanded sub nom. Zubik, 136 S. Ct. 1557.[30]

RLUIPA law. Mack, 839 F.3d at 304 n.103; see Holt v. Hobbs, 135 S. Ct. 853, 860 (2015).

[30] While Zubik vacated our opinion in Geneva College, it did not reach the merits of the Accommodation nor did it "attack our reasoning." Real Alternatives, 867 F.3d at 356

The religious objectors who oppose the Accommodation mechanism disapprove of "what follows from" filing the self-certification form, but under Free Exercise jurisprudence, we examine the conduct of the objector, not third parties. Id. at 439-40. Here, through the Accommodation process, "the actual provision of contraceptive coverage is by a third party," so any possible burden from the notification procedure is not substantial. Id. at 442. For these reasons, RFRA does not require that the Agencies permit religious objectors to decline to provide contraceptive coverage without notifying their insurance issuer, TPA, HHS, or the employees.

Contrary to the Agencies' assertions in the Rule, the Supreme Court has not held that the Accommodation imposes substantial burdens on religious rights. Hobby Lobby ruled that closely-held corporations are entitled to take advantage of the Accommodation process rather than facing fines for non-compliance with the contraceptive mandate, observing that the Accommodation was a less restrictive alternative to forcing objectors to choose between adhering to the mandate or violating their sincerely-held beliefs. 573 U.S. at 730-31. While the Court "did not decide" whether the Accommodation "complies with RFRA," it found that "[a]t a minimum . . . it does not impinge on that plaintiffs' religious belief that providing insurance coverage for [certain contraceptives] violates their religion, and it serves HHS's stated interests equally well." Id. at 731; see also Zubik, 136 S. Ct. at 1561 (Sotomayor, J., concurring) ("The opinion does

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n.18. After Zubik, we repeated that the Accommodation does "not impose a substantial burden." Id.

not . . . endorse the petitioners' position that the existing regulations substantially burden their religious exercise or that contraceptive coverage must be provided through a separate policy, with a separate enrollment process." (internal quotation marks and citations omitted)); Wheaton, 573 U.S. at 960 (noting that Hobby Lobby "expressly rel[ied] on the availability of the religious-nonprofit accommodation" to reach its holding).

Furthermore, the Religious Exemption and the new optional Accommodation would impose an undue burden on nonbeneficiaries—the female employees who will lose coverage for contraceptive care. The Agencies downplayed this burden on women, contradicting Congress's mandate that women be provided contraceptive coverage. "No tradition, and no prior decision under RFRA, allows a religion-based exemption when the [A]ccommodation would be harmful to others—here, the very persons the contraceptive coverage requirement was designed to protect." Hobby Lobby, 573 U.S. at 764 (Ginsburg, J., concurring). As the Agencies recognize, the record shows that thousands of women may lose contraceptive coverage if the Rule is enforced and frustrate their right to obtain contraceptives. Id. at 727 (citation omitted); 42 U.S.C. § 300gg-13(a)(4) (directing the enactment of the Women's Preventive Services Guidelines, which include contraceptives).

In short, the status quo prior to the new Rule, with the Accommodation, did not infringe on the religious exercise of covered employers, nor is there a basis to conclude the Accommodation process infringes on the religious exercise of any employer. For these reasons, RFRA does not demand the Religious Exemption.

D

Because the States demonstrated a likelihood of success on the merits as to their APA claim, we next turn to the remaining equitable factors. To obtain a preliminary injunction, a plaintiff must "demonstrate that irreparable injury is likely in the absence of an injunction." Winter, 555 U.S. at 22 (emphasis omitted). Because the States cannot collect money damages under the APA,[31] 5 U.S.C. § 702 (enabling claimants to obtain "relief other than money damages"); see also California II, 911 F.3d at 581, the States will suffer irreparable harm if the Rules are enforced. The States will face unredressable financial consequences from subsidizing contraceptive services, providing funds for medical care associated with unintended pregnancies, and absorbing medical expenses that arise from decreased use of contraceptive medications for other health conditions. Therefore, the District Court did not abuse its discretion in holding that the States demonstrated a likelihood of irreparable harm.

Furthermore, because the current Accommodation does not substantially burden employers' religious exercise and the Exemption is not necessary to protect a legally-cognizable interest, the States' financial injury outweighs any purported injury to religious exercise. Moreover, the public interest favors minimizing harm to third-parties by ensuring that women who may lose ACA guaranteed contraceptive coverage

[31] Monetary injuries ordinarily do not constitute irreparable harm because they are compensable. See Instant Air Freight Co. v. C.F. Air Freight, Inc., 882 F.2d 797, 801 (3d Cir. 1989).

are able to maintain access to the preventive care to which they are entitled under the ACA and HRSA's comprehensive guidelines while final adjudication of the Rules is pending. Therefore, the District Court did not abuse its discretion in concluding that the balance of the equities and the public interest both favor issuing an injunction.

E

Having determined that a preliminary injunction is warranted, the final question we address is whether the District Court abused its discretion by enjoining the Final Rules nationwide. "Crafting a preliminary injunction is an exercise of discretion and judgment, often dependent as much on the equities of a given case as the substance of the legal issues it presents." Trump v. Int'l Refugee Assistance Project, 137 S. Ct. 2080, 2087 (2017) (per curiam). While courts are vested with the power to issue equitable relief with a nationwide reach, see Texas, 809 F.3d at 188 (quoting U.S. Const. art. III, § 1), they must ensure that "injunctive relief [is] no more burdensome to the defendant than necessary to provide complete relief to plaintiffs," Novartis Consumer Health, Inc. v. Johnson & Johnson-Merck Consumer Pharm. Co., 290 F.3d 578, 598 (3d Cir. 2002) (internal quotation marks and citation omitted). We must also bear in mind that the purpose of injunctions is "not to conclusively determine the rights of the parties, but to balance the equities as the litigation moves forward." Trump, 137 S. Ct. at 2087 (internal citation omitted).

Mindful of these considerations, the District Court did not abuse its discretion in concluding that a nationwide injunction is necessary to afford complete relief to the States

and that it is not "more burdensome to the defendant than necessary" to provide such relief.[32] Groupe SEB USA, Inc. v. Euro-Pro Operating LLC, 774 F.3d 192, 206 (3d Cir. 2014) (internal quotation marks and citations omitted). First, our APA case law suggests that, at the merits stage, courts invalidate—without qualification—unlawful administrative rules as a matter of course, leaving their predecessors in place until the agencies can take further action. See, e.g., Prometheus Radio, 652 F.3d at 453-54 & n.25 (vacating procedurally defective rule and leaving the prior rule in effect); Council Tree Commc'ns, Inc. v. FCC, 619 F.3d 235, 258 (3d Cir. 2010) (same). Congress determined that rule-vacatur was not unnecessarily burdensome on agencies when it provided vacatur as a standard remedy for APA violations. See 5 U.S.C. § 706(2) ("The reviewing court shall . . . hold unlawful and set aside agency action" that is outside an agency's authority, or "without observance of procedure required by law," among other things). While vacatur is the ultimate remedy the States seek, and that is not the relief being granted here, by enjoining enforcement of the Rules we provide a basis to ensure that a regulation that the States have shown likely to be proven to be unlawful is not effective until its validity is finally adjudicated.

Second, a nationwide injunction is necessary to provide the States complete relief. Many individuals work in a state that is different from the one in which they reside. See Amici

[32] Our sister circuit declined to uphold a nationwide injunction concerning the IFRs, but the record before us is substantially more developed than the record before that court. California II, 911 F.3d at 584 ("On the present record, an injunction that applies only to the plaintiff states would provide complete relief to them.").

Curiae Massachusetts, et al., Br. at 24 ("Mass. Amici Br.") (stating that 14% of the workforce in New Jersey and 5.4% in Pennsylvania work out of state, comprising more than 800,000 workers in total). An injunction geographically limited to the States alone will not protect them from financial harm, as some share of their residents who work out-of-state will lose contraceptive coverage originally provided through employers in non-enjoined states who will exempt themselves. Women covered by these plans who live in the States will seek state-funded services, and a state specific injunction will not be sufficient to prevent the resulting financial harm.

Out-of-state college attendance further exacerbates the States' injury. As the Moral Exemption points out, "[o]nly a minority of students in higher education receive health insurance coverage from plans arranged by their colleges or universities." 83 Fed. Reg. at 57,564; 83 Fed. Reg. at 57,619. Instead, most of these students remain on their parents' employer-based plans. Mass. Amici Br. at 26. The States host many such students at their colleges. "Each year, for example, Pennsylvania takes in more than 32,000 first-time out-of-state students alone—the second most of any state in the country." Mass. Amici Br. at 25 (citing Nat'l Ctr. For Educ. Statistics, Residence and Migration of All First-Time Degree/Certificate-Seeking Undergraduates, Digest of Education Statistics (2017)). In the absence of a nationwide injunction, students attending school in the States may lose contraceptive coverage from their parents' out-of-state plans, again leaving programs within the States to pick up the bill.[33] In light of the impact of

[33] It is also likely that residents of the States will attend out-of-state schools that invoke the Exemptions, and that such students will seek contraceptive services through programs in

these interstate activities, the District Court did not abuse its discretion in concluding that a nationwide injunction was necessary to afford the States complete relief.[34]

V

For the foregoing reasons, we will affirm the District Court's order granting the nationwide preliminary injunction.

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their home states, also giving rise to fiscal injuries to the States that only a nationwide injunction can remedy.

[34] The Government also argues that a nationwide injunction takes a toll on the court system, foreclosing "adjudication by a number of different courts and judges," Califano v. Yamasaki, 442 U.S. 682, 702 (1979), thereby preventing legal questions from "percolating" throughout the court system, Gov't Br. at 79-80. The argument has little force in this case. First, other federal courts have examined substantially the same legal issues as we confront here. See generally Massachusetts, 923 F.3d 209; California II, 911 F.3d 558. Second, the extensive litigation surrounding the Exemption and Accommodation have allowed for an airing of the legal issues. See Petition for Writ of Certiorari at 27, The Little Sisters of the Poor Jeanne Jugan Residence v. California (No. 18-1192) ("Further percolation is unnecessary. . . . [T]his issue was adjudicated by ten courts of appeals and dozens of district courts. . . . The arguments have all been aired."). Thus, there is no "percolation" problem here.