

1 XAVIER BECERRA, State Bar No. 118517
 Attorney General of California
 2 KATHLEEN BOERGERS, State Bar No. 213530
 Supervising Deputy Attorney General
 3 NELI PALMA, State Bar No. 203374
 NIMROD PITSKER ELIAS, State Bar No. 251634
 4 LISA CISNEROS, State Bar No. 251473
 KETAKEE R. KANE, State Bar No. 291828
 5 KARLI EISENBERG, State Bar No. 281923
 Deputy Attorneys General
 6 1300 I Street, Suite 125
 Sacramento, CA 94244-2550
 7 Telephone: (916) 210-7913
 Fax: (916) 324-5567
 8 E-mail: Karli.Eisenberg@doj.ca.gov
 Attorneys for Plaintiff State of California
 9 [Additional counsel listed on signature page]

10 IN THE UNITED STATES DISTRICT COURT
 11 FOR THE NORTHERN DISTRICT OF CALIFORNIA

12 **THE STATE OF CALIFORNIA; THE**
STATE OF CONNECTICUT; THE STATE
OF DELAWARE; THE DISTRICT OF
 13 **COLUMBIA; THE STATE OF HAWAII;**
THE STATE OF ILLINOIS; THE STATE
 14 **OF MARYLAND; THE STATE OF**
MINNESOTA, BY AND THROUGH ITS
 15 **DEPARTMENT OF HUMAN SERVICES; THE**
STATE OF NEW YORK; THE STATE OF
 16 **NORTH CAROLINA; THE STATE OF**
RHODE ISLAND; THE STATE OF
 17 **VERMONT; THE COMMONWEALTH OF**
VIRGINIA; THE STATE OF
 18 **WASHINGTON,**
 Plaintiffs,
 19
 20 **THE STATE OF OREGON,**
 Plaintiff-Intervenor,
 21
 22 **THE STATE OF COLORADO; THE STATE**
OF MICHIGAN; THE STATE OF NEVADA,
 23 Proposed-Plaintiffs-Intervenors,
 24
 25 **v.**
ALEX M. AZAR, II, IN HIS OFFICIAL
CAPACITY AS SECRETARY OF THE U.S.
DEPARTMENT OF HEALTH & HUMAN
 26 **SERVICES; U.S. DEPARTMENT OF**
HEALTH AND HUMAN SERVICES; R.
 27 **ALEXANDER ACOSTA, IN HIS OFFICIAL**
CAPACITY AS SECRETARY OF THE U.S.
 28 **DEPARTMENT OF LABOR; U.S.**

4:17-cv-05783-HSG

**STATES' NOTICE OF MOTION AND
 MOTION FOR SUMMARY JUDGMENT,
 WITH MEMORANDUM OF POINTS
 AND AUTHORITIES**

Date: September 5, 2019
 Time: 2:00 p.m.
 Dept: 2, 4th Floor
 Judge: The Honorable Haywood S.
 Gilliam, Jr.

Action Filed: October 6, 2017

1 **DEPARTMENT OF LABOR; STEVEN**
2 **MNUCHIN, IN HIS OFFICIAL CAPACITY AS**
3 **SECRETARY OF THE U.S. DEPARTMENT OF THE**
4 **TREASURY; U.S. DEPARTMENT OF THE**
5 **TREASURY; DOES 1-100,**

Defendants,

6 **THE LITTLE SISTERS OF THE POOR,**
7 **JEANNE JUGAN RESIDENCE; MARCH**
8 **FOR LIFE EDUCATION AND DEFENSE**
9 **FUND,**

Defendant-Intervenors.

10 **TO ALL PARTIES AND THEIR ATTORNEYS OF RECORD:**

11 **PLEASE TAKE NOTICE** that on September 5, 2019, at 2:00 p.m., in Courtroom 2 of the
12 above-entitled court, at 1301 Clay Street, Oakland, California, Plaintiffs the State of California,
13 the State of Connecticut, the State of Delaware, the District of Columbia, the State of Hawaii, the
14 State of Illinois, the State of Maryland, the State of Minnesota, by and through its Department of
15 Human Services, the State of New York, the State of North Carolina, the State of Oregon, the
16 State of Rhode Island, the State of Vermont, the Commonwealth of Virginia, and the State of
17 Washington (collectively, “the States”) will and hereby do move this Court for summary
18 judgment on each of the five causes of action set forth in the Second Amended Complaint. The
19 States respectfully request that the Court enter judgment in their favor because the two interim
20 final rules, 82 Fed. Reg. 47,792 (Oct. 13, 2017) and 82 Fed. Reg. 47,838 (Oct. 13, 2017), and the
21 two final rules, 83 Fed. Reg. 57,536 (Nov. 15, 2018) and 83 Fed. Reg. 57,592 (Nov. 15, 2018),
22 violate the Administrative Procedures Act, 5 U.S.C. § 553 and 5 U.S.C. § 706, and the United
23 States Constitution’s Establishment and Equal Protection Clauses. In the alternative, the States
24 respectfully request that the Court enter judgment as to those causes of action that the Court sees
25 as fit for resolution at this time.

26 This motion is based on this notice, the memorandum of points and authorities, the
27 administrative record, this Court’s file, and any matters properly before the Court.
28

TABLE OF CONTENTS

| | | Page |
|----|--|-------------|
| 1 | | |
| 2 | | |
| 3 | INTRODUCTION | 1 |
| 4 | FACTUAL AND LEGAL BACKGROUND | 1 |
| 5 | I. Providing Contraceptive Coverage Benefits Everyone..... | 1 |
| 6 | II. The ACA Requires Coverage of Women’s Preventive Services, Including Contraceptives..... | 3 |
| 7 | III. The Federal Government Seeks to Protect Women’s Access to Equal Healthcare Coverage and Religious Liberty | 8 |
| 8 | IV. Defendants Promulgated IFRs that Broadly Expanded Employers’ Ability to Deprive Female Employees of Equal Access to Healthcare..... | 11 |
| 9 | V. This Court Enjoined the IFRs and the Ninth Circuit Largely Affirmed | 13 |
| 10 | VI. Defendants Promulgated the Final Exemption Rules | 13 |
| 11 | VII. This Court Enjoined the Final Exemption Rules | 14 |
| 12 | LEGAL STANDARD..... | 15 |
| 13 | ISSUE PRESENTED..... | 15 |
| 14 | ARGUMENT..... | 15 |
| 15 | I. The Exemption Rules Are Contrary to Law | 15 |
| 16 | A. The Exemption Rules Are Contrary to the Women’s Health Amendment..... | 16 |
| 17 | B. The Religious Exemption Rule Is Not Compelled (or Authorized) by RFRA | 21 |
| 18 | 1. The Accommodation Does Not Substantially Burden the Exercise of Religion..... | 22 |
| 19 | 2. The Accommodation Is the Least Restrictive Means of Furthering the Compelling Government Interest in Providing Women with Equal Access to Preventive Care..... | 26 |
| 20 | C. The Moral Exemption Rule is Not Mandated by Any Legislation | 35 |
| 21 | D. The Exemption Rules Create Barriers for Women to Obtain Healthcare Coverage and Impede Timely Access to Healthcare, Thereby Violating the ACA..... | 35 |
| 22 | E. The Exemption Rules Violate the ACA’s Nondiscrimination Provision | 36 |
| 23 | II. The Exemption Rules Are Invalid Because They Are Arbitrary and Capricious | 37 |
| 24 | A. Defendants Failed to Provide a Reasoned Explanation for their Policy Reversal..... | 38 |
| 25 | 1. Because of the Serious Reliance Interests at Stake, Defendants Must Meet a Higher Standard..... | 38 |
| 26 | 2. The Evidence Before the Agency Is Clear that Contraception is Safe and Effective..... | 39 |
| 27 | | |
| 28 | | |

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

TABLE OF CONTENTS

(continued)

Page

3. Defendants Disregarded Extensive Record Evidence to Wrongly Claim that the Contraceptive Mandate Has Not Yielded Benefits..... 41

4. Defendants Failed to Reasonably Account for the Costs of the Rules..... 43

5. Defendants Overlooked Congress’s Intent that HRSA Assess the Efficacy and Safety of Preventive Care Measures 43

B. Defendants’ Justifications Are Implausible Because the Exemption Rules Are Not Tailored to Address the Purported “Problems” the Rules Identify 44

C. Defendants Failed to Meaningfully Respond to Comments Concerning the Rules’ Impacts 46

1. Defendants Failed to Respond to Comments from Medical Associations Describing the Medical Consensus About Contraceptives’ Efficacy 46

2. Defendants Failed to Respond to Comments Outlining the Negative Financial and Health Impacts of Unintended Pregnancy..... 48

3. Defendants Failed to Respond to Comments Concerning the Exemption Rules’ Impact on Patients Experiencing Domestic Violence 50

III. The Exemption Rules and the IFRs Violate the Establishment Clause 51

IV. The Exemption Rules and the IFRs Violate the Equal Protection Clause 54

V. The Exemption Rules Were Improperly Promulgated..... 56

VI. Defendants Violated the APA by Failing to Provide Notice and Comment Before Promulgating the IFRs 58

VII. The Exemption Rules and the IFRs Should Be Set Aside as Invalid 59

VIII. The States Are Entitled to Declaratory and Injunctive Relief..... 60

CONCLUSION 60

TABLE OF AUTHORITIES

| | | <u>Page</u> |
|----|---|---------------|
| 1 | | |
| 2 | | |
| 3 | | |
| 4 | CASES | |
| 5 | <i>Alcaraz v. Block</i> | |
| 6 | 746 F.2d 593 (9th Cir. 1984)..... | 57, 59 |
| 7 | <i>Allied Local & Reg'l Mfrs. Caucus v. EPA</i> | |
| 8 | 215 F.3d 61 (D.C. Cir. 2000) | 41, 46 |
| 9 | <i>Am. Wild Horse Pres. Campaign v. Perdue</i> | |
| 10 | 873 F.3d 914 (D.C. Cir. 2017) | 43 |
| 11 | <i>Arce v. Douglas</i> | |
| 12 | 793 F.3d 968 (9th Cir. 2015)..... | 54 |
| 13 | <i>Arizona Cattle Growers Ass'n v. U.S. Fish & Wildlife</i> | |
| 14 | 273 F.3d 1229 (9th Cir. 2001)..... | 45 |
| 15 | <i>Bd. of Dirs. of Rotary Int'l v. Rotary Club of Duarte</i> | |
| 16 | 481 U.S. 537 (1987)..... | 27 |
| 17 | <i>Biodiversity Legal Found. v. Badgley</i> | |
| 18 | 309 F.3d 1166 (9th Cir. 2002)..... | 60 |
| 19 | <i>BNSF Railway Co. v. Cal. Dep't of Tax and Fee Admin.</i> | |
| 20 | 904 F.3d 755 (9th Cir. 2018)..... | 34 |
| 21 | <i>BP Am. Prod. Co. v. Burton</i> | |
| 22 | 549 U.S. 84 (2006)..... | 16 |
| 23 | <i>Burwell v. Hobby Lobby Stores, Inc.</i> | |
| 24 | 573 U.S. 682 (2014)..... | <i>passim</i> |
| 25 | <i>Caban v. Mohammed</i> | |
| 26 | 441 U.S. 380 (1979)..... | 54 |
| 27 | <i>California v. Azar</i> | |
| 28 | 2019 WL 1877392 (N.D. Cal. Apr. 26, 2019) | <i>passim</i> |
| | <i>California v. Azar</i> | |
| | 911 F.3d 558 (9th Cir. 2018)..... | 13, 59 |
| | <i>Catholic Health Care Sys. v. Burwell</i> | |
| | 796 F.3d 207 (2d Cir. 2015)..... | 23, 24, 26 |

TABLE OF AUTHORITIES

(continued)

| | <u>Page</u> |
|----|-------------|
| 1 | |
| 2 | |
| 3 | |
| 4 | |
| 5 | |
| 6 | |
| 7 | |
| 8 | |
| 9 | |
| 10 | |
| 11 | |
| 12 | |
| 13 | |
| 14 | |
| 15 | |
| 16 | |
| 17 | |
| 18 | |
| 19 | |
| 20 | |
| 21 | |
| 22 | |
| 23 | |
| 24 | |
| 25 | |
| 26 | |
| 27 | |
| 28 | |

| | |
|--|----------------|
| <i>Catholic League for Religious & Civil Rights v. City & Cty. of S.F.</i> 624 F.3d 1043 (9th Cir. 2010) (en banc)..... | 51 |
| <i>Citizens to Preserve Overton Park, Inc. v. Volpe</i> 401 U.S. 402 (1971)..... | 37 |
| <i>City of Boerne v. Flores</i> 521 U.S. 507 (1997)..... | 31 |
| <i>City of Portland, v. EPA</i> 507 F.3d 706 (D.C. Cir. 2007)..... | 46 |
| <i>Corp. of Presiding Bishop of Church of Jesus Christ of Latter-day Saints v. Amos</i> 483 U.S. 327 (1987)..... | 51 |
| <i>Ctr. for Biological Diversity v. U.S. Bureau of Land Mgmt.</i> 698 F.3d 1101 (9th Cir. 2012)..... | 40, 50 |
| <i>Cutter v. Wilkinson</i> 544 U.S. 709 (2005)..... | 34, 52, 53 |
| <i>Del. Dep’t of Nat. Res. & Envtl. Control v. EPA</i> 785 F.3d 1 (D.C. Cir. 2015)..... | 44, 50, 51 |
| <i>Doe v. Boyertown Area Sch. Dist.</i> 897 F.3d 518 (3d Cir. 2018)..... | 27, 28 |
| <i>Doe v. Chao</i> 540 U.S. 614 (2004)..... | 19 |
| <i>E. Tex. Baptist Univ. v. Burwell</i> 793 F.3d 449 (5th Cir. 2015)..... | 26 |
| <i>Employment Division v. Smith</i> 494 U.S. 872 (1990)..... | 31 |
| <i>Encino Motorcars, LLC v. Navarro</i> 136 S. Ct. 2117 (2016)..... | 39, 41, 50 |
| <i>Entergy Corp. v. Riverkeeper, Inc.</i> 556 U.S. 208 (2009)..... | 16 |
| <i>Estate of Thornton v. Caldor, Inc.</i> 472 U.S. 703 (1985)..... | 31, 52, 53, 54 |

TABLE OF AUTHORITIES

(continued)

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

Page

Eternal Word Television Network v. Sec’y of U.S. Dep’t Health & Human Servs.
818 F.3d 1122 (11th Cir. 2016).....24, 26, 28, 29

F.C.C. v. Fox Television Stations, Inc.
556 U.S. 502 (2009).....37, 39

Farmers Union Cent. Exch., Inc. v. F.E.R.C.
734 F.2d 1486 (D.C. Cir. 1984)41

Food & Drug Admin. v. Brown & Williamson Tobacco Corp.
529 U.S. 120 (2000).....20

Geneva Coll. v. Sec’y U.S. Dep’t Health & Human Servs.
778 F.3d 422 (3d Cir. 2015).....23, 26

Gonzales v. O Centro Espirita Beneficente Uniao do Vegetal
546 U.S. 418, 423 (2006).....33

Gonzales v. Oregon
546 U.S. 243 (2006).....21

Grace Schs. v. Burwell
801 F.3d 788 (7th Cir. 2015).....26

Guam v. Guerrero
290 F.3d 1210 (9th Cir. 2002).....22

Guedes v. Bureau of Alcohol, Tobacco, Firearms, and Explosives
920 F.3d 1 (D.C. Cir. 2019)58

Holt v. Hobbs
135 S.Ct. 853 (2015).....24, 33, 52

Humane Soc. of U.S. v. Locke
626 F.3d 1040 (9th Cir. 2010).....48

In re Ozenne
841 F.3d 810 (9th Cir. 2016).....51

INS v. Cardoza-Fonseca
480 U.S. 421 (1987).....20

Int’l Union v. Johnson Controls
499 U.S. 187 (1991).....54

TABLE OF AUTHORITIES

(continued)

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

Page

King v. Burwell
135 S. Ct. 2480 (2015)4

Kingdomware Technologies, Inc. v. United States
136 S. Ct. 1969 (2016)17

Klamath-Siskiyou Wildlands Cir. v. Nat’l Oceanic & Atmospheric Admin.
109 F. Supp. 3d 1238 (N.D. Cal. 2015)60

Kreisner v. City of San Diego
1 F.3d 775 (9th Cir. 1993).....51

La. Pub. Serv. Comm’n v. FCC
476 U.S. 355 (1986)17

Lake Carriers’ Ass’n v. EPA
652 F.3d 1 (D.C. Cir. 2011)59

Landgraf v. USI Film Products
511 U.S. 244 (1994)19

Leatherman v. Tarrant Cnty. Narcotics Intelligence & Coordination Unit
507 U.S. 163 (1993)18

Lemon v. Kurtzman
403 U.S. 602 (1971)51

Levesque v. Block
723 F.2d 175 (1st Cir. 1983)58

Little Sisters of the Poor Home for the Aged, Denver, Colo. v. Burwell
794 F.3d 1151 (10th Cir. 2015).....26

Mich. Catholic Conference & Catholic Family Servs. v. Burwell
807 F.3d 738 (6th Cir. 2015).....26

Michigan v. EPA
135 S. Ct. 2699 (2015)20, 43

Miss. Univ. for Women v. Hogan
458 U.S. 718 (1982)16, 54

Motor Vehicle Mfrs. Ass’n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.
463 U.S. 29 (1983) *passim*

TABLE OF AUTHORITIES
(continued)

| | | <u>Page</u> |
|----|--|--------------------|
| 1 | | |
| 2 | | |
| 3 | <i>N.M. Health Connections v. U.S. Dep’t of Health & Human Servs.</i> | |
| 4 | 312 F. Supp. 3d 1164 (D.N.M 2018) | 47 |
| 5 | <i>Nat. Res. Def. Council v. EPA</i> | |
| 6 | 489 F.3d 1364 (D.C. Cir. 2007) | 60 |
| 7 | <i>Nat. Res. Def. Council v. Nat’l Highway Safety Admin.</i> | |
| 8 | 894 F.3d 95 (2nd Cir. 2018)..... | 57 |
| 9 | <i>Nat’l Fed’n of Indep. Bus. v. Sebelius</i> | |
| 10 | 567 U.S. 519 (2012)..... | 3 |
| 11 | <i>Navajo Nation v. U.S. Forest Serv.</i> | |
| 12 | 535 F.3d 1058 (9th Cir. 2008)..... | 21 |
| 13 | <i>Nevada Dep’t of Human Res. v. Hibbs</i> | |
| 14 | 538 U.S. 721 (2003)..... | 55 |
| 15 | <i>NRDC v. EPA</i> | |
| 16 | 683 F.2d 752 (3d Cir. 1982)..... | 15 |
| 17 | <i>NRDC v. SEC</i> | |
| 18 | 606 F.2d 1031 (D.C. Cir. 1979) | 15 |
| 19 | <i>Nw. Env’tl. Def. Ctr. v. Bonneville Power Admin.</i> | |
| 20 | 477 F.3d 668 (9th Cir. 2007)..... | 16 |
| 21 | <i>Obergefell v. Hodges</i> | |
| 22 | 135 S. Ct. 2584 (2015)..... | 55 |
| 23 | <i>Orr v. Orr</i> | |
| 24 | 440 U.S. 268 (1979)..... | 56 |
| 25 | <i>Pacific Gas & Elec. Co. v. Energy Res. Conservation & Dev. Comm’n</i> | |
| 26 | 461 U.S. 190 (1983)..... | 19 |
| 27 | <i>Paulsen v. Daniels</i> | |
| 28 | 413 F.3d 999 (9th Cir. 2005)..... | 57 |
| | <i>Pennsylvania v. Trump</i> | |
| | 281 F. Supp. 3d 553 (E.D. Pa. 2017) | 17, 57, 58 |
| | <i>Presbytery of N.J. of the Orthodox Presbyterian Church v. Whitman</i> | |
| | 99 F.3d 101 (3d Cir. 1996)..... | 27 |

TABLE OF AUTHORITIES

(continued)

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

Page

Priests For Life v. HHS
772 F.3d 229 (D.C. Cir. 2014)5, 23, 26

Priests for Life v. U.S. Dep’t of Health and Human Servs.
808 F.3d 1 (D.C. Cir. 2015)25, 27, 28

Ragsdale v. Wolverine World Wide, Inc.
535 U.S. 81 (2002)19

Ricci v. DeStefano
557 U.S. 557 (2009)32

Riverbend Farms, Inc. v. Madigan
958 F.2d 1479 (9th Cir. 1992)57, 59

Roberts v. United States Jaycees
468 U.S. 609 (1984)27

Russello v. United States
464 U.S. 16 (1983)35

Santa Fe Indep. Sch. Dist. v. Doe
530 U.S. 290 (2000)53

Schein v. Archer & White Sales
139 S. Ct. 524 (2019)20

Securities Indus. Ass’n v. Bd. of Governors of Fed. Reserve Sys.
468 U.S. 137 (1984)19

Sessions v. Morales-Santana
137 S. Ct. 1678 (2017)55, 56

Sharon Steel Corp. v. EPA
597 F.2d 377 (3d Cir. 1979)57, 58

Sharpe Holdings, Inc. v. U.S. Dep’t of Health & Human Servs.
801 F.3d 927 (8th Cir. 2015)22, 26

Sorenson Commc’ns Inc. v. FCC
755 F.3d 702 (D.C. Cir. 2014)46, 59

Southwest Ctr. For Biological Diversity v. United States Forest Service
100 F.3d 1443 (9th Cir. 1996)44

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

TABLE OF AUTHORITIES
(continued)

| | <u>Page</u> |
|--|--------------------|
| <i>Wheaton College v. Burwell</i> 573 U.S. 958 (2014)..... | 30 |
| <i>Whitman v. Am. Trucking Ass’ns, Inc.</i> 531 U.S. 457 (2001)..... | 20 |
| <i>Winter v. Natural Res. Def. Council, Inc.</i> 555 U.S. 7 (2008)..... | 60 |
| <i>Woodford v. Garceau</i> 538 U.S. 202 (2003)..... | 25 |
| <i>Yakima Valley Cabelvision, Inc. v. F.C.C.</i> 794 F.2d 737 (D.C. Cir. 1986)..... | 41 |
| <i>Zubik v. Burwell</i> 136 S. Ct. 1557 (2016)..... | <i>passim</i> |

TABLE OF AUTHORITIES

(continued)

Page

STATUTES

United States Code

| | | |
|----|----------------------------------|---------------|
| 1 | | |
| 2 | | |
| 3 | | |
| 4 | United States Code | |
| 5 | Title 5 § 551(5)..... | 58 |
| 6 | Title 5 § 553 | 59 |
| 7 | Title 5 § 553(b)..... | 59 |
| 8 | Title 5 § 553(c)..... | 59 |
| 9 | Title 5 § 706(2)(A)..... | 15, 59 |
| 10 | Title 5 § 706(2)(C) | 15 |
| 11 | Title 5 § 706(2)(D)..... | 15, 59 |
| 12 | Title 20 § 1681(a)..... | 37 |
| 13 | Title 28 § 2201(a)..... | 60 |
| 14 | Title 42 § 300gg-13(a) | 43 |
| 15 | Title 42 § 300gg-13(a)(4)..... | 4, 16, 17, 19 |
| 16 | Title 42 § 2000bb-1 | 52 |
| 17 | Title 42 § 2000bb-1(a) | 22 |
| 18 | Title 42 § 2000bb-1(a)-(b) | 21, 22 |
| 19 | Title 42 § 2000bb-1(c) | 32 |
| 20 | Title 42 § 2000bb-4..... | 33, 53 |
| 21 | Title 42 § 2000cc-1 | 52 |
| 22 | Title 42 § 18091 | 19 |
| 23 | Title 42 § 18091(2)(C) | 3, 4 |
| 24 | Title 42 § 18091(2)(F)..... | 3, 4 |
| 25 | Title 42 § 18091(2)(G)..... | 3, 4 |
| 26 | Title 42 § 18113 | 18 |
| 27 | Title 42 § 18114(1)..... | 18, 35 |
| 28 | Title 42 § 18114(2)..... | 18, 35 |
| | Title 42 § 18116 | 36 |
| | Title 42 § 18116(a)..... | 37 |

COURT RULES

| | | |
|----|----------------------------|----|
| 21 | Fed. R. Civ. P. 56(a)..... | 15 |
|----|----------------------------|----|

OTHER AUTHORITIES

Code of Federal Regulations

| | | |
|----|--------------------------------------|--------|
| 24 | Title 45 § 147.131(b)..... | 10 |
| 25 | Title 45 § 147.131(b)(4)..... | 10 |
| 26 | Title 45 § 147.131(b) & (c)(2) | 10 |
| 27 | Title 45 § 147.131(c)-(d)..... | 10, 25 |
| 28 | Title 45 § 147.131(d)(2)(ii)..... | 25 |
| | Title 45 § 147.131(d)-(e)..... | 25 |

| | | |
|----|--|----|
| 28 | 146 Cong. Rec. S7774 (July 27, 2000) | 52 |
|----|--|----|

TABLE OF AUTHORITIES

(continued)

| | <u>Page</u> |
|---|----------------|
| 155 Cong. Rec. S12027 (Dec. 1, 2009)..... | 4, 19, 32 |
| 158 Cong. Rec. S1172-73 (Mar. 1, 2012)..... | 4 |
| 158 Cong. Rec. S538-39 (Feb. 9, 2012)..... | 4, 18 |
| 159 Cong. Rec. S2268 (Mar. 22, 2013)..... | 4, 19 |
| 76 Fed. Reg. 46,621 (Aug. 3, 2011)..... | 9 |
| 77 Fed. Reg. 8,725 (Feb. 15, 2012)..... | <i>passim</i> |
| 78 Fed. Reg. 39,870 (July 2, 2013)..... | 9 |
| 80 Fed. Reg. 72,192 (Nov. 18, 2015)..... | 6 |
| 80 Fed. Reg. 41318 (July 14, 2015)..... | 10 |
| 81 Fed. Reg. 47,741 (July 22, 2016)..... | 11, 12, 22, 46 |
| 82 Fed. Reg. 47,792 (Oct. 13, 2017)..... | <i>passim</i> |
| 82 Fed. Reg. 47,838 (Oct. 13, 2017)..... | <i>passim</i> |
| 83 Fed. Reg. 57,536 (Nov. 15, 2018)..... | <i>passim</i> |
| 83 Fed. Reg. 57,592 (Nov. 15, 2018)..... | <i>passim</i> |
| 84 Fed. Reg. 7,714 (Mar. 4, 2019)..... | 32 |
| <i>About HRSA</i> , https://web.archive.org/web/20190302054343/ www.hrsa.gov/about/index.htm | 17 |
| <i>About the National Academy of Medicine</i> , National Academy of Medicine, https://nam.edu/about-the-nam/ | 5 |
| <i>Birth Control Methods</i> , Office of Women’s Health, HHS, available at https://www.womenshealth.gov/a-z-topics/birth-control-methods | 40, 41 |
| <i>Center for Consumer Info. & Ins. Oversight, Women’s Preventive Services Coverage and Non-Profit Religious Organizations</i> , Ctrs. for Medicare & Medicaid, https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and- FAQs/womens-preven-02012013.html | 10 |
| Commission Decision on Coverage of Contraception, U.S. Equal Employment Opportunity Commission, 2000 WL 33407187 (Dec. 14, 2000)..... | 37 |

TABLE OF AUTHORITIES

(continued)

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

Page

Disease Control and Prevention, NCHS Data Brief (Dec. 2018),
<https://www.cdc.gov/nchs/data/databriefs/db327-h.pdf>.....1

Douglas Nejaime & Reva B. Siegel, *Conscience Wars: Complicity-Based
 Conscience Claims in Religion and Politics*, 124 Yale L.J. 2516 (2015).....24, 30

Elizabeth Sepper, *Religious Exemptions, Harm to Others, and the Indeterminacy
 of A Common Law Baseline*, 106 Ky. L.J. 661 (2018).....52

Employer Health Benefits Survey, Kaiser Family Found. (Oct. 3. 2018),
[https://www.kff.org/report-section/2018-employer-health-benefits-survey-
 section-13-grandfathered-health-plans/](https://www.kff.org/report-section/2018-employer-health-benefits-survey-section-13-grandfathered-health-plans/).....28

Frederick Mark Gedicks & Rebecca G. Van Tassell, *RFRA Exemptions from the
 Contraception Mandate: An Unconstitutional Accommodation of Religion*, 49
 Harv. C.R.-C.L. L. Rev. 343 (2014)52

Jennifer B. Wheller & Austin Rueschhoff, *Improving Women’s Health
 Opportunities and Challenges in Health Reform*, Nat’l Conference of State
 Legislatures (2012), [http://www.ncsl.org/documents/
 health/ImproveWomenshealth12.pdf](http://www.ncsl.org/documents/health/ImproveWomenshealth12.pdf).....19

Micah Schwartzman et. al., *The Costs of Conscience*, 106 Ky. L.J. 781 (2018).....52

Women’s Preventive Services Guidelines, Health Res. & Serv. Admin.,
<https://www.hrsa.gov/womens-guidelines/index.html>.....5, 6

Women’s Preventive Services Guidelines-Guideline Development, Health Res. &
 Serv. Admin., <https://www.hrsa.gov/womens-guidelines-2016/index.html>17

1 **MEMORANDUM OF POINTS AND AUTHORITIES**

2 **INTRODUCTION**

3 Access to contraceptive care—and a woman’s decision about whether and when to use it—
 4 is a fundamental precept of women’s freedom and equality. The Patient Protection and
 5 Affordable Care Act (ACA), through the Women’s Health Amendment and its implementing
 6 regulations, revolutionized women’s access to preventive care by guaranteeing “no cost”
 7 coverage of all approved contraceptive methods and contraceptive counseling, empowering
 8 women to select the best contraception to meet their healthcare needs. Over 62 million women
 9 have benefited from this provision since 2012, saving up to \$1.4 billion, with resulting societal
 10 benefits from greater female engagement in the workforce and economic self-sufficiency. The
 11 Women’s Health Amendment ensures that women have full and equal healthcare coverage
 12 through their employer-sponsored plan. But the Exemption Rules promulgated by Defendants
 13 “transform contraceptive coverage from a legal entitlement to an essentially gratuitous benefit
 14 wholly subject to [an] employer’s discretion.” Dkt. No. 105 at 25-26. This Court should set aside
 15 the Exemption Rules and the interim final rules (IFRs) because they are contrary to law, are
 16 arbitrary and capricious, violate the Constitution, and were improperly promulgated.¹

17 **FACTUAL AND LEGAL BACKGROUND**

18 **I. PROVIDING CONTRACEPTIVE COVERAGE BENEFITS EVERYONE**

19 The benefits of contraception to women—and ultimately society—are universal. Nearly
 20 two-thirds of the 72.2 million women aged 15-49 in the United States use contraceptives.² By the
 21 age of 40, American women have used an average of three or four different methods (many of
 22 which are available only by prescription), after considering their effectiveness, convenience, cost,
 23 accessibility, side effects, drug interactions and hormones, perceived risk of sexually transmitted
 24

25 ¹ Because this Court indicated that the effect of striking down the validity of the Final Rules
 26 would be to reinstate the prior legal regime, Dkt. No. 105 at 28, the States have included their
 challenges to the validity of the IFRs.

27 ² *Current Contraceptive Status Among Women Aged 15-29*, Ctrs. for Disease Control and
 28 Prevention, NCHS Data Brief (Dec. 2018), <https://www.cdc.gov/nchs/data/databriefs/db327-h.pdf>; see also Ex. 57 (D10 00207386-87), Ex. 87 (D12 00804499).

1 infections, desire to control risk of pregnancy, and a host of other factors.³ Ex. 57 (D10
2 00207390). As the American College of Obstetricians and Gynecologists explained, “the benefits
3 of contraception . . . are widely recognized and include improved health and well-being, reduced
4 global maternal mortality, health benefits of pregnancy spacing for maternal and child health,
5 female engagement in the workforce, and economic self-sufficiency for women.” Ex. 87 (D12
6 00804499); *see also* Exs. 1 (D1 0000665-80), Ex. 49 (D10 00207141-42), Ex. 28 (D10
7 00195106-08), Ex. 55 (D10 00207240-47).⁴

8 Since the ACA’s contraceptive-coverage requirement took effect in 2012, more than 62
9 million women nationwide have benefited. Ex. 49 (D10 00207142), Ex. 49 (D10 00207145-46),
10 Ex. 28 (D10 00195105), Ex. 64 (D10 00208988), Ex. 24 (D9 668958-59), Ex. 63 (D10
11 00208945). The cost reductions have been significant, with estimates ranging from \$483 million
12 to \$1.4 billion in savings related to just one form of contraception (the pill) in one year alone.⁵
13 Some studies have concluded that “[w]omen now save an average of 20% annually in out-of-
14 pocket expenses, including \$248 savings for IUDs and \$255 for the contraceptive pill.” Ex. 57
15 (D10 00207311) (citing N.V. Becker, et al., *Women Saw Large Decrease In Out-of-Pocket*
16 *Spending For Contraceptives After ACA Mandate Removed Cost Sharing*, Health Affairs (2015),
17 <http://content.healthaffairs.org/content/34/7/1204.abstract#aff-2>). The government itself
18 acknowledges “that without coverage, many methods would cost women \$50 per month, or
19 upwards of \$600 per year.” Ex. 57 (D10 00207394); *see also* Ex. 16 (D9 570602) (“Between fall
20 2012 and spring 2014 [during which time the coverage guarantee went into wide effect], the

21 _____
22 ³ Because the Exemption Rules intentionally and explicitly target women’s health benefits, this
23 motion frequently uses female pronouns as well as the term “woman,” in discussing the impact of
24 the Rules. However, the States recognize that all persons who may become pregnant, including
25 people who do not identify as women, need access to a full range of reproductive healthcare
26 services, including access to contraception.

⁴ *See also* Ex. 9 (D4 0000401) (“Pregnancy spacing is important because of the increased risk of
adverse pregnancy outcomes for pregnancies that are too closely spaced (within 18 months of a
prior pregnancy).” (citing Exs. 12 (D4 000559-000573), 11 (D4 000544-000551), 10 (D4
000535-000543))).

⁵ Initial estimates from HHS stated that women in 2013 saved \$483.3 million due to the increase
in oral contraceptive prescriptions dispensed with no co-pay. Ex. 17 (D9 571363). A later study,
using a different methodology, estimated that privately insured women saved \$1.4 billion in 2013
on the oral contraceptive alone. Ex. 86 (D12 00715489).

1 proportion of privately insured women paying zero dollars out of pocket for oral contraceptives
 2 increased substantially, from 15% to 67%. Similar changes occurred among privately insured
 3 women using injectable contraception, the vaginal ring and the intrauterine device.”). The
 4 mandate has also enabled women to use contraception more consistently, thereby decreasing the
 5 likelihood of an unintended pregnancy. Ex. 57 (D10 00207389-91) (women who use
 6 contraception consistently are substantially less likely to have an unintended pregnancy), Ex. 57
 7 (D10 00207393-97) (describing empirical evidence that eliminating costs leads to more effective
 8 and consistent use of contraception), Ex. 23 (D9 668358-64) (varying effectiveness of birth
 9 control).

10 Increased access to contraception has had a corresponding impact on society, including the
 11 States. Ex. 57 (D10 00207398-400). For instance, the “ACA’s implementation correlates with a
 12 decrease” in enrollment in state-funded healthcare programs. Ex. 57 (D10 00207357). The
 13 Women’s Health Amendment has also resulted in decreases in the number of unintended
 14 pregnancies, and costs associated with those pregnancies. Ex. 57 (D10 00207348), Ex. 3 (D1
 15 0000695). And because unintended pregnancy is associated with poor birth outcomes and
 16 maternal health complications, the contraceptive-coverage requirement reduces the number of
 17 medically-complicated births and infants born in poor health.⁶

18 **II. THE ACA REQUIRES COVERAGE OF WOMEN’S PREVENTIVE SERVICES, INCLUDING** 19 **CONTRACEPTIVES**

20 The ACA is a landmark piece of legislation through which Congress sought to “increase the
 21 number of Americans covered by health insurance and decrease the cost of health care.” *Nat’l*
 22 *Fed’n of Indep. Bus. v. Sebelius*, 567 U.S. 519, 538 (2012); 42 U.S.C § 18091(2)(C), (F) & (G).
 23 Congress aimed to increase access to affordable and quality healthcare through a series of
 24 reforms, including strengthening consumer protections in the private insurance market, expanding
 25

26 ⁶ Ex. 20 (D9 666689), Ex. 9 (D4 000401-02) (recommending family planning to avoid adverse
 27 pregnancy outcomes), Ex. 25 (D9 669089), Ex. 24 (D9 668955), Ex. 24 (D9 668957)
 28 (recommending that adolescent and adult women have access to the full range of female-
 controlled contraceptives to prevent unintended pregnancy and improve birth outcomes), Ex. 12
 (D4 000559-573), Ex. 22 (D9 667730-667738), Ex. 6 (D1 0000776-777), Ex. 15 (D4 001609).

1 Medicaid, providing subsidies to lower premiums, and creating effective state health insurance
2 exchanges. *Id.*; *see also King v. Burwell*, 135 S. Ct. 2480, 2485-2487 (2015).

3 Among its many reforms to the nation’s healthcare system, the ACA requires that “group
4 health plan[s]” “shall” include women’s “preventive care and screenings” and “shall not impose
5 any cost sharing” on the consumer. 42 U.S.C. § 300gg-13(a)(4). Known as the Women’s Health
6 Amendment, this provision sought to redress the discriminatory practice of charging women more
7 for preventive services than men. 155 Cong. Rec. S12027 (Dec. 1, 2009) (statement of Sen.
8 Gillibrand). Before the ACA, “more than half of women delay[ed] or avoid[ed] preventive care
9 because of its cost.” *Id.* Supporters of the amendment expected that eradicating these
10 discriminatory barriers to preventive care—including contraceptive care—would result in
11 substantially improved health outcomes for women. *See, e.g., id.* at S12052 (statement of Sen.
12 Franken) (describing “family planning services” as a “top priority,” a “fundamental right of every
13 adult American,” and necessary for “women and families to make informed decisions about when
14 and how they become parents,” and stating “affordable family planning services must be
15 accessible to all women in our reformed health care system”); *id.* at S12059 (statement of Sen.
16 Cardin) (“General yearly well-women visits would be covered . . . [including] family planning
17 services.”); *id.* (statement of Sen. Feinstein) (same). After the Women’s Health Amendment was
18 adopted, Congress *twice* rejected legislation that would have permitted broad moral and religious
19 exemptions to the ACA’s coverage requirements. *See* 158 Cong. Rec. S538-39 (Feb. 9, 2012);
20 158 Cong. Rec. S1172-73 (Mar. 1, 2012); 159 Cong. Rec. S2268 (Mar. 22, 2013).

21 Congress delegated to the Health Resources and Services Administration (HRSA) the
22 specific duty to prescribe the exact coverage. 42 U.S.C. § 300gg-13(a)(4). Specifically, the ACA
23 provides that “with respect to women,” health plans shall include “such additional preventive care
24 and screening . . . as provided for in comprehensive guidelines supported by the Health Resources
25 and Services Administration for purposes of this paragraph.” *Id.*

26 Since the ACA’s enactment, HRSA has carried out its statutory duty by convening panels
27 of nationally recognized medical experts to make and update recommendations for the women’s
28 preventive care mandate. In its first response to this Congressional directive, HRSA

1 commissioned the nonpartisan Institute of Medicine (IOM) to assemble an expert committee to
2 determine what should be included in “preventive care” coverage.⁷ After rigorous, independent,
3 and exhaustive review of the scientific evidence, including peer-reviewed medical research, the
4 IOM issued its 2011 expert report, *Clinical Prevention Services for Women: Closing the Gaps*
5 (2011), with a comprehensive set of evidence-based recommendations for implementing women’s
6 preventive healthcare services.⁸ These recommendations addressed gaps in coverage for women,
7 including an annual well-woman preventive care visit, counseling and screening for HIV and
8 domestic violence, services for the early detection of reproductive cancers and sexually
9 transmitted infections, and patient education and counseling for all women with reproductive
10 capacity.⁹ Significantly, the IOM recommended that private health insurance plans be required to
11 cover all FDA-approved contraceptives without cost-sharing.¹⁰

12 Following the IOM’s recommendations on coverage, HRSA issued 2011 guidelines that
13 included a list of each type of preventive service, and the frequency with which it should be
14 offered.¹¹ Defendants also promulgated regulations, consistent with HRSA’s guidelines,
15 requiring that employers offering group health insurance plans cover all FDA-approved
16 contraceptive methods. 77 Fed. Reg. 8,725, 8,725-26 (Feb. 15, 2012).¹²

17
18 ⁷ In 2015, the IOM changed its name to the National Academy of Medicine. Founded in 1970 as
19 the Institute of Medicine, the National Academy of Medicine is one of three National Academies
20 in the United States. *About the National Academy of Medicine*, National Academy of Medicine,
21 <https://nam.edu/about-the-nam/>. According to their 1863 Congressional charter, the National
22 Academies were created to “provide objective advice on matters of science, technology, and
23 health.” *Id.*; see also Ex. 9 (D4 000289).

24 ⁸ Inst. Medicine, *Clinical Preventive Services for Women: Closing the Gaps*, 1-2 (2011), Ex. 9
25 (D4 0000286-534) [hereinafter “IOM Report”]; *id.* at Ex. 9 (D4 0000377-454).

26 ⁹ See *id.* at Ex. 9 (D4 0000407); *id.* at Ex. 9 (D4 0000377-454).

27 ¹⁰ *Id.* at Ex. 9 (D4 0000317, 400-408). Before the ACA, contraceptives accounted for between
28 30-44% of out-of-pocket healthcare spending for women. Ex. 57 (D10 00207398), Ex. 28 (D10
00195108).

¹¹ *Women’s Preventive Services Guidelines*, Health Res. & Serv. Admin.,
<https://www.hrsa.gov/womens-guidelines/index.html>.

¹² Certain plans that existed before the ACA’s enactment were statutorily exempted from the
contraceptive coverage requirement. These so-called “grandfathered plans” are a “transitional
measure,” meant to ease regulated entities into compliance with the ACA, and “will be eliminated
as employers make changes to their health care plans.” *Priests For Life v. HHS*, 772 F.3d 229,
266 (D.C. Cir. 2014), *vacated and remanded sub nom. Zubik v. Burwell*, 136 S. Ct. 1557 (2016);

1 In 2016, HRSA established a process for the ongoing review, development, and update of
2 the medically-approved women’s preventive care guidelines. Ex. 20 (D9 666688). Pursuant to
3 an agreement with HRSA, the Women’s Preventive Services Initiative was launched and led by
4 the American College of Obstetricians and Gynecologists. *Id.* WPSI “convene[d] a coalition of
5 clinician, academic, and consumer-focused health professionals,” including the American
6 Academy of Family Physicians, the American College of Physicians, the National Association of
7 Nurse Practitioners in Women’s Health, American Academy of Pediatrics, physician scientists
8 from the Pacific Northwest Evidence-based Practice Center at Oregon Health & Science
9 University, and federal partners such as the Centers for Disease Control and Prevention (CDC)
10 and the Office on Women’s Health. *Id.*; Ex. 25 (D9 669077-78). Following a rigorous
11 methodology of reviewing medically-approved, high-quality evidence, WPSI issued a final
12 report. Ex. 25 (D9 669080) (Final Report explaining, “[a] best evidence approach was applied
13 when reviewing abstracts and selecting studies to include for the updates that involves using the
14 most relevant studies with the strongest methodologies”). Like the IOM report, WPSI also
15 recommended that all FDA-approved methods be included in “preventive care.” Ex. 24 (D9
16 668955-668970) (Contraception Recommendations, Evidence Map, Evidence Summaries).
17 Again, HRSA guidelines adopted that evidence-based recommendation. Ex. 20 (D9 666688).
18 These guidelines remain the standard today.¹³

19 Both the IOM report and the WPSI report were the product of medical and public health
20 experts reviewing and weighing scientific evidence and medical research. Based on their
21 reviews, the reports reached a number of conclusions supporting broader access to contraception,
22 including:

- 23 • Contraception has been found to be essential for women to avoid unwanted
24 pregnancies and to space their pregnancies to promote optimal birth and maternal
25 health outcomes. Exs. 9 (D4 000402-03), Ex. 24 (D9 668963). When women are able
26

27 80 Fed. Reg. 72,192, 72,216 (Nov. 18, 2015) (Grandfathered plans are designed to “ease the
28 transition required by the market reforms”).

¹³ See <https://www.hrsa.gov/womens-guidelines/index.html>.

1 to space and time their pregnancies, the risk of negative health outcomes for them and
2 their children declines. *See* Ex. 9 (D4 000401) (recognizing that “[p]regnancy spacing
3 is important because of the increased risk of adverse pregnancy outcomes for
4 pregnancies that are too closely spaced (within 18 months of a prior pregnancy)”).

5 Multiple studies showed that short interpregnancy intervals have been associated with
6 low birth weight, prematurity, and small for gestational age births. Ex. 12 (D4
7 000559-73), Ex. 11 (D4 000544-51), Ex. 10 (D4 000535-43).

- 8 • Women who face unintended childbearing encounter a variety of health risks,
9 including higher levels of depression and anxiety, and a decline in psychological well-
10 being. Ex. 9 (D4 000401), Ex. 14 (D4 001279-001299), Ex. 24 (D9 668959-60).
- 11 • Pregnancy poses grave health risks for women with certain serious medical conditions,
12 including but not limited to pulmonary hypertension, certain forms of heart disease,
13 and Marfan Syndrome. Ex. 9 (D4 000401-402) (IOM citing various studies).
- 14 • Women with unintended pregnancies are more likely than those with planned
15 pregnancies to receive later or no prenatal care, to smoke and consume alcohol during
16 pregnancy, and to experience domestic violence during pregnancy. Ex. 9 (D4
17 000401), Ex. 24 (D9 668959-60).
- 18 • Prenatal and preconception visits optimize the chance of a healthy pregnancy through
19 various health screenings and promoting practices that help prevent birth defects, but
20 women with unintended pregnancies are less likely to pursue this care. Ex. 24 (D9
21 668959-60).
- 22 • There are significantly increased odds of preterm birth and low birth weight among
23 unintended pregnancies ending in live births compared with pregnancies that were
24 intended. Ex. 9 (D4 000401); Ex. 24 (D9 668959), Ex. 14 (D4 001279-001299).
- 25 • U.S. children born as the result of unintended pregnancies are less likely to be
26 breastfed or are breastfed for a shorter duration than children born as the result of
27 intended pregnancies. Ex. 9 (D4 000401), Ex. 14 (D4 001279-001299).

- 1 • Our nation’s leading healthcare professional associations and other organizations
2 recommend the use of family planning services, including contraception, as part of
3 preventative care for women. These organizations include the American College of
4 Obstetrics and Gynecology, the American Academy of Family Physicians, the
5 American Academy of Pediatrics, the Society of Adolescent Medicine, the American
6 Medical Association, the American Public Health Association, the Association of
7 Women’s Health, and Obstetric and Neonatal Nurses. Ex. 9 (D4 000402), Ex. 24 (D9
8 668963).
- 9 • The CDC has recommended family planning services as part of preventive visits for
10 preconception health. Ex. 9 (D4 000430); Ex. 24 (D9 668960).
- 11 • Removing cost barriers for the “most effective contraceptive methods,” particularly
12 for “long-acting, reversible contraceptive methods” with “high up-front costs” is
13 critical for women’s preventive care. Ex. 9 (D4 000405-06), Ex. 2 (D1 0000685-94);
14 *see also* Ex. 9 (D4 000316-318).
- 15 • WPSI recognized that the ACA had had a significant impact on reducing out-of-
16 pocket expenses for FDA-approved contraceptive methods and vastly increased the
17 number of women currently accessing birth control without copayments. Ex. 24 (D9
18 668958-59).

19 All together, in formulating the guidelines to implement the Women’s Health Amendment,
20 the expert panels found abundant evidence of the effectiveness of contraception, the importance
21 of contraception for women’s and children’s health and wellbeing, and increased usage of
22 contraceptives when cost barriers are eliminated. Therefore, both IOM and WPSI recommended
23 that all FDA-approved contraceptive methods be included as “preventive services,” a
24 recommendation adopted by HRSA which still applies today.

25 **III. THE FEDERAL GOVERNMENT SEEKS TO PROTECT WOMEN’S ACCESS TO EQUAL** 26 **HEALTHCARE COVERAGE AND RELIGIOUS LIBERTY**

27 From the outset, Defendants recognized that some employers would have religious
28 objections to contraceptive coverage. To address those concerns, in 2011, Defendants exempted

1 houses of worship from the contraceptive mandate, with the understanding that line-level
2 employees would share their employer’s religious objection to contraception. 76 Fed. Reg.
3 46,621-01, 46,623 (Aug. 3, 2011) (“the Departments seek to provide for a religious
4 accommodation that respects the unique relationship between a house of worship and its
5 employees in ministerial positions”); 77 Fed. Reg. at 8,728.¹⁴ This “church exemption” imported
6 a long-standing category of employers defined in the Internal Revenue Code. *Burwell v. Hobby*
7 *Lobby Stores, Inc.*, 573 U.S. 682, 698 (2014) (quoting 26 U.S.C. § 6033(a)(3)(A)(i) and (iii)).
8 The agencies declined to implement a broader exemption out of concern that it might sweep in
9 employers “more likely to employ individuals who have no religious objection to the use of
10 contraceptive services,” and thereby risk “subject[ing] [such] employees to the religious views of
11 [their] employer.” 77 Fed. Reg. at 8,728. In creating the church exemption, Defendants did not
12 identify any provision in the ACA authorizing them to create such an exemption. 76 Fed. Reg. at
13 46,623.

14 Two years later, the agencies implemented additional regulations to promote “two
15 important policy goals”: (1) to “advanc[e] the compelling government interests in safeguarding
16 public health and ensuring that women have equal access to health care;” and (2) to “advance
17 these interests in a narrowly tailored fashion that protects certain religious organizations with
18 religious objections to providing contraceptive coverage from having to contract, arrange, pay, or
19 refer for such coverage.” 78 Fed. Reg. 39,870, 39,872 (July 2, 2013). To accomplish these goals,
20 the rule instituted an “accommodation” process for religious affiliated non-profits. 78 Fed. Reg.
21 at 39,876-77.

22 Under the accommodation—a process unnecessary for and inapplicable to houses of
23 worship—a nonprofit employer certified its religious objection to the federal government or to the
24

25 ¹⁴ As defined by the regulations, a “religious employer”: “(1) Has the inculcation of religious
26 values as its purpose; (2) primarily employs persons who share its religious tenets; (3) primarily
27 serves persons who share its religious tenets; and (4) is a non-profit organization [under the
28 relevant statutes, which] refer[] to churches, their integrated auxiliaries, and conventions or
associations of churches, as well as to the exclusively religious activities of any religious order.”
Id. at 8726.

1 insurer, and the insurer became responsible for providing separate contraceptive coverage for
2 female employees. 45 C.F.R. § 147.131(c)(2). Upon notification, the government worked with
3 the insurer to guarantee that women received coverage.¹⁵ This process ensured a seamless,
4 automatic mechanism for female employees and dependents to receive contraceptives to which
5 they are statutorily entitled outside of their employer-sponsored health plan. 45 C.F.R. §
6 147.131(b).¹⁶ In short, Defendants concluded that the accommodation process protected the
7 rights of female employees to equal healthcare coverage while safeguarding religiously affiliated
8 nonprofit employers' ability to opt out of providing or paying for this coverage. *See* 80 Fed. Reg.
9 at 41,318; 45 C.F.R. § 147.131(c)-(d).

10 The religious accommodation was later expanded to include certain closely held for-profit
11 organizations with religious objections to contraceptives, consistent with *Hobby Lobby*, 573 U.S.
12 682; 80 Fed. Reg. at 41,318; 45 C.F.R. § 147.131(c)(4). The Court stated that its opinion in that
13 case "should not be understood to hold that an insurance-coverage mandate must necessarily fall
14 if it conflicts with employer's religious beliefs." *Hobby Lobby*, 573 U.S. at 733.

15 In *Zubik v. Burwell*, nonprofit employers challenged the accommodation process itself,
16 arguing that the act of opting out of providing contraceptive coverage violated the Religious
17 Freedom Restoration Act of 1993 (RFRA) because it caused the provision of contraceptive
18 coverage by the insurer or third party administrator (TPA). 136 S. Ct. 1557, 1559-60 (2016).
19 The Court vacated and remanded the matters to the Courts of Appeals to afford the parties an
20 opportunity to resolve the matter in light of their evolving legal positions. *Id.* at 1560. The Court
21 emphasized that it was expressing no view on the merits. *Id.* ("The Court expresses no view on
22 the merits of the cases."). Significantly, however, the Court declined to hold that the
23 accommodation process violated the RFRA, and instead instructed that: "the parties on remand
24 should be afforded an opportunity to arrive at an approach going forward that accommodates

25 ¹⁵ The health insurer covered the contraceptive benefits and services, and, in turn, could be
26 reimbursed with a fee for providing such benefits and services from the federal government. 80
Fed. Reg. 41,318, 41,346 (July 14, 2015).

27 ¹⁶ *Ctr. for Consumer Info. & Ins. Oversight, Women's Preventive Services Coverage and Non-*
28 *Profit Religious Organizations, Ctrs. for Medicare & Medicaid Servs.*,
<https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/womens-preven-02012013.html>.

1 [religious organizations’] religious exercise while *at the same time ensuring that women covered*
2 *by [religious organizations’] health plans receive full and equal health coverage, including*
3 *contraceptive coverage.”* *Id.* at 1559-60 (emphasis added) (internal quotation marks and citation
4 omitted). As this Court recognized, in *Zubik* Defendants represented to the Supreme Court that
5 the government “has a compelling interest in ensuring access to” contraceptive coverage for
6 women. Dkt. No. 105 at 1-2 (citation omitted).

7 In response to *Zubik*, Defendants published a Request for Information in the Federal
8 Register on July 22, 2016, seeking input on whether and how the regulations could be changed to
9 resolve the objections asserted by Plaintiffs in *Zubik*, while still ensuring that affected women
10 receive full and equal health coverage. 81 Fed. Reg. 47,741 (July 22, 2016). Notably, the
11 Request did not propose a “moral” exemption and did not propose expanding the religious
12 exemption to all employers, insurers, and individuals. Upon review, the agencies concluded on
13 January 9, 2017 that the accommodation complied with RFRA by protecting the interests of
14 religious objectors, while also fulfilling the agencies’ statutory duty to ensure women retained
15 access to no-cost contraceptive coverage. Ex. 19 (D9 666661-62);¹⁷ *see also* 82 Fed. Reg. at
16 47,798 n.17; 83 Fed. Reg. at 57,539. Specifically, the agencies found that “the accommodation is
17 the least restrictive means of furthering the government’s compelling interest in ensuring that
18 women receive full and equal health coverage, including contraceptive coverage.” Ex. 19 (D9
19 666662).

20 **IV. DEFENDANTS PROMULGATED IFRS THAT BROADLY EXPANDED EMPLOYERS’** 21 **ABILITY TO DEPRIVE FEMALE EMPLOYEES OF EQUAL ACCESS TO HEALTHCARE**

22 On October 6, 2017, Defendants promulgated sweeping new rules upending women’s
23 entitled contraceptive coverage in two interim final rules (IFRs), effective immediately, denying
24 the public an opportunity to comment before these drastic changes went into effect. Dkt. Nos. 24-
25 1 & 24-2. The “Religious Exemption IFR” vastly expanded the scope of the exemption to the
26

27 ¹⁷ *Also available at U.S. Dep’t Labor, FAQs About Affordable Care Act Implementation Part 36,*
28 *at 4-5 (Jan. 09, 2017), <https://www.dol.gov/sites/default/files/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-36.pdf>.*

1 contraceptive-coverage requirement, permitting any employer (regardless of corporate structure
2 or religious affiliation), individual, or even a health insurer with religious objections to coverage
3 of all or a subset of FDA-approved contraceptives, to exempt themselves. The “Moral Exemption
4 IFR” provided that nearly any employer could stop covering contraceptive services for their
5 employees if they have a “moral” objection. Like the Religious Exemption IFR, the Moral
6 Exemption IFR extended to employers, insurers, and individuals, allowing those objectors to
7 exempt themselves as well.

8 Under the IFRs, employers did not need to use the regulatory accommodation, which
9 ensured that women received their statutorily guaranteed contraceptive coverage. The IFRs did
10 not require that employers notify the federal government or even tell their affected employees.
11 Rather, employers “objected” by simply exempting themselves from the statutory requirement,
12 resulting in female employees losing their contraceptive coverage. The only way a woman would
13 discover that her employer has exempted itself from providing contraceptives is by examining her
14 annual notice of benefits and coverage or by receiving a surprise medical bill.

15 In determining the impact of the IFRs, Defendants expressly relied on state and local
16 programs to fill in the gaps of coverage. 82 Fed. Reg. at 47,803 (noting that state and local
17 programs “provide free or subsidized contraceptives for low-income women” and concluding that
18 this “existing inter-governmental structure for obtaining contraceptives significantly diminishes”
19 the impact of the expanded exemptions).

20 Since issuing the IFRs, Defendants have entered numerous stipulated judgments with
21 objecting employers in pending litigation. *See* Dkt. Nos. 197 at 10 n. 4 (listing the stipulated
22 injunctions); 197-1; Dkt. No. 234 at 30 (recognizing that “the Federal Defendants [have] simply
23 reversed their position and stopped defending the accommodation, and [do] not seemingly
24 disavow any obligation to ensure coverage under the ACA. As a result, the post-*Zubik* orders
25 were entered without objection by the government, based on the agencies’ new position that the
26 accommodation violates RFRA.”).

27 ///

28 ///

V. THIS COURT ENJOINED THE IFRS AND THE NINTH CIRCUIT LARGELY AFFIRMED

On December 21, 2017, this Court enjoined implementation of the IFRs. This Court held that the States were likely to succeed on their claim that Defendants violated the Administrative Procedure Act (APA) by issuing the IFRs without advance notice and comment; that absent a preliminary injunction, the States would suffer irreparable substantive and procedural injuries; and that the equities and public interest tipped in the States' favor. Dkt. No. 105 at 17-28. This Court rejected Defendants' standing challenge because the States had demonstrated that they would incur economic harm, either to cover contraceptive services necessary to fill in the gaps left by the IFRs or for costs associated with unintended pregnancies. *Id.* at 12-16.

On December 13, 2018, the Ninth Circuit largely upheld this Court's decision. *California v. Azar*, 911 F.3d 558 (9th Cir. 2018). The Ninth Circuit held that the States have standing to sue because the declarations showed that the IFRs would "first lead to women losing employer-sponsored contraceptive coverage, which [would] then result in economic harm to the states." *Id.* at 571. The Court explained that "it is reasonably probable that women in the plaintiff states will lose some or all employer-sponsored contraceptive coverage due to the IFRs." *Id.* at 572. The Court noted that even the Defendants' "own regulatory impact analysis (RIA)—which explains the anticipated costs, benefits, and effects of the IFRs—estimates that between 31,700 and 120,000 women nationwide will lose some coverage." *Id.* The Court highlighted Defendants' estimate of direct cost of filling the coverage loss as \$18.5 or \$63.8 million per year and Defendants' identification of state and local programs to fill that gap; thus, the Defendants' analysis "assumed that state and local governments will bear additional economic costs." *Id.* The Ninth Circuit also concluded that the States were likely to succeed on their APA notice-and-comment claim. *Id.* at 575-581.

VI. DEFENDANTS PROMULGATED THE FINAL EXEMPTION RULES

On November 15, 2018, Defendants promulgated the final Exemption Rules (Exemption Rules). 83 Fed. Reg. at 57,536; 83 Fed. Reg. at 57,592. These Rules are very similar to the IFRs, with two noteworthy differences. First, the regulatory impact analysis in the final Exemption Rules estimates that even *more* women will be harmed by the expanded exemptions—up to

1 126,400. *See, e.g.*, 83 Fed. Reg. at 57,551 n.26, 57,578. Second, the Rules suggest that women
 2 take additional steps—outside of their employer-sponsored coverage—and seek out contraceptive
 3 coverage through the federal Title X family planning clinics, a safety-net program designed for
 4 low-income populations. 83 Fed. Reg. at 57,548, 57,551; 83 Fed. Reg. at 57,605, 57,608.¹⁸ As
 5 the record demonstrates, the Title X program is ill-equipped to replicate or replace the seamless
 6 contraceptive-coverage requirement.¹⁹ Ex. 57 (D10 00207405-08), Ex. 44 (D10 00207048-49),
 7 Ex. 44 (D10 00207048) (“[A] recent study published in the American Journal of Public Health
 8 confirms that reductions in funding for Title X limit the number of patients Title X-funded
 9 providers are able to serve, concluding that Congress would have to increase federal funding for
 10 Title X by over \$450 million to adequately address the existing need for publicly funded family
 11 planning services.”), Ex. 28 (D10 00195115-18), Ex. 30 (D10 00195141-42), Ex. 64 (D10
 12 00208990-94), Ex. 60 (D10 00207662-66), Ex. 55 (D10 00207247-52), Ex. 57 (D10 00207405-
 13 06) (“With its current resources, Title X is only able to serve one-fifth of the nationwide need for
 14 publicly funded contraceptive care.”), Ex. 82 (D12 00651932-33) (Congressional leaders noting
 15 current efforts to undermine and dismantle Title X), Ex. 57 (D10 00207347), Ex. 74 (D11
 16 00373535-39).

17 **VII. THIS COURT ENJOINED THE FINAL EXEMPTION RULES**

18 On January 13, 2019, this Court issued a preliminary injunction enjoining implementation
 19 of the Exemption Rules. Dkt. No. 234. The Court held that the States had shown that they were
 20 likely to succeed in showing that the Exemption Rules violated the APA. *Id.* at 21-24. The Court
 21 rejected Defendants’ assertion that the Women’s Health Amendment “delegated total authority
 22 [to Defendants] to exempt anyone they wish from the contraceptive mandate.” *Id.* at 22. The
 23 Court then concluded that the religious Exemption Rule is not required by RFRA, noting its
 24 agreement with the eight Courts of Appeals that have concluded that the “accommodation does

25 _____
 26 ¹⁸ Defendants have proposed drastic changes to the Title X program, making it even more
 27 unsuitable as a stop-gap for the Rules. *See* Second Am. Compl. ¶¶ 7, 54-55, 218-222; Ex. 44
 28 (D10 00207044).

¹⁹ The Title X program is subject to discretionary funding. Ex. 57 (D10 00207405). From 2010-
 2014, even as the number of women in need of publicly funded contraceptive care grew by 5%,
 (an additional 1 million women), Congress cut funding for Title X by 10%. *Id.*

1 not impose a substantial burden on objectors’ exercise of religion.” *Id.* at 24-25. The Court
 2 further concluded that the States were likely to succeed on their claim that the Exemption Rules
 3 are arbitrary and capricious because the agencies failed to provide a reasoned explanation for
 4 disregarding facts and circumstances that underlay the prior policy. *Id.* at 37-38. The Court also
 5 concluded that the Moral Exemption Rule was likely contrary to the ACA (*id.* at 38-39), and that
 6 absent a preliminary injunction the States would suffer irreparable harm (*id.* at 39-40).

7 **LEGAL STANDARD**

8 A moving party is entitled to summary judgment if that party demonstrates the absence of a
 9 genuine issue as to any material fact and that he or she is entitled to judgment as a matter of law.
 10 Fed. R. Civ. P. 56(a). Section 706 of the APA governs judicial review of administrative
 11 decisions. Agency actions must be set aside where they are “arbitrary, capricious, an abuse of
 12 discretion, or otherwise not in accordance with law,” or are promulgated “without observance of
 13 procedure required by law.” 5 U.S.C. § 706(2)(A), (D). In contrast to the deferential standard
 14 applied to substantive agency decision-making, “review of an agency’s procedural compliance
 15 with statutory norms is an exacting one.” *NRDC v. SEC*, 606 F.2d 1031, 1048 (D.C. Cir. 1979).
 16 Moreover, in reviewing an agency’s adherence to procedural requirements, courts have found it
 17 appropriate to “scrutinize the procedures employed by the agency all the more closely where the
 18 agency has acted, within a compressed time frame, to reverse itself by the procedure under
 19 challenge.” *NRDC v. EPA*, 683 F.2d 752, 760 (3d Cir. 1982).

20 **ISSUE PRESENTED**

21 Do the Exemption Rules and the IFRs violate the APA and the Constitution?

22 **ARGUMENT**

23 **I. THE EXEMPTION RULES ARE CONTRARY TO LAW**

24 The Exemption Rules must be held “unlawful and set aside” because they are “not in
 25 accordance with the law” and are “in excess of statutory jurisdiction.” 5 U.S.C. §§ 706(2)(A),
 26 706(2)(C).²⁰ Here, Defendants’ Rules are not in accordance with the implementing statute—the
 27 Women’s Health Amendment. Nor is the Religious Exemption Rule compelled or authorized by

28 ²⁰ Although this section refers to the Exemption Rules, the argument applies to the IFRs as well.

1 RFRA. The Rules are also contrary to Section 1554 and Section 1557 of the ACA because they
2 create barriers for women to obtain healthcare coverage, impede timely access to healthcare, and
3 permit employers to exclude women from full and equal participation in their employer-
4 sponsored health plan.

5 **A. The Exemption Rules Are Contrary to the Women’s Health Amendment**

6 Congress did not delegate to HRSA, or any other agency, the ability to promulgate rules
7 undermining the Affordable Care Act’s requirement that women receive no-cost preventive care.
8 The limited authority delegated to HRSA was to issue “guidelines” that would outline what
9 “additional preventive care” “shall” be covered by regulated health plans. The Exemption Rules
10 simply cannot be reconciled with the text or purpose of the Women’s Health Amendment or the
11 ACA—which seek to expand access to women’s healthcare, not limit it.

12 The Rules cannot be harmonized with the plain text of the Women’s Health Amendment.
13 Statutory interpretation “start[s], of course, with the statutory text,” and “statutory terms are
14 generally interpreted in accordance with their ordinary meaning.” *BP Am. Prod. Co. v.*
15 *Burton*, 549 U.S. 84, 91 (2006). Here, the Rules are contrary to the implementing statute itself,
16 which states that “a group health plan and a health insurance issuer offering group or individual
17 health insurance coverage *shall*, at a minimum provide coverage for and shall not impose any cost
18 sharing requirements for . . . (4) with respect to *women*, such additional preventive care and
19 screenings . . . as provided for in comprehensive guidelines supported by the Health Resources
20 and Services Administration for purposes of this paragraph.” 42 U.S.C. § 300gg-13(a)(4)
21 (emphasis added). The statute makes clear that “preventive care” for “women” “shall” be
22 provided by the specified regulated entities. Nothing in this provision either expressly or
23 implicitly allows HRSA to “contradict[] what Congress has said” by crafting exemptions that
24 permit nearly any employer, university, plan sponsor, issuer, or individual to exempt themselves
25 from the statutory requirement. *Entergy Corp. v. Riverkeeper, Inc.*, 556 U.S. 208, 218 n.4 (2009);
26 *Nw. Env’tl. Def. Ctr. v. Bonneville Power Admin.*, 477 F.3d 668, 681-86 (9th Cir. 2007) (setting
27 aside agency action that is contrary to law).

28 ///

1 While Congress did not provide a fixed list of covered “preventive services,” it directed
2 HRSA to delineate the required preventive services. This was reasonable given that HRSA is the
3 “primary federal agency for improving health care to people” and its mission is to “improve
4 health and achieve health equity through access to quality services.”²¹ But Congress made the
5 services defined by HRSA mandatory, by stating that they “shall” be provided.²² See
6 *Kingdomware Technologies, Inc. v. United States*, 136 S. Ct. 1969, 1977 (2016) (“Shall” is a
7 mandatory term that “normally creates an obligation impervious to judicial [or agency]
8 discretion”); see also *Pennsylvania v. Trump*, 281 F. Supp. 3d 553, 578 (E.D. Pa. 2017) (use of
9 the word “shall” indicates that “no exemptions created by HHS are permissible (unless they are
10 required by RFRA)”).

11 Furthermore, Congress did not just instruct HRSA to develop “comprehensive guidelines,”
12 but to do so “for purposes of this paragraph.” 42 U.S.C. § 300gg-13(a)(4). Thus, HRSA’s
13 express, limited role is to craft guidelines carrying out the purpose of the Women’s Health
14 Amendment by determining which additional preventive care services must be provided. HRSA
15 does not have the authority to decide that some employers are exempt from providing statutorily
16 mandated preventive care. See 42 U.S.C. § 300gg-13(a)(4) (mandating that “a group health plan
17 and a health insurance issuer offering group or individual health insurance coverage *shall*,”
18 provide defined preventive services).

19 Here, having included all FDA-approved contraceptives within women’s “preventive
20 care”—first, based on the Institute of Medicine’s recommendations in 2011 and then, based on
21 WPSI’s recommendations in 2016—HRSA cannot now declare that some employers need not
22 provide the care that it determined is statutorily required. See *La. Pub. Serv. Comm’n v. FCC*,

23 ²¹ *About HRSA*, [https://web.archive.org/web/20190302054343/
24 www.hrsa.gov/about/index.html](https://web.archive.org/web/20190302054343/www.hrsa.gov/about/index.html). Notably, HRSA’s expertise is in *providing* access to medical
25 care; it has no expertise in crafting religious or moral exceptions to such care.

26 ²² It would be untenable practically to expect Congress—a body of individuals without medical
27 training—to expressly enumerate the specific services contained within the broad category of
28 “preventive services.” In an evolving discipline such as medicine, new treatments and therapies
are developed and added (and sometimes deleted from or rendered obsolete) to the provider’s
toolkit every year. HRSA itself notes that since the guidelines were originally established in 2011
“there have been advancements in science and gaps identified in the existing guidelines.” See
<https://www.hrsa.gov/womens-guidelines-2016/index.html>.

1 476 U.S. 355, 374 (1986) (“an agency literally has no power to act . . . unless and until Congress
2 confers power upon it”). Even if HRSA would have authority to remove contraceptives from the
3 guidelines, it is very clear that it did not do that. *See* 83 Fed. Reg. at 57,537 (“The rules do not
4 remove the contraceptive coverage requirement generally from HRSA’s guidelines.”). And
5 HRSA clearly does *not* have authority to create exemptions for certain types of employers.

6 Additional statutory text within the ACA demonstrates that Defendants’ interpretation is
7 erroneous. For instance, Congress expressly considered which employers to exempt from the
8 Women’s Health Amendment (grandfathered plans), and it did not exempt employers with
9 religious or moral objections. Further, in enacting the ACA, Congress created moral and
10 religious exemptions—just not for the Women’s Health Amendment. *See, e.g.*, 42 U.S.C. §
11 18113 (providing a statutory exemption for those who have a religious objection to participating
12 in aid-in-dying procedures). And “[w]hen Congress provides exceptions in a statute,” “[t]he
13 proper inference . . . is that Congress considered the issue of exceptions and, in the end, limited
14 that statute to the ones set forth.” *United States v. Johnson*, 529 U.S. 53, 58 (2000); *see*
15 *Leatherman v. Tarrant Cnty. Narcotics Intelligence & Coordination Unit*, 507 U.S. 163, 168
16 (1993) (“*Expressio unius est exclusio alterius*”). Lastly, in enacting the ACA, Congress expressly
17 prohibited HHS from promulgating regulations that would “create[] any unreasonable barriers” to
18 medical care *or* “impede[] timely access to health care services.” 42 U.S.C. § 18114(1), (2); *see*
19 *infra* at 35-36. These statutory indicators undermine Defendants’ position that Congress
20 delegated to them broad authority to promulgate rules permitting employers to exempt themselves
21 from statutory requirements.

22 In fact, Congress rejected an amendment that would have permitted broad moral and
23 religious exemptions to the ACA’s coverage requirements—the same moral and religious
24 exemptions that are reflected in the IFRs and the Exemption Rules. 158 Cong. Rec. S539
25 (suggesting that a “conscience amendment” was necessary because the ACA does not allow
26 employers or plan sponsors “with religious or moral objections to specific items or services to
27
28

1 decline providing or obtaining coverage of such items or services”).²³ This Court should reject
2 Defendants’ attempt to accomplish by regulation what Congress itself expressly declined to do.
3 *See Landgraf v. USI Film Products*, 511 U.S. 244, 285 n.38 (1994) (Courts are “not free to
4 fashion remedies that Congress has specifically chosen not to extend.”); *Pacific Gas & Elec. Co.*
5 *v. Energy Res. Conservation & Dev. Comm’n*, 461 U.S. 190, 220 (1983) (it is “improper [] to
6 give a reading to [an] Act that Congress considered and rejected”); *Doe v. Chao*, 540 U.S. 614,
7 622 (2004) (reversing grant of general damages because the “drafting history show[ed] that
8 Congress cut out the very language in the bill that would have authorized” them).

9 Lastly, the Exemption Rules cannot be squared with Congress’s purpose. Specifically, the
10 ACA’s requirement that certain health plans cover women’s “preventive care and screenings” (42
11 U.S.C. § 300gg-13(a)(4)) was added by the Women’s Health Amendment. The Amendment was
12 designed to ensure that women have equal access to healthcare and are not required to pay more
13 than men for preventive care. The Women’s Health Amendment sought to end the widespread
14 practice of systematically charging “women more than men” for preventive services. 155 Cong.
15 Rec. S12027.²⁴ The Exemption Rules disregard what the Women’s Health Amendment sought to
16 accomplish. *See Securities Indus. Ass’n v. Bd. of Governors of Fed. Reserve Sys.*, 468 U.S. 137,
17 143 (1984) (court must reject construction of a statute that is “inconsistent with the statutory
18 mandate or that frustrate[s] the policy that Congress sought to implement”).

19 More broadly, the ACA, including the Women’s Health Amendment, sought to *provide*
20 affordable, high-quality healthcare to millions of Americans. 42 U.S.C § 18091. Defendants’
21 Rules—which allow employers to eliminate contraceptives from health plans—contravene not
22 only the intent of the Women’s Health Amendment, but the ACA itself. *See Ragsdale v.*

23 _____
24 ²³ *See also Hobby Lobby*, 573 U.S. at 719 n.30; *id.* at 744 (Ginsburg, J., dissenting); 159 Cong.
Rec. S2268.

25 ²⁴ *See id.* at S12051; *id.* at S12027 (“women of child-bearing age spend 68 percent more in out-
26 of-pocket health care costs than men”); *id.* at S12051. This Amendment also fit into the ACA’s
27 overall goals, including Congressional goals of eliminating gender rating, providing maternity
28 coverage, ensuring preventive care for domestic violence survivors, and providing public health
programs for women. Jennifer B. Wheller & Austin Rueschhoff, *Improving Women’s Health
Opportunities and Challenges in Health Reform*, Nat’l Conference of State Legislatures (2012),
<http://www.ncsl.org/documents/health/ImprovWomenshealth112.pdf>.

1 *Wolverine World Wide, Inc.*, 535 U.S. 81, 91-92, 95-96 (2002) (concluding that the challenged
2 regulation is invalid as inconsistent with Congress’s intent).

3 Defendants’ interpretation of the Women’s Health Amendment is not only contrary to the
4 plain statutory text and Congressional purpose, but it runs afoul of separation-of-powers
5 principles and, practically speaking, would render Defendants’ authority limitless. *Whitman v.*
6 *Am. Trucking Ass’ns, Inc.*, 531 U.S. 457, 485 (2001) (agency “may not construe the statute in a
7 way that completely nullifies textually applicable provisions meant to limit its discretion”);
8 *Schein v. Archer & White Sales*, 139 S. Ct. 524, 530 (2019) (the parties and the Court “may not
9 engraft [their] own exceptions onto the statutory text.”). Under their interpretation, HRSA—and
10 by extension HHS, Labor, or Treasury—could exempt all employers from the Women’s Health
11 Amendment because, in their view, HRSA has the authority to determine the “scope” of who
12 must abide by the statutory requirements. But Congress clearly did not intend for HRSA to have
13 unlimited authority to exempt any and all employers from the Women’s Health Amendment; such
14 a notion would defeat the statute itself. *Food & Drug Admin. v. Brown & Williamson Tobacco*
15 *Corp.*, 529 U.S. 120, 133 (2000) (in its statutory interpretation, the court “must be guided to a
16 degree by common sense as to the manner in which Congress is likely to delegate a policy
17 decision of such economic and political magnitude to an administrative agency”). As a branch of
18 a federal agency, HRSA may not issue a regulation unless it has “textual commitment of
19 authority” to do so. *Whitman*, 531 U.S. at 468. This is a fundamental principle of separation of
20 powers. *See Util. Air. Reg. Grp. v. EPA*, 573 U.S. 302, 327 (2014) (allowing an agency to act
21 inconsistently with an “unambiguous statute” violates separation of powers).²⁵

22 _____
23 ²⁵ Defendants are not owed any *Chevron* deference because where Congress has spoken on the
24 issue—here, HRSA’s delegated authority—“the inquiry is at an end; the court must give effect to
25 the unambiguously expressed intent of Congress.” *Food & Drug Admin.*, 529 U.S. at 132
26 (concluding that the FDA lacked authority to regulate certain tobacco products). “Regardless of
27 how serious the [purported] problem an administrative agency seeks to address, [], it may not
28 exercise its authority ‘in a manner that is inconsistent with the administrative structure that
Congress enacted into law.’” *Id.* at 125. As the Court has stated, *Chevron* deference “does not
license interpretive gerrymanders under which an agency keeps parts of statutory context it likes
while throwing away parts it does not.” *See Michigan v. EPA*, 135 S. Ct. 2699, 2708 (2015).
Furthermore, “[a]n agency interpretation . . . which conflicts with the agency’s earlier
interpretation is ‘entitled to considerably less deference’ than a consistently held agency view.”
INS v. Cardoza-Fonseca, 480 U.S. 421, 446 n.30 (1987).

1 **B. The Religious Exemption Rule Is Not Compelled (or Authorized) by RFRA**

2 RFRA provides that the government “shall not substantially burden a person’s exercise of
3 religion even if the burden results from a rule of general applicability” unless the burden: (1) is in
4 furtherance of a compelling governmental interest; and (2) is the least restrictive means of
5 furthering that compelling governmental interest. 42 U.S.C. § 2000bb-1(a)-(b). A “‘substantial
6 burden’ is imposed [] when individuals are . . . coerced to act contrary to their religious beliefs by
7 the threat of civil or criminal sanctions . . .” *Navajo Nation v. U.S. Forest Serv.*, 535 F.3d 1058,
8 1069-70 (9th Cir. 2008). Only after “the plaintiff first proves the government action substantially
9 burdens his exercise of religion” must the government demonstrate that it has employed the least
10 restrictive means of furthering a compelling interest. *Id.* at 1069.

11 Defendants assert that the Religious Exemption Rule is necessary because the
12 accommodation—which was crafted with the sole purpose of relieving any burden on the exercise
13 of religion—itself substantially burdens the exercise of religion. *See, e.g.*, 83 Fed. Reg. at 57,546,
14 57538.²⁶ But that assertion fails at the first step of the analysis. As eight Courts of Appeals have
15 concluded, the act of opting out of providing contraceptive coverage does not substantially
16 burden the exercise of religion. And the existing accommodation is the least restrictive means of
17 furthering the compelling governmental interest in ensuring that women have full and equal
18 access to preventive care, including contraceptives.²⁷ The Religious Exemption Rule, moreover,
19 requires tens of thousands of women to bear the cost of their employers’ religious views about
20 contraceptives. That extensive harm to third parties distinguishes this case from *Hobby Lobby*,
21 *Wheaton College*, and *Zubik*, where the Supreme Court insisted—time and again—that no woman
22 would lose access to coverage for the full range of FDA-approved contraceptives because
23 employers with objections could use the accommodation, which ensures women receive crucial
24 healthcare benefits. RFRA does not require female employees and their female dependents to

25 _____
26 ²⁶ Defendants do not claim that the Moral Exemption Rule is authorized by RFRA. Indeed, Ninth
27 Circuit precedent forecloses any such argument. *See, e.g., United States v. Christie*, 825 F.3d
28 1048, 1056 (9th Cir. 2016).

²⁷ Defendants do not have—nor do they assert—interpretive authority over RFRA. Thus, their
reading of RFRA is entitled to no deference. *See Gonzales v. Oregon*, 546 U.S. 243, 258-259
(2006).

1 forgo their statutorily guaranteed benefits for the sake of their employers’ religious beliefs.

2 **1. The Accommodation Does Not Substantially Burden the Exercise of**
 3 **Religion**

4 Defendants assert that the Religious Exemption Rule was legally mandated because
 5 requiring entities to comply with “the accommodation violate[s] RFRA.” 83 Fed. Reg. at 57,546.
 6 Defendants claim that an employer’s act of informing the government of its religious objections is
 7 inherently problematic because it “triggers” the employers’ insurers to separately provide
 8 contraceptive coverage to their employees, which the employers sincerely believe renders them
 9 “complicit” in the provision of contraceptive coverage. *Id.*; *see also* 82 Fed. Reg. at 47,800. In
 10 other words, Defendants’ complicity-based RFRA argument posits that: opting out of a
 11 generally-applicable requirement will cause the government to reach out to others to fill the
 12 resulting gap, which will cause third parties to engage in lawful conduct that the objector regards
 13 as morally wrong, which would thus make the objector complicit in that moral wrong by way of
 14 their relationship to that third party (such as an employer-employee relationship).

15 Whether a law substantially burdens religious exercise is a legal question for the courts to
 16 decide. Defendants assert that as long as religious employers sincerely believe that participating
 17 in the accommodation makes them complicit in the provision of contraceptive coverage, that
 18 belief establishes—as a matter of law—that the accommodation substantially burdens the exercise
 19 of religion. *See* 83 Fed. Reg. at 57,546; *see also Sharpe Holdings, Inc. v. U.S. Dep’t of Health &*
 20 *Human Servs.*, 801 F.3d 927 (8th Cir. 2015). The States do not question the sincerity of religious
 21 employers’ beliefs. But sincerely held religious beliefs cannot—in and of themselves—answer
 22 the legal question of whether a law imposes a substantial burden under RFRA. 42 U.S.C.
 23 § 2000bb-1(a); *see also Guam v. Guerrero*, 290 F.3d 1210, 1222 n.20 (9th Cir. 2002) (“Whether a
 24 prosecution for importation of marijuana substantially burdens one’s religion is a legal question
 25 for courts to decide.”).

26 First, the text and structure of RFRA do not support Defendants’ position. RFRA expressly
 27 requires that there be a “substantial[] burden” on a person’s “exercise of religion.” 42 U.S.C. §
 28 2000bb-1(a)-(b). Yet Defendants’ argument would “read out of RFRA the condition that only

1 *substantial* burdens on the exercise of religion trigger the compelling interest requirement.”
2 *Catholic Health Care Sys. v. Burwell*, 796 F.3d 207, 217 (2d Cir. 2015) (emphasis added). In
3 other words, RFRA “requires a substantial burden, and assessing substantiality is a matter for the
4 court.” *Id.* at 218. “RFRA’s reference to ‘substantial’ burdens expressly calls for a qualitative
5 assessment of the burden that the accommodation imposes on the [] exercise of religion.”
6 *Geneva Coll. v. Sec’y U.S. Dep’t Health & Human Servs.*, 778 F.3d 422, 442 (3d Cir. 2015).
7 Therefore, “[w]hether a law substantially burdens religious exercise under RFRA is a question of
8 law for courts to decide, not a question of fact.” *Priests for Life v. HHS*, 772 F.3d 229, 247 (D.C.
9 Cir. 2014).

10 Second, Defendants’ contention that a substantial burden is present anytime a litigant
11 sincerely believes it would “collapse the distinction between beliefs and substantial burden, such
12 that the latter could be established simply through the sincerity of the former.” *Catholic Health*
13 *Care Sys.*, 796 F.3d at 218. No case sanctions that result. Defendants misconstrue *Hobby Lobby*
14 in arguing that the accommodation violates RFRA as a matter of law, 83 Fed. Reg. at 57,545,
15 57,546. In that case, HHS took the position that complying with the contraceptive mandate
16 (without the accommodation option) did not burden religion because the connection between
17 providing comprehensive health insurance coverage and the morally objectionable end result “is
18 simply too attenuated.” 573 U.S. at 723. The Court rejected that argument, explaining that:

19 This argument dodges the question that RFRA presents (whether the HHS mandate imposes
20 a substantial burden on the ability of the objecting parties to conduct business in accordance
21 with their religious beliefs) and instead addresses a very different question that the federal
22 courts have no business addressing (whether the religious belief asserted in a RFRA case is
23 reasonable).

22 *Id.* at 724 (second emphasis added); see also *Catholic Health Care Sys.*, 796 F.3d at 218 (“[T]he
23 fact that a RFRA plaintiff considers a regulatory burden substantial does not make it a substantial
24 burden. Were it otherwise, no burden would be insubstantial.”)

25 The Court went on to explain that the accommodation “does not impinge on the plaintiffs’
26 religious belief that providing insurance coverage for the contraceptives at issue here violates
27 their religion, and it serves HHS’s stated interests equally well.” 573 U.S. at 731 (emphasis
28

1 added). The Supreme Court, therefore, accepted the sincerity of petitioners’ religious belief while
2 *also* concluding that the accommodation would not burden it. *Id.* Sincerely held beliefs and
3 substantial burden may not be collapsed into a single inquiry under RFRA.²⁸

4 Third, there would be no limiting principle if courts were required to treat sincerely held
5 beliefs and substantial burden as one and the same. If “RFRA plaintiffs need only to assert that
6 their religious beliefs were substantially burdened, federal courts would be reduced to rubber
7 stamps, and the government would have to defend innumerable actions demanding strict scrutiny
8 analysis.” *Catholic Health Care Sys.*, 796 F.3d at 218. Every plaintiff with a sincere belief that
9 governmental action burdened his or her exercise of religion would be granted an exemption
10 unless the government could meet the “exceptionally demanding” least-restrictive-means
11 standard. *Hobby Lobby*, 573 U.S. at 728.

12 In fact, under this view of RFRA, *any* religious accommodation requiring objectors to
13 notify the government of their objections could be considered a substantial burden on religious
14 exercise solely because of the governmental action taken in response. For example, as several
15 courts have pointed out, a religious conscientious objector to the military draft could object to
16 even notifying the government of his religious opposition because “his act of opting out triggers
17 the drafting of another person in his place.” *Eternal Word Television Network v. Sec’y of U.S.*
18 *Dep’t Health & Human Servs.*, 818 F.3d 1122, 1150 (11th Cir. 2016). Yet the courts “would
19 reject the assertion that the government’s subsequent act of drafting another person in his
20 place . . . transforms the act of lodging a conscientious objection into a substantial burden.” *Id.*;
21 *see also Univ. of Notre Dame v. Burwell*, 786 F.3d 606, 623 (7th Cir. 2015) (same).

22 Fourth, adopting Defendants’ RFRA interpretation would cause significant harm to third
23 parties. *See* Douglas Nejaime & Reva B. Siegel, *Conscience Wars: Complicity-Based*
24 *Conscience Claims in Religion and Politics*, 124 Yale L.J. 2516, 2526-28 (2015). As the
25

26 ²⁸ The Supreme Court has since reaffirmed that evaluating belief and substantial burden is a two-
27 part inquiry. *Holt v. Hobbs*, 135 S.Ct. 853, 862 (2015) (“In addition to showing that the relevant
28 exercise of religion is grounded in a sincerely held religious belief, petitioner bore the burden of
proving that the Department’s grooming policy substantially burdened that exercise of religion.”).

1 government acknowledges, the Religious Exemption Rule will cause up to 126,400 women to
2 lose their contraceptive coverage. 83 Fed. Reg. at 57,551. That is a heavy burden that falls on
3 innocent third parties.²⁹ As discussed below, Defendants’ complicity-based religious claims are
4 far removed from the traditional Free Exercise claims that led to the passage of RFRA. In
5 traditional Free Exercise cases, the effects of the religious accommodation were limited and borne
6 by the government or society as a whole. Discrete groups of citizens were not singled out to bear
7 the costs of another’s religious exercise. Yet that is the result expressly contemplated by the
8 Exemption Rules. RFRA was never intended to inflict such harm on third parties. *See Woodford*
9 *v. Garceau*, 538 U.S. 202, 209 (2003) (relying on the “legal backdrop” against which “Congress
10 legislated” to clarify what Congress enacted).

11 As the statutory text, purpose, and case law demonstrate, whether the accommodation
12 substantially burdens religious exercise is a question of law for this Court to decide.

13 In assessing this legal question, the Court should conclude that the accommodation—
14 carefully designed by HHS to accommodate religious beliefs—does not substantially burden
15 religious exercise because it allows religious objectors to opt out of providing, paying for,
16 referring, contracting, or arranging for contraceptive coverage. *See* 45 C.F.R. § 147.131(d)-(e).
17 Once the insurer is notified by the employer or the Secretary, it “must *expressly exclude*
18 contraceptive coverage from the group health insurance coverage provided in connection with the
19 group health plan and provide *separate* payments for any contraceptive services required to be
20 covered” 45 C.F.R. § 147.131(d)(2)(i) (emphases added). And those separate payments
21 “occur entirely outside the employers’ plans.” *Zubik*, Resp. Supplemental Reply Br., 2016 WL
22 1593410, at *2.

23 Furthermore, the insurer “must segregate premium revenue collected from the eligible
24 organization from the monies used to provide payments for contraceptive services.” 45 C.F.R.

25
26 ²⁹ The need to avoid third party harm has been widely recognized. *See, e.g., Priests for Life v.*
27 *U.S. Dep’t of Health and Human Servs.*, 808 F.3d 1, 26 (D.C. Cir. 2015) (Kavanaugh, J.,
28 dissenting from the denial of rehearing en banc) (“The Government may *of course* continue to
require religious organizations’ *insurers* to provide contraceptive coverage to the religious
organizations’ employees, even if the religious organizations object.” (first emphasis added)).

1 § 147.131(d)(2)(ii). And the insurer must provide separate, written notice to plan participants and
2 beneficiaries that their employer “will not contract, arrange, pay, or refer for contraceptive
3 coverage. Instead, [the insurer] will provide separate payments for contraceptive services that
4 you use” and the employer “will not administer or fund these payments.” *Id.* at (e).

5 Therefore, the accommodation process meticulously separates the employer’s health plan
6 from any involvement in the provision of contraceptive coverage. It is telling that eight out of the
7 nine Courts of Appeals to have considered this issue concluded that the accommodation does not
8 substantially burden the exercise of religion.³⁰ The Supreme Court itself has described the
9 accommodation as “effectively exempt[ing] certain religious nonprofit organizations . . . from the
10 contraceptive mandate.” *Hobby Lobby*, 573 U.S. at 698.

11 As the Eleventh Circuit concluded, “we simply cannot say that RFRA affords the plaintiffs
12 the right to prevent women from obtaining contraceptive coverage to which federal law entitles
13 them based on the de minimis burden that the plaintiffs face in notifying the government that they
14 have a religious objection.” *Eternal Word*, 818 F.3d at 1150.

15 **2. The Accommodation Is the Least Restrictive Means of Furthering the**
16 **Compelling Government Interest in Providing Women with Equal**
17 **Access to Preventive Care**

18 If the Court reaches the second RFRA prong, it should conclude that women’s seamless
19 access to contraceptives is a compelling government interest. As discussed above, the text,
20 structure, purpose, and legislative history of the Women’s Health Amendment demonstrate that
21 Congress viewed women’s full and equal access to preventive healthcare—including
22 contraceptive services—as a compelling governmental interest.

23 Until recently, the federal government expressly recognized the many important benefits of
24 cost-free contraceptive coverage, including: (1) enabling women to avoid the health problems
25 that may occur from unintended pregnancies; (2) avoiding the increased risk of adverse

26 ³⁰ See *Catholic Health Care Sys.*, 796 F.3d at 217-226; *Geneva Coll.*, 778 F.3d at 435-442; *E.*
27 *Tex. Baptist Univ. v. Burwell*, 793 F.3d 449 (5th Cir. 2015); *Mich. Catholic Conference &*
28 *Catholic Family Servs. v. Burwell*, 807 F.3d 738 (6th Cir. 2015); *Univ. of Notre Dame*, 786 F.3d
at 612-619; *Grace Schs. v. Burwell*, 801 F.3d 788 (7th Cir. 2015); *Sharpe Holdings*, 801 F.3d at
941; *Little Sisters of the Poor Home for the Aged, Denver, Colo. v. Burwell*, 794 F.3d 1151 (10th
Cir. 2015); *Eternal Word*, 818 F.3d at 1143-51; *Priests for Life*, 772 F.3d at 247-56.

1 pregnancy outcomes when pregnancies are too closely spaced together; (3) preventing pregnancy
2 when women have medical conditions which would make pregnancy dangerous or life
3 threatening; and (4) securing health benefits from contraceptives that are unrelated to pregnancy,
4 including preventing certain cancers, menstrual disorders, and pelvic pain. *Zubik*, Resp. Br., 2016
5 WL 537623, at *55-57. And contraceptive coverage without cost sharing is especially important
6 because cost barriers discourage the use of contraceptives, particularly IUDs, which have high up-
7 front costs but are especially reliable and effective. *Id.* at *57. The Supreme Court, too, has held
8 that preventing gender discrimination qualified as a compelling government interest. *Roberts v.*
9 *United States Jaycees*, 468 U.S. 609, 625 (1984) (“Assuring women equal access to such goods,
10 privileges, and advantages clearly furthers compelling state interests.”).³¹

11 Defendants do not seriously dispute the extensive legislative history underlying the
12 Women’s Health Amendment, or the bevy of medical, scientific, and public health evidence
13 regarding the importance of contraceptives. Instead, Defendants point to immaterial and
14 irrelevant factors to undermine the compelling interest at stake. 83 Fed. Reg. at 57,546-57,548.
15 Essentially Defendants argue that guaranteeing contraceptive coverage was an act of
16 administrative grace, rather than a Congressional directive that federal agencies are duty-bound to
17 implement. The Supreme Court, however, has recognized that the contraceptive coverage
18 requirement is an important—and likely compelling—interest. *See Hobby Lobby*, 573 U.S. at
19 737-39, 761; *see also Priests for Life*, 808 F.3d at 15 (Kavanaugh, J., dissenting from the denial
20 of rehearing en banc) (“*Hobby Lobby* strongly suggests that the Government has a compelling
21 interest in facilitating access to contraception for the employees of these religious
22 organizations.”). Justice Kennedy was the fifth vote in *Hobby Lobby*, and he noted that religious

23
24 ³¹ *See also Bd. of Dirs. of Rotary Int’l v. Rotary Club of Duarte*, 481 U.S. 537 (1987) (holding
25 that the State was justified in enacting protections for persons, regardless of sex, to full and equal
26 privileges in all business establishments because it had a compelling interest in preventing
27 discrimination against women); *Presbytery of N.J. of the Orthodox Presbyterian Church v.*
28 *Whitman*, 99 F.3d 101 (3d Cir. 1996) (holding that New Jersey had a compelling interest of
preventing discrimination when it added sexual orientation to its list of protected classes); *Doe v.*
Boyertown Area Sch. Dist., 897 F.3d 518 (3d Cir. 2018) (upholding a policy allowing students to
use bathrooms consistent with their gender identity on the grounds that the state had a compelling
interest in protecting transgender students from discrimination).

1 exercise may not “unduly restrict other persons, such as employees, in protecting their own
2 interests, interests the law deems *compelling*.” *Hobby Lobby*, 573 U.S. at 738 (Kennedy, J.,
3 concurring) (emphasis added); *see also Priests for Life*, 808 F.3d at 22-23 (Kavanaugh, J.,
4 dissenting from the denial of rehearing en banc) (“It is not difficult to comprehend” why
5 facilitating access to contraceptive coverage is a “compelling interest”).³²

6 Defendants also claim that the contraceptive coverage requirement cannot be a compelling
7 governmental interest primarily because: (1) the ACA exempted small businesses, grandfathered
8 health plans, and churches; and (2) various state programs provide contraceptives. 83 Fed. Reg.
9 57,547, 57,548. Neither of these rationales is persuasive.

10 First, that the ACA exempted some employers from providing contraceptive coverage does
11 not undermine the compelling nature of the underlying interest. Grandfathered plans are a short-
12 lived and transitional measure;³³ small employers need not provide health insurance at all but are
13 required to provide contraceptive coverage if they choose to do so;³⁴ and exempting houses of
14 worship acknowledges “our nation’s longstanding history of deferring to a house of worship’s
15 decisions about its internal affairs.” *Eternal Word*, 818 F.3d at 1155-1157. Every compelling
16 governmental interest—including raising revenue through taxation, conscripting an army through
17 a draft, and protecting citizens from discrimination in a wide range of areas—might be subject to
18 exceptions under appropriate circumstances. *See, e.g., United States v. Lee*, 455 U.S. 252, 261
19 (1982) (recognizing exemption to participating on the social security system for self-employed
20 Amish, but not for employees of an Amish employer).

21 _____
22 ³² *See also id.* (further noting that “50% of all pregnancies in the United States are unintended”
which “causes significant social and economic costs” and thus “numerous benefits would follow
from reducing the number of unintended pregnancies . . .”).

23 ³³ *See Hobby Lobby*, 573 U.S. at 764 (Ginsburg, J., dissenting) (Grandfathering these plans was a
24 “temporary,” transitional measure, “intended to be a means for gradually transitioning employers
25 into mandatory coverage.”); *see also 2018 Employer Health Benefits Survey*, Kaiser Family
26 Found. (Oct. 3, 2018), [https://www.kff.org/report-section/2018-employer-health-benefits-survey-
section-13-grandfathered-health-plans/](https://www.kff.org/report-section/2018-employer-health-benefits-survey-section-13-grandfathered-health-plans/) (showing decline in percentage of workers enrolled in a
grandfathered plan from 36% in 2013 to 26% in 2014 and to 17% in 2017); Ex. 13 (D4 000663).

27 ³⁴ Moreover, “[f]ederal statutes often include exemptions for small employers, and such
28 provisions have never been held to undermine the interests served by these statutes.” *Hobby
Lobby*, 573 U.S. at 763 (Ginsburg, J., dissenting).

1 Second, the fact that *some* (a minority of) states provide contraceptives to low-income
2 women does not diminish the federal government’s interest in ensuring that female employees
3 across the country receive preventive care at no cost, just like their male colleagues. *See* 77 Fed.
4 Reg. at 8,728 (explaining that pre-ACA coverage created a “disparity” that “place[d] women in
5 the workplace at a disadvantage compared to their male co-workers”). Indeed, the federal
6 government previously estimated that the contraceptive mandate protects over 100 million
7 employees and dependents. *Zubik, Resp. Br.*, 2016 WL 537623, at *62. The final Rule itself
8 estimates “that 55.6 million women aged 15 to 64 were covered by private insurance [that] had
9 preventive services coverage under the Affordable Care Act.” 83 Fed. Reg. at 57,578. State
10 programs come nowhere close to replicating that, nor do they have the capacity to do so. *See*
11 *generally* Ex. 58 (D10 00207600-05), Ex. 57 (D10 00207355-58), Ex. 57 (D10 00207374), Ex.
12 57 (D10 00207381-82), Ex. 57 (D10 00207410-18). And such programs exist only in certain
13 states and are typically means-tested; they are not broadly available to all women. *See, e.g.*, Ex.
14 57 (D10 00207405-08). Nor is there any legal support for the notion that because states have also
15 taken steps to address a problem, the federal government’s interest in solving the same problem is
16 less compelling.

17 In light of the text, structure, purpose, and legislative history of the Women’s Health
18 Amendment, the contraceptive mandate furthers a compelling governmental interest. No
19 appellate court has ruled to the contrary.

20 The accommodation is the least restrictive means of ensuring that women continue to
21 receive their statutorily entitled benefits, while accommodating religion. Providing contraceptive
22 services seamlessly with other health services—and without cost-sharing or additional logistical
23 or administrative hurdles to receiving that coverage—is the most effective means of ensuring that
24 women have full and complete access to contraceptives. *See, e.g., Eternal Word*, 818 F.3d at
25 1158 (“Because there are no less restrictive means available that serve the government’s interest
26 equally well, we hold that the mandate and accommodation survive strict scrutiny under
27 RFRA.”).

28 ///

1 In determining whether the accommodation is the least restrictive means of furthering a
2 compelling interest, a primary consideration is whether other alternatives would impose harm on
3 third parties. In *Hobby Lobby*, the Court instructed that “courts must take adequate account of the
4 burdens a requested accommodation may impose on nonbeneficiaries” which “will often inform
5 the analysis of the Government’s compelling interest and the availability of a less restrictive
6 means of advancing that interest.” 573 U.S. at 729 n.37; *see also id.* at 739 (Kennedy, J.,
7 concurring) (religious exercise should not “unduly restrict other persons, such as employees, in
8 protecting their own interests, interests the law deems compelling.”).

9 Here, the Religious Exemption Rule requires tens of thousands of women (at a minimum)
10 to bear the cost of their employers’ religious views about contraceptives. That result sets this case
11 apart from every other contraceptive mandate case that has come before the Supreme Court. The
12 common thread in *Hobby Lobby*, *Wheaton College*, and *Zubik* was the Supreme Court’s
13 insistence that no woman would lose access to the full range of FDA-approved contraceptives
14 because of the accommodation—a result that is no longer the case under the Religious and Moral
15 Exemption Rules. *See Hobby Lobby*, 573 U.S. at 693 (“Under that accommodation, these women
16 would still be entitled to all FDA-approved contraceptives without cost sharing.”); *Wheaton*
17 *College v. Burwell*, 573 U.S. 958 (2014) (“Nothing in this interim order affects the ability of the
18 applicant’s employees and students to obtain, without cost, the full range of FDA approved
19 contraceptives”); *Zubik*, 136 S. Ct. at 1560-61 (“Nothing in this opinion . . . is to affect the ability
20 of the Government to ensure that women covered by petitioners’ health plans ‘obtain, without
21 cost, the full range of FDA approved contraceptives.’”) (internal citation omitted).

22 The Court’s emphatic and repeated insistence in these cases that women would not lose
23 their statutory right to contraceptive coverage is no accident. The Court’s concern about third
24 party harm reflects the fact that in traditional Free Exercise cases, the effects of the religious
25 accommodation were limited and borne by the government or society as a whole. That is,
26 discrete groups of citizens were not singled out to bear the costs of another’s religious exercise.³⁵

27 _____
28 ³⁵ *See* Nejaime & Siegel, 124 Yale L.J. at 2526-28 (in the free exercise decisions that led to the

1 In particular, Congress enacted RFRA “in direct response” to the Supreme Court’s decision in
2 *Employment Division v. Smith*, 494 U.S. 872 (1990). *City of Boerne v. Flores*, 521 U.S. 507,
3 512-13 (1997). In *Smith*, the Supreme Court rejected a Free Exercise claim brought by members
4 of the Native American Church who were denied unemployment benefits when they lost their
5 jobs for using peyote (a banned substance) for sacramental purposes. *Id.* Critically, the religious
6 accommodation sought in *Smith*—and in other seminal cases—would not have harmed third
7 parties in order to accommodate religion.

8 This principle has held true in both Free Exercise and Establishment Clause cases. For
9 example, in another Free Exercise case, the Court rejected religious claims that would “impose
10 the employer’s religious faith on the employees.” *Lee*, 455 U.S. at 261 (refusing to exempt
11 Amish employer and his employees from social security taxes). Conversely, courts have invoked
12 the Establishment Clause to invalidate accommodations which “would require the imposition of
13 significant burdens on other employees.” *Estate of Thornton v. Caldor, Inc.*, 472 U.S. 703, 710
14 (1985) (invalidating Connecticut statute which gave Sabbath observers an absolute and
15 unqualified right not to work on the Sabbath).

16 Thus, harm to third party employees is an important part of the RFRA analysis. *Hobby*
17 *Lobby*, 573 U.S. at 729 n.37. The existing accommodation is the least restrictive means of
18 ensuring that women continue to receive the benefits to which they are statutorily entitled,
19 especially when the alternative proposed—any employer with a religious or moral objection can
20 self-exempt without informing anyone—would deprive those employers’ female employees and
21 female dependents of contraceptive coverage.

22 To the extent that Defendants assert that the federal government could directly provide
23 contraceptives for affected women, such as through the Title X program, such an argument must
24 fail. Such a solution would not serve the government’s interests equally well because eligible
25 women: (1) would be required to take additional steps outside of their normal coverage to access
26 care, thereby undermining the “fundamental inequity” that the Women’s Health Amendment

27 _____
28 passage of RFRA, “accommodating the religious liberty claims would not have harmed
specifically identified third parties,” citing *Sherbert v. Verner*, *Wisconsin v. Yoder*, and
Employment Division v. Smith).

1 sought to remedy (155 Cong. Rec. S12027); (2) are not guaranteed to receive contraceptives
2 through Title X because Title X provides that “the project director *may* consider” a woman as
3 eligible;³⁶ and (3) would not receive contraceptives within their normal healthcare framework and
4 from their current doctors. The Title X program is also ill-equipped to replace the seamless
5 contraceptive-coverage requirement. Ex. 57 (D10 00207405-08), Ex. 58 (D10 00207607-10), Ex.
6 44 (D10 00207048-49), Ex. 75 (D11 00373565-69), Ex. 57 (D10 00207351), Ex. 27 (D10
7 00195098), Ex. 80 (D11 00454733-36), Ex. 55 (D10 00207247-51), Ex. 73 (D11 00373509), Ex.
8 74 (D11 00373535-36). This purported remedy does not erase the threat inflicted by the Rules; it
9 compounds the injury and expects the States to pick up the costs.

10 For all of these reasons, the Religious Exemption Rule is not required by RFRA. Nor does
11 RFRA independently authorize the Religious Exemption Rule. Defendants have cited no case for
12 the proposition that RFRA gives federal agencies sweeping authority to create broad exemptions
13 to generally applicable statutory law. That failure is remarkable given that RFRA—and its
14 companion statute, the Religious Land Use and Institutionalized Persons Act of 2000
15 (RLUIPA)—have been the basis for hundreds of federal lawsuits over the past decades.
16 Defendants’ only case supporting this argument is *Ricci v. DeStefano*, 557 U.S. 557 (2009), but
17 that is not even a RFRA case. There, the Court addressed how to resolve a conflict between Title
18 VII’s disparate treatment and disparate impact provisions. *Id.* at 584. That analysis was limited
19 to those statutory provisions and sheds no light on whether RFRA grants federal agencies license
20 to create broad exemptions from otherwise applicable federal law.

21 Defendants’ argument also overlooks that the language and structure of RFRA envisions
22 *individualized* exceptions to generally applicable laws. And such exceptions are recognized by
23 the courts on a case-by-case basis. *See* 42 U.S.C. § 2000bb-1(c) (“[a] *person* whose religious
24 exercise has been burdened in violation of this section may assert that violation as a claim or
25 defense in a judicial proceeding and obtain appropriate relief against a government.” (emphasis
26 added). The legislative history underscores that one of the express “purposes” of RFRA was “to
27

28 ³⁶ *See* 84 Fed. Reg. 7,714 (Mar. 4, 2019).

1 provide a claim or defense to persons whose religious exercise is substantially burdened by
2 government.” *See* Religious Freedom Restoration Act of 1993, PL 103–141, November 16, 1993,
3 107 Stat. 1488 (emphasis added).

4 Supreme Court precedent affirms this statutory framework. In *Gonzales v. O Centro*
5 *Espirita Beneficente Uniao do Vegetal*, 546 U.S. 418, 423 (2006), the Supreme Court upheld an
6 injunction against prosecuting members of a religious sect that received communion by drinking a
7 sacramental tea that included banned hallucinogens. The Court explained that “RFRA requires
8 the Government to demonstrate that the compelling interest test is satisfied through application of
9 the challenged law ‘to the person’—the particular claimant whose sincere exercise of religion is
10 being substantially burdened.” *Id.* at 430-31 (emphasis added). The Court further noted that
11 “RFRA, however, plainly contemplates that *courts* would recognize exceptions—that is how the
12 law works.” *Id.* at 434. And the Court emphasized that “[w]e reaffirmed just last Term the
13 feasibility of case-by-case consideration of religious exemptions to generally applicable rules.”
14 *Id.* at 436 (citing *Cutter v. Wilkinson*, 544 U.S. 709 (2005)); *see also Hobbs*, 135 S. Ct. at 859
15 (“We hold that the Department’s policy, as applied *in this case*, violates [RLUIPA].” (emphasis
16 added)). RFRA contemplates courts granting individual exemptions to federal statutes on a case-
17 by-case basis. There is no statutory basis for the notion that RFRA permits agencies to impose
18 broad, categorical exemptions to federal statutes that are not premised on a case-specific
19 evaluation of the need for an exemption.³⁷

20 Even setting aside the issue of whether federal agencies maintain the broad authority
21 claimed by Defendants in this case, the question remains whether RFRA leaves space for
22 governmental action that is “permissible under RFRA, even if it is not mandated by RFRA.” Dkt
23 No. 234 at 34. In raising this question, the Court noted that “there is room for play in the joints”
24 between the Free Exercise and Establishment Clauses, such that there is “some space for

25 _____
26 ³⁷ The Little Sisters have also pointed to 42 U.S.C. § 2000bb-4, but that provision—titled
27 “Establishment clause unaffected”—merely provides that exemptions that otherwise comply with
28 the Establishment Clause “shall not constitute a violation of this chapter.” That provision does
not authorize federal agencies to affirmatively create categorical exemptions to federal statutes
based on their view of RFRA. Defendants have pointed to no authority so stating, and the
Plaintiffs are aware of none.

1 legislative action neither compelled by the Free Exercise Clause nor prohibited by the
2 Establishment Clause.” *Id.* (citing *Cutter*, 544 U.S. at 719). As a preliminary matter, as
3 discussed *infra*, the Religious Exemption Rule *does* violate the Establishment Clause. Moreover,
4 whatever “play in the joints” might exist in other circumstances, such flexibility cannot exist
5 where, as here, it deprives tens of thousands of women of their rights under a different federal
6 statute (the Women’s Health Amendment). In *Cutter*, a unanimous Court emphasized that
7 “courts must take adequate account of the burdens a requested accommodation may impose on
8 nonbeneficiaries” and that a religious accommodation “must be measured so that it does not
9 override other significant interests.” *Cutter*, 544 U.S. at 720, 722. That principle is especially
10 true where, as here, third parties would be deprived of their statutorily-guaranteed rights. RFRA
11 neither requires nor permits the exceptionally broad Religious Exemption Rule.

12 To the extent that Defendants are arguing that RFRA and the Women’s Health Amendment
13 are fundamentally incompatible, such that the former displaces the latter, that contention lacks
14 merit. The Ninth Circuit recently emphasized that “[w]e will not easily conclude that one federal
15 statute preempts another. A party seeking to suggest that two statutes cannot be harmonized, and
16 that one displaces the other, bears the heavy burden of showing a clearly expressed congressional
17 intention that such a result should follow.” *BNSF Railway Co. v. Cal. Dep’t of Tax and Fee*
18 *Admin.*, 904 F.3d 755, 761 (9th Cir. 2018) (internal citations omitted). To the extent that an
19 apparent conflict exists between two federal statutes, “the courts must strive to harmonize the two
20 laws, giving effect to both laws if possible.” *Id.* (citing *Ass’n of Am. R.R. v. S. Coast Air Quality*
21 *Mgmt. Dist.*, 622 F.3d 1094, 1097 (9th Cir. 2010)). The Religious Exemption Rule, which
22 disavows any obligation to ensure contraceptive coverage under the ACA while permitting nearly
23 any employer to unilaterally disregard the contraceptive mandate, categorically fails to harmonize
24 these two congressional directives. It simply prioritizes one federal statute at the expense of
25 another, which it cannot lawfully do. *Id.*

26 For all of these reasons, the Religious Exemption Rule is neither compelled nor authorized
27 by RFRA.

28 ///

1 **C. The Moral Exemption Rule is Not Mandated by Any Legislation**

2 Defendants do not point to a specific congressional enactment authorizing the agencies to
3 promulgate the Moral Exemption Rule. Instead, Defendants broadly assert that the Moral Rule is
4 generally supported by “founding principles,” various congressional enactments, federal
5 regulations, court precedents, and other state laws and regulations. *See generally* 83 Fed. Reg.
6 57,599-57,601. Defendants argue that these laws highlight “Congress’s history of providing”
7 conscience protections. 83 Fed. Reg. 57,596. But, as this Court noted, these laws “highlight[]
8 the problem; here, it was the agencies, not Congress, that implemented the Moral Exemption, and
9 it is inconsistent with the language and purpose of the statute that it purports to interpret.” Dkt
10 No. 234 at 38-39.

11 In fact, Defendants highlight that the ACA itself contains conscience protections pertaining
12 to euthanasia. 83 Fed. Reg. 57,618 (citing 42 U.S.C. § 18113). But “where Congress includes
13 particular language in one section of a statute but omits it in another section of the same Act, it is
14 generally presumed that Congress acts intentionally and purposely in the disparate inclusion or
15 exclusion.” *Russello v. United States*, 464 U.S. 16, 23 (1983). Here, Congress did not include
16 such an exemption for the Women’s Health Amendment. On the contrary, as discussed above,
17 Congress considered—and rejected—adding a conscience amendment to the Women’s Health
18 Amendment. *See supra* at 18-19.

19 **D. The Exemption Rules Create Barriers for Women to Obtain Healthcare
20 Coverage and Impede Timely Access to Healthcare, Thereby Violating the
ACA**

21 Congress was clear in its directive to HHS: The Secretary “shall not promulgate *any*
22 regulation that—(1) creates *any* unreasonable barrier to the ability of an individual to obtain
23 appropriate medical care [or] (2) impedes *timely access* to health care services.” 42 U.S.C.
24 § 18114(1), (2) (emphasis added). These Exemption Rules, at a minimum, will result in women
25 *losing* full and equal healthcare coverage, which necessarily will create additional barriers for
26 women seeking healthcare. Without complete coverage, women will need to pay out-of-pocket
27 for their basic healthcare services, unless they secure funding from other sources. Ex. 57 (D10
28 00207394) (without coverage, contraceptives cost \$50 per month or upwards of \$600 per year);

1 *id.* (cost of IUD exceeds \$1000, which equates to a month’s salary for a woman working full time
2 at the federal minimum wage of \$7.25 an hour); *see also* Ex. 57 (D10 00207310-11) (describing
3 cost barriers to various highly effective methods of contraception). Women who lose
4 contraceptive coverage may also need to locate and secure a separate qualified medical provider,
5 which may require transferring medical records or re-providing a complete medical history to a
6 new provider to ensure proper care. Ex. 57 (D10 00207368-69), Ex. 57 (D10 207401-02)
7 (explaining the importance of seamless holistic coverage to ensure that women’s “chosen
8 provider” can “manage all health conditions and needs at the same time”). Women may also need
9 to switch to a less expensive, but less effective, contraceptive method given the requirement to
10 pay out-of-pocket. Ex. 57 (D10 00207393-94) (“[e]xtensive empirical evidence demonstrates
11 what common sense would predict: eliminating costs leads to more effective and continuous use
12 of contraception”); Ex. 57 (D10 00207395), Ex. 57 (D10 00207311-12). By impeding access to
13 contraceptives, these obstacles, “in turn, will increase those women’s risk of unintended
14 pregnancy and interfere with their ability to plan and space wanted pregnancies. These barriers
15 could therefore have considerable negative health, social and economic impacts for those women
16 and their families.” Ex. 57 (D10 00207401), Ex. 57 (D10 00207402-04) (describing health,
17 economic and social harms to women facing unintended pregnancies). These consequences
18 demonstrate that the Rules undeniably create barriers obstructing women’s access to care; this
19 disruption in continuity of care results in delayed or no access to contraception. *See California v.*
20 *Azar*, 2019 WL 1877392, at *24 (N.D. Cal. Apr. 26, 2019) (concluding that HHS likely violated
21 Section 1554 where Title X regulations “obfuscate and obstruct patients from receiving
22 information and treatment for their pressing medical needs”).

23 **E. The Exemption Rules Violate the ACA’s Nondiscrimination Provision**

24 The Exemption Rules must be held unlawful and set aside because they permit employers
25 to exclude women from full and equal participation in their employer-sponsored health plan, deny
26 women full and equal healthcare benefits, and license employers to discriminate on the basis of
27 sex. 42 U.S.C. § 18116. Section 1557 of the ACA states that an “individual shall not . . . be
28 excluded from participation in, be denied the benefits of, or be subjected to discrimination under,

1 any health program or activity” on the basis of sex. 42 U.S.C. § 18116(a); 20 U.S.C. § 1681(a);
2 *see also* Commission Decision on Coverage of Contraception, U.S. Equal Employment
3 Opportunity Commission, 2000 WL 33407187 (Dec. 14, 2000) (concluding that offering
4 coverage for preventive prescription drugs and services but not contraception constitutes
5 discrimination on the basis of sex).

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

13 **II. THE EXEMPTION RULES ARE INVALID BECAUSE THEY ARE ARBITRARY AND**
14 **CAPRICIOUS**

15 A rule is arbitrary and capricious if the agency has (1) “entirely failed to consider an
16 important aspect of the problem,” (2) “offered an explanation for its decision that runs counter to
17 the evidence before the agency,” (3) “relied on factors which Congress has not intended it to
18 consider,” or (4) “is so implausible that it could not be ascribed to a difference in view or the
19 product of agency expertise.” *Motor Vehicle Mfrs. Ass’n of U.S., Inc. v. State Farm Mut. Auto.*
20 *Ins. Co.*, 463 U.S. 29, 43 (1983) (“*State Farm*”). In reviewing Defendants’ actions, this Court
21 must engage in “a thorough, probing, in-depth review.” *Citizens to Preserve Overton Park, Inc.*
22 *v. Volpe*, 401 U.S. 402, 416 (1971), *overruled on other grounds by Califano v. Sanders*, 430 U.S.
23 99, 105 (1977). And where an agency departs from a prior policy, it must “display awareness that
24 it is changing position,” show that “there are good reasons” for the reversal, and demonstrate that
25 its new policy is “permissible under the statute.” *F.C.C. v. Fox Television Stations, Inc.*, 556 U.S.
26 502, 515 (2009); *see also State Farm*, 463 U.S. at 42 (an agency rescinding a rule must supply a
27
28

1 reasoned analysis for the change). Here, Defendants' Exemption Rules fail for the
2 aforementioned reasons.³⁸

3 **A. Defendants Failed to Provide a Reasoned Explanation for their Policy**
4 **Reversal**

5 Since 2012 Defendants have required coverage of women's preventive services provided
6 for in the HRSA guidelines, including all FDA-approved contraceptives. 77 Fed. Reg. at 8,725.
7 The prior regulatory scheme, including the 2016 exemption and accommodation process,
8 involved several years of reasoned process, including consideration of the IOM's 2011 expert
9 committee report, WPSI's 2016 Final Report, public comment, and two Supreme Court decisions.
10 Indeed, the IOM's committee and WPSI included expert researchers, practitioners, and other
11 leaders in preventive and women's medicine, used a rigorous methodology, examining high-
12 quality systematic evidence, peer-reviewed studies, federal priorities, and existing professional
13 guidelines, and state, federal, and international practices to "systematically query support for each
14 potential preventive measure."³⁹ Most recently, after considering over 54,000 responses to a
15 request for information, Defendants concluded on January 9, 2017, that the accommodation
16 complied with RFRA by protecting the interests of religious objectors, while also fulfilling the
17 agencies' statutory duty to ensure women retained access to no-cost contraceptive coverage.⁴⁰
18 Defendants' Exemption Rules constitute a complete change in position and Defendants have
19 failed to adequately explain this reversal.

20 **1. Because of the Serious Reliance Interests at Stake, Defendants Must**
21 **Meet a Higher Standard**

22 Where, as here, "serious reliance interests [are] at stake," Defendants' "conclusory
23

24 ³⁸ Although this section generally refers to the Exemption Rules, the arguments apply to the IFRs
as well.

25 ³⁹ Ex. 9 (D4 000289-293) (IOM committee members and reviewers), Ex. 9 (D4 000312)
26 (structure for updating preventive services), Ex. 9 (D4 000374) (four categories of evidence "to
27 systematically query support for each potential preventive measure"), Ex. 25 (D9 669077-78)
(WPSI structure and participating organizations), Ex. 25 (D9 669080) (best evidence approach),
Ex. 24 (D9 668955-668970) (recommendations, evidence map, and study summaries).

28 ⁴⁰ Ex. 19 (D9 666661-62) (also available at www.dol.gov/sites/default/files/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-36.pdf), Ex. 19 (D9 666650-51).

1 statements do not suffice to explain its decision.” *Encino Motorcars, LLC v. Navarro*, 136 S. Ct.
2 2117, 2127 (2016). As this Court previously concluded, given the “serious reliance interests” of
3 women who would lose coverage to which they are statutorily entitled if the Final Rules go into
4 effect, a reasoned explanation for disregarding facts and circumstances that underlay or were
5 engendered by the prior policy is required. Dkt. No. 234 at 37. Indeed, since 2012, millions of
6 women across the country have relied on the ACA’s contraceptive-coverage requirement. Ex. 57
7 (D10 00207404), Ex. 49 (D10 00207145-46), Ex. 30 (D10 00195139-41) (noting that women of
8 color made up the majority of those who gained contraceptive coverage and thus will be the
9 population most affected by efforts to curtail those gains), Ex. 76 (D11 00396709-711), Ex. 47
10 (D10 00207116-17), Ex. 68 (D10 00209104-06), Ex. 29 (D10 00195127), Ex. 37 (D10
11 00206955-56), Ex. 55 (D10 00207238), Ex. 54 (D10 00207234). HHS itself estimated that 30
12 million women gained access to contraceptive coverage due to the Women’s Health Amendment.
13 Ex. 17 (D9 571363); *see also* 83 Fed. Reg. at 57,551 (estimating that up to 126,400 women stand
14 to lose contraceptive coverage due to the Religious Exemption Rule). As HHS’s own statements
15 demonstrate, women nationwide rely on the Women’s Health Amendment for full and equal
16 healthcare coverage. Because Defendants’ policy reversal implicates these “serious reliance
17 interests,” it must be justified by a more “reasoned explanation.” *Encino Motorcars*, 136 S. Ct. at
18 2125-26; *see also Fox*, 556 U.S. at 535-36 (Kennedy, J., concurring). And when agencies seek to
19 disregard facts underlying the original rule, they must provide “a more detailed justification than
20 what would suffice for new policy created on a blank slate.” *Fox*, 556 U.S. at 515; *Encino*
21 *Motorcars*, 136 S. Ct. at 2126. For the reasons explained below, Defendants have failed to meet
22 that test.

23 **2. The Evidence Before the Agency Is Clear that Contraception is Safe** 24 **and Effective**

25 Defendants’ Exemption Rules fail to provide the requisite reasoned explanation,
26 particularly given the lack of any material change in the underlying factual and legal
27 circumstances that supported their prior position. *Encino Motorcars*, 136 S. Ct. at 2126 (“a
28 reasoned explanation is needed for disregarding facts and circumstances that underlay or were

1 engendered by the prior policy,” or the “unexplained inconsistency” will be held arbitrary and
2 capricious); *State v. Bureau of Land Mgmt.*, 277 F. Supp. 3d 1106, 1123 (N.D. Cal. 2017)
3 (concluding that agency violated the APA when it failed to provide a reasoned explanation for its
4 decision to suspend a rule based on the rule’s costs, while ignoring its benefits).

5 Defendants primarily explain that their changed policy is due in part to “more uncertainty”
6 regarding the efficacy and health benefits of contraceptives. 83 Fed. Reg. at 57,552-55. But the
7 rulemaking record does not conclude that the health benefits of contraceptives are scientifically
8 less certain. *Id.* Rather, Defendants simply cite commentators on both sides of the issue and then
9 conclude that “we do not take a position on the variety of empirical questions discussed above.”
10 83 Fed. Reg. at 57,555. Nevertheless, they used the purported “uncertainty surrounding these
11 weighty and important issues” to justify the new, expanded exemptions. *Id.*

12 But this explanation runs counter to Defendants’ own statements and evidence. As a
13 threshold matter, HRSA guidelines continue to require coverage of the full range of FDA-
14 approved contraceptive methods. And HHS continues to inform women that birth control is
15 generally safe, depending on the type of birth control used and a woman’s individual health, and
16 directs women to talk to their doctor about the right method.⁴¹ And absent “[n]ew facts or
17 evidence coming to light, considerations that [the agency] left out in its previous analysis, or
18 some other concrete basis supported in the record,” Defendants cannot just “casually ignor[e] all
19 of [the] previous findings and arbitrarily chang[e] course.” *State v. Bureau of Land Mgmt.*, 286 F.
20 Supp. 3d 1054, 1068 (N.D. Cal. 2018); *see also U.S. Bureau of Land Mgmt.*, 277 F. Supp. 3d. at
21 1123 (new administrations are entitled to change policy positions, but they must give reasoned
22 explanations for those changes and address the prior factual findings).

23 Moreover, Defendants’ explanation runs counter to the evidence before the agencies in this
24 rulemaking. Our country’s leading medical organizations filed comment letters explaining that
25 the assertions in the IFRs regarding purported “uncertainty” were inaccurate. *See infra* at 46-48
26 (listing the comment letters); *see also, e.g.*, Ex. 71 (D11 00328171-72) (letter from ACOG

27 _____
28 ⁴¹ Ex. 23 (D9 668365-66); *see also Birth Control Methods*, Office of Women’s Health, HHS,
available at <https://www.womenshealth.gov/a-z-topics/birth-control-methods>.

1 describing statements within the IFRs as “false and misleading”). The overwhelming evidence
2 before the agency, consistent with the conclusions rendered by the IOM and the WPSI—and
3 adopted by HRSA and HHS—demonstrate that there is no “uncertainty” about contraceptives.
4 *See California*, 2019 WL 1877392, at *36 (finding arbitrary and capricious Title X regulations
5 based on “confusion” manufactured by HHS that was contrary to an industry-accepted
6 understanding). Given this, Defendants’ Exemption Rules fail to provide the requisite reasoned
7 explanation, particularly given the lack of any material change in the underlying factual and legal
8 circumstances that supported their prior position. *Encino Motorcars*, 136 S. Ct. at 2126.

9 And Defendants do not explain why any purported “uncertainty” regarding health risks
10 cannot be adequately addressed through a woman’s consultation with her personal physician, a
11 fact that several commenters noted. Ex. 40 (D10 00206988-91) (American Academy of Nursing
12 objecting to the IFRs interference with the patient-provider relationship). An agency must
13 consider significant alternatives to the course it ultimately chooses. *Allied Local & Reg’l Mfrs.*
14 *Caucus v. EPA*, 215 F.3d 61, 80 (D.C. Cir. 2000); *Yakima Valley Cabelvision, Inc. v. F.C.C.*, 794
15 F.2d 737, 746 n.36 (D.C. Cir. 1986) (“The failure of an agency to consider obvious alternatives
16 has led uniformly to reversal”) (citing cases); *Farmers Union Cent. Exch., Inc. v. F.E.R.C.*, 734
17 F.2d 1486, 1511 (D.C. Cir. 1984) (“It is well established that an agency has a duty to consider
18 responsible alternatives to its chosen policy and to give a reasoned explanation for its rejection of
19 such alternatives.”). Defendants’ refusal to consider this alternative is inconsistent with HHS’s
20 position elsewhere that women seeking access to contraception can manage health risks by
21 consulting and following the guidance of their personal physician. Ex. 23 (D9 668365-66); *see*
22 *also Birth Control Methods*, Office of Women’s Health, HHS, available at
23 <https://www.womenshealth.gov/a-z-topics/birth-control-methods>.

24 **3. Defendants Disregarded Extensive Record Evidence to Wrongly** 25 **Claim that the Contraceptive Mandate Has Not Yielded Benefits**

26 Defendants attempt to justify the Exemption Rules by asserting that the contraceptive
27 coverage requirement is not increasing contraceptive use or reducing unintended pregnancy. 83
28 Fed. Reg. at 57,555. But the evidence overwhelmingly contradicts this justification. As a

1 preliminary matter, expert panels involved in the IOM and WPSI reviews that underlie the HRSA
2 guidelines recognized the importance of cost reductions in improving access to contraception, and
3 increasing consistent, correct usage of contraception. Ex. 9 (D4 000405-07); Ex. 24 (D9 668960-
4 65). Indeed, in prior litigation, Defendants also took the position that the coverage mandates will
5 decrease costs for women, which will improve access and use of contraceptives. *See Hobby*
6 *Lobby*, 573 U.S. at 727 (“HHS tells us that ‘studies have demonstrated that even moderate
7 copayments for preventive services can deter patients from receiving those services.’”).

8 A multitude of established medical groups vigorously disputed Defendants’ new claim that
9 the contraceptive mandate is ineffective, but yet again Defendants declined to respond. *See infra*
10 at 46-48. Defendants instead relied on a handful of limited studies. But, as commenters pointed
11 out, these studies are incomplete and inaccurate because they analyze population-wide data to
12 discern a statistically significant uptick in contraceptive usage, though the contraceptive
13 requirement only impacted a subset of the population overall. Ex. 57 (D10 00207399-400), Ex.
14 56 (D10 00207259). Furthermore, as one expert explained, multiple variables affect women’s
15 contraceptive use in various ways, and this complicates the development of empirical evidence to
16 prove the mandate’s precise impact. *Id.*

17 Indeed, the record evidence includes multiple studies, including some cited by Defendants,
18 that show the positive impact of the Women’s Health Amendment. Ex. 57 (D10 00207398-400).
19 For example, the Guttmacher Institute informed HHS that “[e]xtensive evidence demonstrates
20 what common sense would predict: eliminating costs leads to more effective and continuous use
21 of contraception. This is because cost can be a substantial barrier.” Ex. 57 (D10 00207393). The
22 Institute further explained that the ACA’s “contraceptive coverage guarantee has had a positive
23 impact.” Ex. 57 (D10 00207398). Prior to the ACA, contraceptives accounted for between 30-
24 44% of out-of-pocket healthcare spending for women. *Id.* In a nationally representative survey
25 of women aged 18-39, two-thirds of those who had health insurance and were using a hormonal
26 contraceptive method reported having no copays; among those women, 80% agreed that paying
27 nothing out of pocket increased their use of birth control, 71% agreed this helped them use their
28 birth control consistently, and 60% agreed that having no copayment helped them choose a better

1 method. *Id.* Other studies showed increased usage of the most effective and expensive forms of
2 contraception (long acting reversible contraception) among women aged 20-24 (the age group at
3 highest risk for unintended pregnancy). Ex. 57 (D10 00207399). Defendants did not address this
4 evidence submitted in the public record and did not establish that the factual underpinnings for
5 the contraceptive requirement had changed.

6 **4. Defendants Failed to Reasonably Account for the Costs of the Rules**

7 Despite numerous commenters highlighting the impact and associated costs of the
8 Exemption Rules (*infra* at 46-48), Defendants boldly proclaim that they have not calculated the
9 “related costs [women] may incur for contraceptive coverage or the results associated with any
10 unintended pregnancies.” 83 Fed. Reg. at 57,574, 57,626. Failure to account for the actual costs
11 of the Exemption Rules renders them arbitrary and capricious. *California*, 2019 WL 1877392, at
12 *32-34; *Michigan*, 135 S. Ct. at 2707 (“[R]easonable regulation ordinary requires paying
13 attention to the advantages and the disadvantages of agency decisions”); *Am. Wild Horse Pres.*
14 *Campaign v. Perdue*, 873 F.3d 914, 932 (D.C. Cir. 2017) (agency cannot “brush[] aside critical
15 facts”). This is particularly problematic here, where the Exemption Rules allow employers to
16 exempt themselves from the mandate without any type of notification, thereby guaranteeing that
17 neither the agencies nor the public will ever know the extent of the Rules’ impact.

18 Defendants also fail to account for the costs to the States. While Defendants provide that
19 the Exemption Rules will result in “transfer costs,” amounting to \$68.9 million (Religious
20 Exemption Rule) and \$8,760 (Moral Exemption Rule), Defendants fail to explicitly detail who
21 will bear such costs. 83 Fed. Reg. at 57,538; 83 Fed. Reg. 57,593. The Rules fail to acknowledge
22 both the populations most likely to be harmed by the Rules (*see infra* at 49-51) and the impact on
23 the states’ public fiscs. Ex. 57 (D10 00207358), Ex. 57 (D10 00207348-49), Ex. 57 (D10
24 00207409), Ex. 57 (D10 00207374).

25 **5. Defendants Overlooked Congress’s Intent that HRSA Assess the** 26 **Efficacy and Safety of Preventive Care Measures**

27 Through the ACA and the Women’s Health Amendment, Congress mandated that an
28 expert entity, HRSA, set guidelines for specific services that advance preventive care. 42 U.S.C.

1 § 300gg-13(a). Congress identified HRSA as the arbiter of safe and efficacious women’s
2 preventive care for purposes of the ACA’s coverage mandate. Since 2011, HRSA has fulfilled its
3 duty by convening panels of nationally recognized experts to make and update recommendations
4 for women’s preventive care. In the IOM report and WPSI recommendations, our nation’s
5 preeminent medical experts guided the systematic and methodical reviews of medical and public
6 health evidence that resulted in the HRSA guidelines. Defendants diverged from Congress’s
7 stated intent in promulgating their Exemption Rules by independently, albeit vaguely, concluding
8 that some uncertainties with respect to the efficacy and safety of contraceptives exist. But as
9 Congress explicitly stated, HRSA, the expert agency, is charged with promulgating guidelines
10 that define “preventive services.” The Exemption Rules jettison this required statutory process.
11 Because Defendants relied on factors and a process that Congress did not intend it to consider, the
12 new exemptions are arbitrary and capricious. *State Farm*, 463 U.S. at 43; *cf. Southwest Ctr. For*
13 *Biological Diversity v. United States Forest Service*, 100 F.3d 1443, 1449 (9th Cir. 1996) (where
14 agency “had no obligation to consider the views of other agencies” in issuing regulation, no APA
15 violation).

16 **B. Defendants’ Justifications Are Implausible Because the Exemption Rules**
17 **Are Not Tailored to Address the Purported “Problems” the Rules Identify**

18 The Exemption Rules are not plausibly tied to the existing record because the purported
19 problems Defendants have identified are not mitigated by the expanded exemptions. If the safety
20 of contraceptives were broadly in question, as Defendants contend, the exemptions would not
21 enhance protection for the entire population of women facing the alleged health risks. Instead,
22 the Rules are limited to women who happen to be employed by organizations or insured by
23 companies that would assert religious or moral objections to the contraceptive requirement.

24 Similarly, Defendants further justify the Exemption Rules by citing concerns (though no
25 evidence) that access to contraceptive coverage may increase the prevalence of teen pregnancy.
26 83 Fed. Reg. at 57,554. Yet the new Exemption Rules do not relate to the age of the plan
27 beneficiary. *See Del. Dep’t of Nat. Res. & Envtl. Control v. EPA*, 785 F.3d 1, 17-18 (D.C. Cir.
28 2015) (setting aside a regulation because it was not tailored to address the identified problems).

1 Defendants also claim that the Exemption Rules are necessary because the contraception
2 coverage requirement was not narrowly tailored to the populations of women most at-risk for
3 unintended pregnancies, specifically women who are aged 18 to 24 years, unmarried, have a low
4 income, are not high school graduates, and are members of racial or ethnic minorities. 83 Fed.
5 Reg. at 57,547. As a threshold matter, Defendants’ narrow view of who is entitled to
6 contraceptive coverage runs counter to Congress’s intent that health plans generally “shall”
7 provide women’s preventive care without cost-sharing. Congress did not limit this statutory
8 benefit to a certain category of women. Defendants’ position also runs counter to the ample
9 record evidence of high rates of unintended pregnancies, regardless of age or population
10 subgroup, and the risk of unintended pregnancy for sexually active couples that do not use a
11 contraceptive method. *See e.g.*, Ex. 57 (D10 00207386) (“A typical woman in the United States
12 wishing to have only two children will, on average, spend three decades—roughly 90% of her
13 adult life—avoiding unintended pregnancy”); Ex. 1 (D1 0000666) (Sexually active couples
14 forgoing any contraceptive method face an approximately 85% chance of pregnancy in a one-year
15 period). And even taking Defendants’ claim at face value, the Exemption Rules are still arbitrary
16 and capricious because they are not narrowly tailored to any subgroups with particularly high
17 risks.

18 The serious lack of alignment between the purported “problems” Defendants cited as a
19 basis for the Exemption Rules and the scope of the new policy they seek to implement
20 demonstrates that the Rules are arbitrary and capricious. *State Farm*, 463 U.S. at 43 (A rule is
21 arbitrary and capricious if it “is so implausible that it could not be ascribed to a difference in view
22 or the product of agency expertise.”); *Bureau of Land Mgmt.*, 286 F. Supp. 3d at 1066-67 (finding
23 that even if the agency had provided factual evidence to support its claim that the new regulations
24 burdened small operators, a “blanket suspension” of the regulation was arbitrary and capricious
25 because the suspension was “not properly tailored” to address the allegedly errant provision).

26 Indeed, the Rules are “a solution in search of a problem.” *California*, 2019 WL 1877392, at
27 *36 (citing *Nat’l Fuel Gas Supply Corp. v. F.E.R.C.*, 468 F.3d 831, 837 (D.C. Cir. 2006));
28 *Arizona Cattle Growers Ass’n v. U.S. Fish & Wildlife*, 273 F.3d 1229, 1244 (9th Cir. 2001);

1 *Sorenson Commc'ns Inc. v. FCC*, 755 F.3d 702, 708 (D.C. Cir. 2014). The broad scope of the
 2 Exemption Rules is not supported by the record. For example, Defendants concede that they are
 3 not aware of any publicly traded entities that have religious objections to providing contraceptive
 4 coverage, but they nevertheless expand the exemption to include such entities. 83 Fed. Reg. at
 5 57,562. Similarly, Defendants cite only three employers to justify the entirety of the Moral
 6 Exemption Rule. 83 Fed. Reg. at 57,626 & n.74. And, Defendants have stipulated to injunctions
 7 barring them from enforcing contraceptive-coverage requirement against several employers,
 8 including “open-ended” injunctions that allow additional employers to join. *See* Dkt. Nos. 197 at
 9 10 n. 4 (listing the stipulated injunctions); 197-1; Dkt. No. 234 at 30.

10 **C. Defendants Failed to Meaningfully Respond to Comments Concerning the**
 11 **Rules’ Impacts**

12 In promulgating the Exemption Rules, Defendants ignored several key issues regarding
 13 contraceptive coverage. A rule is arbitrary and capricious if the agency “failed to consider an
 14 important aspect of the problem[.]” *State Farm*, 463 U.S. at 43. “For an agency’s
 15 decisionmaking to be rational, it must respond to significant points raised during the public
 16 comment period.” *Allied Local & Reg’l Mfrs. Caucus*, 215 F.3d at 80. And while Defendants
 17 need not address every comment, Defendants must address “significant” comments or those
 18 “which, if true, raise points relevant to the agency’s decision.” *City of Portland, v. EPA*, 507 F.3d
 19 706, 715 (D.C. Cir. 2007). Defendants failed to meet this standard.

20 **1. Defendants Failed to Respond to Comments from Medical**
 21 **Associations Describing the Medical Consensus About**
 22 **Contraceptives’ Efficacy**

23 Defendants failed to respond to vital public comments submitted by medical professionals.
 24 Significantly, Defendants failed to respond to the letter submitted the American College of
 25 Obstetrics and Gynecologists (ACOG), joined by the American Academy of Pediatrics and the
 26 Society for Adolescent Health and Medicine, challenging the IFRs’ inaccurate assessment of the
 27 potential health risks purportedly associated with contraception, including venous thrombosis
 28 (blood clots), cancer, and depression. 82 Fed. Reg. at 47,804; Ex. 46 (D10 00207106), Ex. 71
 (D11 00328171-72) (“As with any medication, certain types of contraception may be

1 contraindicated for patients with certain medical conditions [P]atients and physicians, . . . ,
2 should determine the right contraceptive for a patients’ health care needs.”). The comment notes
3 that the IFRs include several false and misleading statements, and “greatly exaggerate[] the harms
4 of contraception.” *Id.* at 00328171-72. Defendants failed to directly address the specific
5 concerns that these organizations raised. 83 Fed. Reg. at 57,555.

6 This public comment is especially vital to this rulemaking process because these
7 professional organizations are official partners in HHS’s Women’s Preventive Services Initiative
8 process, and ACOG is a central stakeholder. Ex. 25 (D9 669078). The WPSI is responsible for
9 reviewing and updating women’s preventive care guidelines. The Departments, through the
10 HRSA, launched the WPSI, and awarded ACOG a multi-year cooperative agreement to
11 coordinate the guideline effort. Ex. 25 (D9 669074). Defendants failed to address ACOG and its
12 partners’ objections or to explain Defendants’ inconsistent positions with respect to the health
13 risks associated with contraception. Failure to respond to a public comment is grounds for setting
14 aside the rule if “the points raised in the comments were sufficiently central that agency silence
15 would demonstrate the rulemaking to be arbitrary and capricious.” *N.M. Health Connections v.*
16 *U.S. Dep’t of Health & Human Servs.*, 312 F. Supp. 3d 1164, 1216 (D.N.M 2018) (citing *Natural*
17 *Res. Def. Council, Inc. v. EPA*, 859 F.2d 156, 188 (D.C. Cir. 1988)).

18 Consistent with the ACOG comment letter, many other medical associations warned
19 Defendants that the IFRs were predicated on an inaccurate assessment of the science and
20 medicine concerning contraception, whereas the guidelines were developed based on the best
21 clinical and scientific evidence. Objecting medical associations included the American Public
22 Health Association (D10 00206908-909), Physicians for Reproductive Health (D10 00195097-
23 98), the American Academy of Nursing (D10 00206990-91 & Ex. 80 (D11 0454730)), and the
24 American College of Physicians (D10 00207148-49). *See also* Ex. 83 (D12 00697151) (Asian &
25 Pacific Islander American Health Forum), Ex. 86 (D12 00715496-97) (Women’s Health and
26 Family Planning Association of Texas), Ex. 79 (D11 00435049) (National Center for Health
27 Research), A.R. D11 00427847-50 (California Planned Parenthood Education Fund and Planned
28 Parenthood Affiliates of California), Ex. 31 (D10 00206845-851) (National Health Law

1 Program), Ex. 36 (D10 00206916) (Guttmacher Institute), Ex. 74 (D11 00373535-36) (County of
 2 Santa Clara), Ex. 28 (D10 00195113-15) & Ex. 53 (D10 00207185-87) (National Partnership for
 3 Women & Families), Ex. 60 (D10 00207671-73) (National Latina Institute for Reproductive
 4 Health), Ex. 64 (D10 00208995-96) (National Family Planning & Reproductive Health
 5 Association), Ex. 33 (D10 00206889-91) (Lift Louisiana), Ex. 34 (D10 00206899-901) (National
 6 Network of Abortion Funds), 00206998-00207000 (Power to Decide), Ex. 39 (D10 00206981-83)
 7 (Wisconsin Alliance for Women’s Health), Ex. 43 (D10 00207037-38) (NARAL Pro-Choice
 8 America), Ex. 62 (D10 00207745-47) (Reproductive Rights and Justice Practicum at Yale Law
 9 School), Ex. 66 (D10 00209051-53) (Yale Students for Reproductive Justice), Ex. 48 (D10
 10 00207134-36) (Ibis Reproductive Health), Ex. 76 (D11 00396711-13) (Colorado Consumer
 11 Health Initiative). And according to one member of the IOM committee convened by HHS, the
 12 new rules are “not based upon sound scientific or empirical evidence.” Ex. 58 (D10 00207496-
 13 502). Defendants’ failure to “examine the relevant data and articulate a satisfactory explanation
 14 for its action including a rational connection between the facts found and the choice made,”
 15 renders the result “arbitrary and capricious.” *State Farm*, 463 U.S. at 43; *see also Humane Soc. of*
 16 *U.S. v. Locke*, 626 F.3d 1040, 1049 (9th Cir. 2010).

17 **2. Defendants Failed to Respond to Comments Outlining the Negative**
 18 **Financial and Health Impacts of Unintended Pregnancy**

19 A significant cross-section of stakeholders commented that the expanded exemptions
 20 would undercut access to contraception and create significant burdens associated with unintended
 21 pregnancies, including negative financial and health impacts of unintended pregnancies on
 22 women and their families—impacts which Defendants previously recognized as significant. Ex.
 23 79 (D11 00435049), A.R. D11 00427850, Ex. 42 (D10 00207019), Ex. 31 (D10 206845-46), A.R.
 24 D11 00435091, Ex. 28 (D10 00195106), Ex. 58 (D10 00207498), Ex. 30 (D10 00195137-40), Ex.
 25 64 (D10 00208989), Ex. 60 (D10 00207659-61), Ex. 55 (D10 00207242), Ex. 57 (D10 00207310-
 26 11), Ex. 57 (D10 00207320-21), Ex. 57 (D10 00207328-29), Ex. 57 (D10 00207334-35), Ex. 57
 27 (D10 00207402-03), Ex. 85 (D12 00715480), Ex. 61 (D10 00207709), Ex. 72 (D11 00328183);
 28 *see, e.g.*, 77 Fed. Reg. at 8,727 (“[s]tudies show a greater risk of preterm birth and low birth

1 weight among unintended pregnancies compared with pregnancies that were planned”).

2 Additionally, several commenters discussed the importance of contraception, noting it:

- 3 • “enables women to be equal participants in the social, political, and economic life of
4 the nation,” Ex. 51 (D10 00207159-61); Ex. 45 (D10 10 00207072-76) (IFRs harm
5 women’s health, equality, and economic security); Ex. 77 (D11 00396717-19) (IFRs
6 undermine women’s human rights); Ex. 38 (D10 00206967-73) (noting that even
7 women of faith reported that considerations such as their health or the health of their
8 children took precedence over their religion’s view of contraception), Ex. 68 (D10
9 00209103-06) (no-cost contraception coverage is vital to women of all faith);
- 10 • is important to women’s professional and educational opportunities, Ex. 62 (D10
11 00207737-40), Ex. 67 (D10 00209066-67) (discussing adverse impacts of unintended
12 pregnancies on women, children, and society);
- 13 • is vital for women in rural areas, Ex. 29 (D10 00195127);
- 14 • is important for women of color, Ex. 29 (D10 00195127); Ex. 65 (D10 00209032-36)
15 (IFRs will have a disparate impact on women of color); and
- 16 • is crucial for the LGBT community, Ex. 32 (D10 00206861-65), Ex. 37 (D10
17 00206954-56) (discussing impact on LGBT community), Ex. 52 (D10 00207178-79)
18 (IFRs will increase health disparities faced by LGBT community), Ex. 61 (D10
19 00207707-10) (IFRs strip women and LGBT community of coverage guaranteed by
20 federal law).

21 Defendants wholesale bundled these concerns before summarily dismissing them:

22 Other commenters . . . assert[ed] that the expanded exemptions unacceptably burden
23 women who might lose contraceptive coverage as a result. They contended the
24 exemptions may remove contraceptive coverage, causing women to have higher
25 contraceptive costs, fewer contraceptive options, less ability to use contraceptives more
consistently, more unintended pregnancies, births spaced more closely, and workplace,
economic, or societal inequality.

26 83 Fed. Reg. at 57,548; *see also* 83 Fed. Reg. at 57,606. Defendants then concluded that the
27 exemptions do not impermissibly burden third parties because they incorrectly assumed that the
28

1 ACA does not require contraceptive care without cost sharing,⁴² and thus “if some third parties do
 2 not receive contraception coverage from private parties who the government chose not to coerce,
 3 that result exists in the absence of government action.” *Id.* at 57549; 83 Fed. Reg. at 57,606.
 4 Defendants’ willingness to dismiss summarily the central grounds for promulgating the prior
 5 rules is the opposite of a “reasoned explanation.” *Encino Motorcars*, 136 S. Ct. at 2126.
 6 Defendants’ failure to meaningfully acknowledge, engage, and to respond to these significant
 7 issues raised by numerous commenters further renders the Rules arbitrary and capricious. *Del.*
 8 *Dep’t of Nat. Res. & Env’tl. Control*, 785 F.3d at 15; *see also Ctr. for Biological Diversity v. U.S.*
 9 *Bureau of Land Mgmt.*, 698 F.3d 1101, 1125 (9th Cir. 2012). In fact, in issuing a preliminary
 10 injunction, Judge Chen recently concluded that Defendants’ failure to adequately consider the
 11 patient and public health costs of unintended pregnancies renders a rule arbitrary and capricious.
 12 *See California*, 2019 WL 1877392, at *29-32.

13 3. Defendants Failed to Respond to Comments Concerning the 14 Exemption Rules’ Impact on Patients Experiencing Domestic 15 Violence

16 Numerous commenters discussed the benefits of contraceptive use and its impact on
 17 domestic violence. For instance, the Black Women’s Health Imperative commented that
 18 decreased access to contraceptives leads to an increase in unintended pregnancies and women
 19 facing an unintended pregnancy are more likely to experience domestic violence during
 20 pregnancy. Ex. 69 (D10 00209110), Ex. 78 (D11 00396759-60); *see also* Ex. 28 (D10
 21 00195106), Ex. 58 (D10 00207498), Ex. 57 (D10 00207320). A domestic violence survivor and
 22 counselor stated:

23 I worked in a domestic violence shelter and was myself receiving services from an
 24 organization that supported survivors. Time and time again, I had to provide emotional
 25 support to women who had been forced or coerced by their partners into having unwanted
 26 sex. I was also a victim of such sexual exploitation. When sex is used to get a woman
 27 pregnant in order to inhibit her ability to leave an abusive partner (it happens far more
 28 often than we’d like to believe), birth control is one way that a woman can take back some
 control over her life.

⁴² Contrary to this assumption, this Court noted that it “knows of no Supreme Court, court of appeal or district court decision that did not presume that the ACA requires specified categories of health insurance plans and issuers to provide contraceptive coverage at no cost to women.” Dkt. No. 234 at 37.

1 Ex. 70 (D10 00262440); *see also* 77 Fed. Reg. at 8,728 & n.12 (Defendants previously
 2 recognizing that contraception improves the social and economic status of women, including
 3 affording them greater freedom to make marriage decisions); Ex. 9 (D4 000401 (IOM Report)
 4 (women facing an unintended pregnancy “are more likely than those with intended pregnancies to
 5 receive late or no prenatal care, to smoke and consume alcohol during pregnancy, to suffer from
 6 perinatal mood disorders, and to experience domestic violence during the pregnancy”)); Ex. 24
 7 (D9 668960). Yet discussion of domestic violence appears nowhere in the Exemption Rules.
 8 Defendants’ failure to consider this important aspect of the issue renders the Exemption Rules
 9 arbitrary and capricious. *State Farm*, 463 U.S. at 43; *Del. Dep’t of Nat. Res. & Env’tl. Control*,
 10 785 F.3d at 15.

11 **III. THE EXEMPTION RULES AND THE IFRS VIOLATE THE ESTABLISHMENT CLAUSE⁴³**

12 The Religious Exemption Rule and the Religious IFR violate the Establishment Clause
 13 because, in the name of religious accommodation, it strips third parties—employees, students,
 14 and dependents—of health insurance to which they are entitled by law, imposing substantial costs
 15 and burdens on them. Government conduct may not have a primary effect, which advances a
 16 particular religious practice. *Catholic League for Religious & Civil Rights v. City & Cty. of S.F.*,
 17 624 F.3d 1043, 1054-55 (9th Cir. 2010) (en banc) (citing *Lemon v. Kurtzman*, 403 U.S. 602, 612-
 18 13 (1971)).⁴⁴ Conduct unlawfully advances religion by favoring religion at the expense of the
 19 rights, beliefs, and health of others. *Corp. of Presiding Bishop of Church of Jesus Christ of*
 20 *Latter-day Saints v. Amos*, 483 U.S. 327, 334-35 (1987) (“At some point, accommodation may
 21 devolve into ‘an unlawful fostering of religion.’”).

23
 24 ⁴³ Because the States’ APA claims demonstrate that this Court should set aside the Exemption
 25 Rules, this Court need not even reach the Constitutional claims. *See In re Ozenne*, 841 F.3d 810,
 814 (9th Cir. 2016) (“as a fundamental rule of judicial restraint, [the court] must consider
 26 nonconstitutional grounds for decision before reaching any constitutional questions” (internal
 quotation marks and citations omitted)).

27 ⁴⁴ The Supreme Court has “repeatedly emphasized [its] unwillingness to be confined to any single
 28 test or criterion in this sensitive area,” but generally applies the *Lemon* test to evaluate
 Establishment Clause violations. *Kreisner v. City of San Diego*, 1 F.3d 775, 780 (9th Cir. 1993)
 (citing *Lynch v. Donnelly*, 465 U.S. 668, 669 (1984)).

1 The Supreme Court has consistently held that government conduct that shifts the burden for
2 religious exercise to third parties is a violation of the Establishment Clause. In *Caldor*, 472 U.S.
3 at 709, the Court held that a Connecticut statute guaranteeing employees the right not to work on
4 a chosen Sabbath Day violated the Establishment Clause because “the statute takes no account of
5 the convenience or interests of the employer or those of other employees who do not observe a
6 Sabbath.” Further, the statute did not provide any exceptions to the “right not to work” on a
7 chosen Sabbath, causing the employer “substantial economic burdens” and the “imposition of
8 significant burdens on other employees required to work in place of the Sabbath observers.” *Id.*
9 at 709. Similarly, in *Texas Monthly, Inc. v. Bullock*, 489 U.S. 1, 18 (1989) (plurality op.), the
10 Court held that a tax-exemption for religious periodicals violated the Establishment Clause
11 because it “burden[ed] nonbeneficiaries by increasing their tax bills by whatever amount was
12 needed to offset the benefit bestowed on subscribers to religious publications.” *Id.* at 18 n.8. The
13 Court explained that religious exemptions from general laws are permissible when they do not
14 “impose substantial burdens on non-beneficiaries while allowing others to act according to their
15 religious beliefs.” *Id.*

16 Further, in considering whether an exemption from a generally applicable rule sought under
17 RLUIPA violates the Establishment Clause, the Court has recognized that it “must take adequate
18 account of the burdens a requested accommodation may impose on nonbeneficiaries.”⁴⁵ *Cutter v.*
19 *Wilkinson*, 544 U.S. 709, 720 (2005). In *Cutter*, three prisoners complained that prison officials
20 failed to grant exemptions for their religious practices, in violation of RLUIPA.⁴⁶ The prisoners

21 ⁴⁵ See Elizabeth Sepper, *Religious Exemptions, Harm to Others, and the Indeterminacy of A*
22 *Common Law Baseline*, 106 Ky. L.J. 661, 662 (2018) (“[T]he Supreme Court has regularly
23 rejected exemptions that would transfer the burdens of religious compliance from objectors to
24 other third parties.”); Micah Schwartzman et. al., *The Costs of Conscience*, 106 Ky. L.J. 781, 791
(2018); Frederick Mark Gedicks & Rebecca G. Van Tassell, *RFRA Exemptions from the*
Contraception Mandate: An Unconstitutional Accommodation of Religion, 49 Harv. C.R.-C.L. L.
Rev. 343, 361 (2014).

25 ⁴⁶ RFRA and RLUIPA have virtually identical language and fulfill the same purpose. Compare
26 42 U.S.C. § 2000bb-1 with 42 U.S.C. § 2000cc-1. RLUIPA applies “the same standard as set
27 forth in RFRA.” *Holt*, 135 S. Ct. at 860 (citations omitted), and RLUIPA’s legislative history
28 indicates that it is to be interpreted by reference to RFRA and First Amendment jurisprudence.
See 146 Cong. Rec. S7774, S7776 (July 27, 2000) (“The term ‘substantial burden’ as used in this
Act is not intended to be given any broader interpretation than the Supreme Court’s articulation of

1 argued that they were denied access to religious materials, denying them opportunities for group
 2 worship, and forbidding them to adhere to the dress mandates of their religion. *Id.* In that case,
 3 the religious exemption did not violate the Establishment Clause because “it d[id] not override
 4 other significant interests,” like the safety of other prisoners and prison staff. *Id.* at 722; *see also*
 5 *Hobby Lobby*, 573 U.S. at 730 n.37 (citing *Cutter* approvingly in holding that “[i]t is certainly
 6 true that in applying RFRA ‘courts must take adequate account of the burdens a requested
 7 accommodation may impose on nonbeneficiaries.’” (*Cutter*, 544 U.S. at 720)).⁴⁷

8 Here, the Religious Exemption Rule and the Religious IFR violate the Establishment
 9 Clause because, if implemented, it will significantly burden female employees and female
 10 covered dependents. As a result of the Rule, employers can exempt themselves from the
 11 contraceptive mandate, thereby ensuring that their female employees and female dependents will
 12 not receive their statutorily guaranteed full and equal benefits.⁴⁸ Instead, under these Exemption
 13 Rules, female employees and female covered dependents must obtain contraceptive coverage
 14 outside their employer-sponsored health plan at their own expense or the state’s expense *or* forgo
 15 contraceptives altogether, with little to no warning.

16 Further, as in *Caldor*, there are no exceptions under the Religious Exemption Rule or the
 17 Religious IFR for circumstances like the health of the female employees and female dependents.
 18 472 U.S. at 709. Some women use contraceptives if they have a health condition for which
 19 “pregnancy is contraindicated,” such as congenital heart disease. *Hobby Lobby*, 573 U.S. at 743
 20 (Kennedy, J., concurring). Hormonal contraceptives also provide long-term benefits against
 21 certain cancers like endometrial and ovarian cancer. Ex. 1 (D1 0000670), Ex. 9 (D4 00405), Ex.

22 _____
 23 the concept of substantial burden on religious exercise”).

24 ⁴⁷ “Nothing in [RFRA] shall be construed to affect, interpret, or in any way address that portion
 25 of the First Amendment prohibiting laws respecting the establishment of religion (referred to in
 26 this section as the ‘Establishment Clause’).” 42 U.S.C. § 2000bb-4; *see also Santa Fe Indep. Sch.*
Dist. v. Doe, 530 U.S. 290, 302 (2000) (“The principle that government may accommodate the
 free exercise of religion does not supersede the fundamental limitations imposed by the
 Establishment Clause.”).

27 ⁴⁸ In contrast, in *Hobby Lobby*, the Supreme Court held that there was no “detrimental third party
 28 effect” because the government still ensured that women received contraceptive coverage through
 the exemption and accommodation process. *Hobby Lobby*, 573 U.S. at 730 n. 37. This is no
 longer the case under the Religious Exemption Rule.

1 22 (D9 667792), Ex. 57 (D10 207319-20). But the Religious Exemption Rule fails to consider
2 any such circumstances or interests. *See Caldor*, 472 U.S. at 709 (Religious concerns may not
3 “automatically control over all secular interests at the workplace.”). And, as discussed above, the
4 suggestion that affected women can still obtain contraceptive coverage through Title X is illusory.
5 *See infra* at 31-32.

6 Therefore, the Religious Exemption Rule and the Religious IFR violate the Establishment
7 Clause because they place a significant burden on female employees and female dependents.

8 **IV. THE EXEMPTION RULES AND THE IFRS VIOLATE THE EQUAL PROTECTION CLAUSE**

9 The Equal Protection component of the Fifth Amendment prohibits the federal government
10 from denying equal protection of the laws. Although the ACA requires coverage for many
11 different types of preventive services, the Exemption Rules and the IFRs single out women’s
12 healthcare—specifically, the Rules target contraceptive coverage. In so doing, these Rules create
13 an explicit and constitutionally impermissible gender-based classification. *See Caban v.*
14 *Mohammed*, 441 U.S. 380 (1979); *Int’l Union v. Johnson Controls*, 499 U.S. 187 (1991); *Arce v.*
15 *Douglas*, 793 F.3d 968, 977 (9th Cir. 2015). The Rules do not create generally applicable
16 religious or moral exemptions; they explicitly target contraceptive coverage, essential for
17 women’s reproductive health—and a necessary component of equality between men and women
18 because it allows women to control their health, education and livelihoods. *See Hobby Lobby*,
19 573 U.S. at 737 (Kennedy, J., concurring); *Johnson Controls*, 499 U.S. at 211 (“It is no more
20 appropriate for the courts than it is for individual employers to decide whether a woman’s
21 reproductive role is more important to herself and her family than her economic role”).

22 Because the Exemption Rules and the IFRs create a gender-based classification by singling
23 out women’s healthcare coverage, Defendants must demonstrate an “exceedingly persuasive
24 justification” for the IFRs and the Exemption Rules. *United States v. Virginia*, 518 U.S. 515, 531
25 (1996); *Miss. Univ. for Women v. Hogan*, 458 U.S. 718, 724 (1982). The Supreme Court has
26 “repeatedly recognized that neither federal nor state government acts compatibly with the equal
27 protection principle when a law . . . denies to women, simply because they are women, full
28 citizenship stature—equal opportunity to aspire, achieve, participate in and contribute to society

1 based on individual talents and capacities.” *Virginia*, 518 U.S. at 532 (court must “carefully
2 inspect[] official act that closes a door or denies opportunity to women”). In such instances, the
3 government must meet a “demanding” standard of review. *Id.* at 533. The government must
4 show “at least that the [challenged] classification serves important government objectives and that
5 the discriminatory means employed are substantially related to the achievement of those
6 objectives.” *Sessions v. Morales-Santana*, 137 S. Ct. 1678, 1690 (2017); *see also Nevada Dep’t*
7 *of Human Res. v. Hibbs*, 538 U.S. 721, 728-29 (2003) (“heightened scrutiny” analysis requires
8 that the government’s justification not rely on overbroad generalizations about women).

9 Defendants cannot meet this rigorous standard. First, the Exemption Rules and the IFRs do
10 not serve an important government interest. The Moral Exemption Rule and the Moral IFR is
11 purportedly needed to ensure that non-religious entities can exercise their moral objections to
12 providing women’s healthcare services. As support for such a rule, Defendants cite only three
13 employers: two who filed suit against the prior regulatory scheme (March for Life and Real
14 Alternatives, Inc.) and one who submitted a comment letter (Americans United for Life). 83 Fed.
15 Reg. at 57,626 & n.74. Accommodating requests from these three lone employers does not
16 amount to an “important” government interest such that it supersedes the rights of millions of
17 women to access statutorily guaranteed healthcare. *See, e.g., Virginia*, 518 U.S. at 541-42, 550.⁴⁹
18 Nor can Defendants demonstrate an “important government interest” to support the expansive
19 breadth of the Religious Exemption Rule. This Rule’s vast expansion of the available exemption
20

21
22 ⁴⁹ To the extent Defendants rely on historical letters penned by the Founding Fathers to religious
23 organizations, the Supreme Court has repeatedly recognized that in considering a gender
24 discrimination case, the Court must bear in mind that “[o]ur nation has had a long and unfortunate
25 history of sex discrimination.” *Virginia*, 518 U.S. at 531 (explaining that women did not count
26 among “We the People” and even after gaining the right to vote, the government could “withhold
27 from women opportunities accorded men” for any reason); *Hibbs*, 538 U.S. at 729. As Justice
28 Kennedy explained, “The nature of injustice is that we may not always see it in our times. The
generations that wrote and ratified the Bill of Rights and Fourteenth Amendment did not presume
to know the extent of freedom in all of its dimensions and so they entrusted future generations a
charter protecting the right of all persons to enjoy liberty as we learn its meaning.” *Obergefell v.*
Hodges, 135 S. Ct. 2584, 2598 (2015). Thus, reliance on these historical letters cannot justify the
IFRs’ and Exemption Rules’ vast expansion to accommodate objections to the detriment of
millions of women.

1 from “churches” to *all* employers, including publicly traded companies and insurers, is without
2 justification in the ACA or RFRA. *See supra* at 16-33.

3 Second, even if Defendants could demonstrate an important government interest,
4 Defendants cannot demonstrate that the “means employed” are “substantially related” to the
5 purported “important government interest.” *Sessions*, 137 S. Ct. at 1690. Defendants have
6 undertaken several actions that severely limit women’s ability to access their statutorily
7 guaranteed healthcare benefits and services, without showing that such actions are substantially
8 related to achieving Defendants’ purported important goals. *See, e.g., Orr v. Orr*, 440 U.S. 268,
9 280-81 (1979) (classification did not substantially relate to objectives where it was gratuitous in
10 that there was a feasible solution, with little additional burden on the State that would eliminate
11 discrimination and would still achieve the government’s objectives). Defendants have (1) vastly
12 expanded the exemption to include (a) religious objections of *all* employers, including publicly
13 traded for-profit corporations; and (b) moral objections of nearly all employers and (2) eliminated
14 the prior safety net that ensured that women would obtain their statutorily entitled benefits and
15 services, even if their employer exercised its objection. These Rules and IFRs fail the “means
16 test” because they are much broader than necessary to achieve any purported goal with respect to
17 accommodating employers and fail to account for the compelling interest of providing full and
18 equal healthcare to women.

19 **V. THE EXEMPTION RULES WERE IMPROPERLY PROMULGATED**

20 Defendants evaded their obligations under the APA by promulgating rules without proper
21 notice and comment. Nevertheless, Defendants claim that their failure to abide by the APA is
22 cured as to the Final Exemption Rules because the public could comment on the IFRs post-
23 promulgation. 83 Fed. Reg. at 57,552. Such a claim runs contrary to the plain language of the
24 APA and, practically speaking, would provide an end-run for agencies to avoid compliance with
25 the APA, which requires agencies to provide the public notice and an opportunity to be heard
26 *before* promulgating a regulation.

27 Several courts, including the Ninth Circuit, have addressed how a post-promulgation
28 comment period undermines the purposes of § 553: to reintroduce the public voice when a matter

1 has been delegated to unrepresentative agencies, and to educate the agency while it is in the
2 process of developing its policies. *See Alcaraz v. Block*, 746 F.2d 593, 611 (9th Cir. 1984);
3 *Paulsen v. Daniels*, 413 F.3d 999, 1005 (9th Cir. 2005) (“It is antithetical to the structure and
4 purpose of the APA . . . to implement a rule first, and then seek comment later”); *see also, e.g.,*
5 *Sharon Steel Corp. v. EPA*, 597 F.2d 377, 381 (3d Cir. 1979) (“Provision of prior notice and
6 comment allows effective participation in the rulemaking process while the decisionmaker is still
7 receptive to information and argument”). Procedural error is not taken lightly in the
8 administrative context, where substantive challenges are difficult due to an agency’s discretion to
9 make policy contrary to the comments it receives; therefore, procedural error is only harmless
10 where the mistake “clearly had no bearing on the procedure used or the substance of decision
11 reached.” *Riverbend Farms, Inc. v. Madigan*, 958 F.2d 1479, 1487 (9th Cir. 1992).

12 As a result, several circuit courts have held that post-promulgation comments may not
13 replace pre-promulgation comments, or have placed limits on the situations in which such a
14 replacement will stand. *See, e.g., Nat. Res. Def. Council v. Nat’l Highway Safety Admin.*, 894
15 F.3d 95 (2nd Cir. 2018); *United States v. Brewer*, 766 F.3d 884 (8th Cir. 2014); *United States v.*
16 *Reynolds*, 710 F.3d 498 (3d Cir. 2013); *United States v. Dean*, 604 F.3d 1275 (11th Cir. 2010);
17 *U.S. Steel Corp. v. EPA*, 595 F.2d 207 (5th Cir. 1979). In so doing, courts express concern that
18 post-promulgation comments effectively nullify Congress’s intent that agencies receive and
19 consider public comments before issuing regulations. *See Pennsylvania*, 351 F. Supp. 3d at 813-
20 14 (this practice “would allow [an agency] to substitute post-promulgation notice and comment
21 procedures for pre-promulgation notice and comment procedures at any time by taking an action
22 without complying with the APA, and then establishing a notice and comment procedure on the
23 question of whether that action should be continued We cannot countenance such a result.”)
24 (citing *NRDC*, 683 F.2d at 767); *Sharon Steel Corp.*, 597 F.2d at 381 (“If a period for comments
25 after issuance of a rule could cure a violation of the APA’s requirements, an agency could negate
26 at will the Congressional decision that notice and an opportunity for comment must proceed
27 promulgation.”); *U.S. Steel Corp.*, 595 F.2d at 214 (finding judicial acceptance of this process
28 would render § 553’s notice and comment provisions unenforceable).

1 Courts rejecting the equivalence of public comments received before and after a regulation
2 goes into effect have highlighted the status quo bias that agencies exhibit toward a regulation
3 already in effect. *See, e.g., Levesque v. Block*, 723 F.2d 175, 187 (1st Cir. 1983) (finding
4 comments “must come at a time when they can feasibly influence the final rule,” before it has
5 become the status quo); *Sharon Steel Corp.*, 597 F.2d at 381 (“After the final rule is issued, the
6 petitioner must come hat-in-hand and run the risk that the decisionmaker is likely to resist
7 change”). To counter this bias, some courts require that the agency provide affirmative evidence
8 that it considered post-promulgation comments with an “open mind.” *See, e.g., Guedes v. Bureau*
9 *of Alcohol, Tobacco, Firearms, and Explosives*, 920 F.3d 1, 13 (D.C. Cir. 2019). Here,
10 Defendants cannot meet this burden, having barely altered the Exemption Rules beyond their
11 admission that more women would be harmed than the IFRs predicted, and having failed to
12 meaningfully respond to the comments. *See supra* 46-51. Nor is it reasonable to conclude that
13 comments submitted for IFRs and those submitted for Exemption Rules necessarily address the
14 same question. *See Pennsylvania*, 351 F. Supp. 3d at 814 (holding the issuance of IFRs
15 “fundamentally changed” the question submitted to the public from whether the rule should be
16 changed at all to whether the rule should be finalized, in case addressing same rules as instant
17 litigation) (citing *NRDC*, 683 F.2d at 767). In short, post-promulgation comments prevent the
18 public from submitting comments to the most accurate question at the time the agency will be
19 most receptive and are thus inconsistent with § 553. Defendants’ failure to abide by the APA in
20 promulgating the Final Exemption Rules renders them unlawful.

21 **VI. DEFENDANTS VIOLATED THE APA BY FAILING TO PROVIDE NOTICE AND**
22 **COMMENT BEFORE PROMULGATING THE IFRS**

23 Defendants evaded their obligations under the APA by promulgating the IFRs without
24 proper notice and comment. The APA requires agencies to provide the public notice and an
25 opportunity to be heard before formulating, amending, or repealing a rule. 5 U.S.C. §§ 551(5),
26 553. The agency must publish in the Federal Register a notice of proposed rulemaking that
27 includes “(1) a statement of the time, place, and nature of public rule making proceedings; (2)
28 reference to the legal authority under which the rule is proposed; and (3) either the terms or

1 substance of the proposed rule or a description of the subjects and issues involved.” 5 U.S.C. §
2 553(b). After the notice has issued, “the agency shall give interested persons an opportunity to
3 participate in the rulemaking through submission of written data, views, or arguments with or
4 without opportunity for oral presentation.” *Id.* § 553(c).

5 In narrow circumstances, the APA exempts agencies from this notice and comment process
6 where they can show “good cause” that the process would be either “impracticable, unnecessary,
7 or contrary to the public interest.” *Id.* § 553(b)(B). The burden is on the agency to demonstrate
8 good cause, and courts have interpreted the exception narrowly. *See, e.g., Lake Carriers’ Ass’n v.*
9 *EPA*, 652 F.3d 1, 6 (D.C. Cir. 2011) (exception “‘must be narrowly construed and only
10 reluctantly countenanced’”). An agency’s legal conclusion that good cause has been shown is
11 entitled to no deference. *Sorenson Commc’ns*, 755 F.3d at 706.

12 It is undisputed that Defendants bypassed the APA’s notice and comment requirements in
13 promulgating the IFRs and they, therefore, had the burden to demonstrate good cause for such
14 action. As this Court and the Ninth Circuit already concluded, Defendants failed to demonstrate
15 good cause for not providing notice and allowing public comment *before* these rules took effect.
16 Dkt. No. 105 at 17-25; *California*, 911 F.3d at 575-81. As noted immediately above, Defendants’
17 post-promulgation acceptance of comments is no substitute. Notice and comment are particularly
18 important in legally and factually complex circumstances like those presented here—they allow
19 affected parties to explain the practical effects of a rule before implementation, and ensure that
20 the agency proceeds in a fully informed manner, exploring less harmful alternatives. *Riverbend*
21 *Farms*, 958 F.2d at 1483-1484; *Alcaraz*, 746 F.2d at 611. Because Defendants failed to follow
22 the notice and comment procedures, the IFRs are invalid.

23 **VII. THE EXEMPTION RULES AND THE IFRS SHOULD BE SET ASIDE AS INVALID**

24 Under the APA, a reviewing court shall “. . . hold unlawful and set aside agency action,
25 findings, and conclusions found to be . . . arbitrary, capricious, an abuse of discretion, otherwise
26 not in accordance with law; [or] without observance of procedure required by law.” 5 U.S.C. §
27 706(2)(A) & (D). Thus, by statute, Congress has directed reviewing courts as to what the remedy
28 must be: the Court must “set aside” unlawful rules. This Court should follow Congress’s express

1 instruction. *See, e.g., State v. Ross*, 358 F. Supp. 3d 965, 1050-51 (N.D. Cal. 2019); *Klamath-*
2 *Siskiyou Wildlands Cir. v. Nat'l Oceanic & Atmospheric Admin.*, 109 F. Supp. 3d 1238, 1241
3 (N.D. Cal. 2015); *Nat. Res. Def. Council v. EPA*, 489 F.3d 1364, 1374 (D.C. Cir. 2007). Here,
4 the Exemption Rules and the IFRs must be set aside because they are unlawful.

5 **VIII. THE STATES ARE ENTITLED TO DECLARATORY AND INJUNCTIVE RELIEF**

6 This Court may grant declaratory relief because an actual controversy exists between the
7 parties within the meaning of 28 U.S.C. § 2201(a). The central question is “whether the facts
8 alleged, under all the circumstances, show that there is a substantial controversy, between parties
9 having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a
10 declaratory judgment.” *Biodiversity Legal Found. v. Badgley*, 309 F.3d 1166, 1174-75 (9th Cir.
11 2002). Here, an actual controversy exists about the validity of the Exemption Rules and the IFRs.

12 The States are also entitled to injunctive relief. On January 13, 2019, this Court
13 preliminarily enjoined the Exemption Rules, finding that:

14 Plaintiffs have shown that they are likely to succeed, or at a minimum have raised
15 serious questions going to the merits, on their claim that the Religious Exemption and
16 the Moral Exemption are inconsistent with the Women’s Health Amendment, and
17 thus violate the APA. Plaintiffs also have shown that they are likely to suffer
irreparable harm as a result of this violation, that the balance of hardships tips sharply
in their favor, and that the public interest favors granting the injunction.

18 Dkt. No. 234 at 21-24. The standard for a permanent injunction is the same except that the States,
19 as they have shown above, must demonstrate actual success on the merits. *Winter v. Natural Res.*
20 *Def. Council, Inc.*, 555 U.S. 7, 32 (2008); *W. Watersheds Project v. Abbey*, 719 F.3d 1035, 1054
21 (9th Cir. 2013). In the event the Court requests evidence to support the issuance of a permanent
22 injunction, that evidence will once again show that a balance of harms and public interest support
23 issuance of injunctive relief. *See* Dkt. No. 275 at 2 (directing the parties to focus their briefing on
24 the substantive merits and seeking only “a concise explanation of the remedies they seek, and the
25 legal basis for that relief.”); *see Ross*, 358 F. Supp. 3d at 1050-51.

26 **CONCLUSION**

27 The Court should grant the States’ motion for summary judgment.
28

1 Dated: April 30, 2019

Respectfully submitted,

2 XAVIER BECERRA
3 Attorney General of California
4 MICHAEL L. NEWMAN
5 Senior Assistant Attorney General
6 KATHLEEN BOERGERS
7 Supervising Deputy Attorney General

/s/ Karli Eisenberg

8 KARLI EISENBERG
9 NELI N. PALMA
10 NIMROD PITSKER ELIAS
11 LISA CISNEROS
12 KETAKEE R. KANE
13 Deputy Attorneys General
14 *Attorneys for Plaintiff the State of California*

15 WILLIAM TONG
16 Attorney General of Connecticut
17 MAURA MURPHY OSBORNE
18 Assistant Attorney General
19 *Attorneys for Plaintiff the State of Connecticut*

20 KATHLEEN JENNINGS
21 Attorney General of Delaware
22 ILONA KIRSHON
23 Deputy State Solicitor
24 JESSICA M. WILLEY
25 DAVID J. LYONS
26 Deputy Attorneys General
27 *Attorneys for Plaintiff the State of Delaware*

28 KARL A. RACINE
Attorney General of the District of Columbia
ROBYN R. BENDER
Deputy Attorney General
VALERIE M. NANNERY
Assistant Attorney General
Attorneys for Plaintiff the District of Columbia

CLARE E. CONNORS
Attorney General of Hawaii
ERIN N. LAU
Deputy Attorney General
Attorneys for Plaintiff the State of Hawaii

KWAME RAOUL
Attorney General of Illinois
HARPREET K. KHERA
Deputy Bureau Chief, Special Litigation
Bureau
Attorneys for Plaintiff the State of Illinois

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

BRIAN E. FROSH
Attorney General of Maryland
CAROLYN A. QUATTROCKI
Deputy Attorney General
STEVE M. SULLIVAN
Solicitor General
KIMBERLY S. CAMMARATA
Director, Health Education and Advocacy
Attorneys for Plaintiff the State of Maryland

KEITH ELLISON
Attorney General of Minnesota
JACOB CAMPION
Assistant Attorney General
*Attorney for Plaintiff the State of Minnesota,
by and through its Department of Human
Services*

LETITIA JAMES
Attorney General of New York
LISA LANDAU
Bureau Chief, Health Care Bureau
SARA HAVIVA MARK
Special Counsel
ELIZABETH CHESLER
Assistant Attorney General
Attorneys for Plaintiff the State of New York

JOSHUA H. STEIN
Attorney General of North Carolina
SRIPRIYA NARASIMHAN
Deputy General Counsel
*Attorneys for Plaintiff the State of North
Carolina*

ELLEN F. ROSENBLUM
Attorney General of Oregon
J. NICOLE DEFEVER
Senior Assistant Attorney General
*Attorneys for Plaintiff-Intervenor the State of
Oregon*

PETER F. NERONHA
Attorney General of Rhode Island
MICHAEL W. FIELD
Assistant Attorney General
*Attorneys for Plaintiff the State of Rhode
Island*

THOMAS J. DONOVAN, JR.
Attorney General of Vermont
ELEANOR SPOTTSWOOD
Assistant Attorney General
Attorneys for Plaintiff the State of Vermont

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

MARK R. HERRING
Attorney General of Virginia
SAMUEL T. TOWELL
Deputy Attorney General
Attorneys for Plaintiff the Commonwealth of Virginia

ROBERT F. FERGUSON
Attorney General of Washington
JEFFREY T. SPRUNG
ALICIA O. YOUNG
Assistant Attorneys General
Attorneys for Plaintiff the State of Washington

SA2017109209
13617714.doc