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9 **UNITED STATES DISTRICT COURT**
10 **FOR THE EASTERN DISTRICT OF WASHINGTON**
11 **AT YAKIMA**

12 STATE OF WASHINGTON,

No. 2:19-cv-00183-SAB

13 Plaintiff,

UNOPPOSED MOTION OF THE
INSTITUTE FOR POLICY
INTEGRITY AT NEW YORK
UNIVERSITY SCHOOL OF LAW
FOR LEAVE TO FILE AS *AMICUS*
CURIAE IN SUPPORT OF
PLAINTIFF'S MOTION FOR
PRELIMINARY INJUNCTION

14 v.

15 ALEX M. AZAR II, in his official
16 capacity as Secretary of the United
States Department of Health and
17 Human Services; and UNITED
STATES DEPARTMENT OF
18 HEALTH AND HUMAN
SERVICES,

NOTED FOR: July 17, 2019
With Oral Argument at 1:30 p.m.

19 Defendants.
20

1 The Institute for Policy Integrity at New York University School of Law
2 (“Policy Integrity”) hereby moves the Court for leave to file the accompanying
3 *amicus curiae* brief in the above-captioned case in support of Plaintiff’s Motion for
4 Preliminary Injunction, calendared for hearing before this Court on July 17, 2019
5 at 1:30 p.m. Policy Integrity has conferred with the parties concerning the filing of
6 this motion. Counsel for Plaintiff and Defendants have consented to this motion.

7 **I. LEGAL STANDARD**

8 The court has discretion to grant an *amicus curiae* permission to file a brief.
9 *Hoptowit v. Ray*, 682 F.2d 1237, 1260 (9th Cir. 1982), *abrogated on other grounds*
10 *by Sandin v. Conner*, 515 U.S. 472 (1995). “An *amicus* brief should normally be
11 allowed . . . when the *amicus* has unique information or perspective that can help
12 the court beyond the help that the lawyers for the parties are able to provide.”
13 *Cnty. Ass’n for Restoration of the Env’t (CARE) v. DeRuyter Bros. Dairy*, 54 F.
14 Supp. 2d 974, 975 (E.D. Wash. 1999). To “fulfill [its] role” and *amicus curiae*
15 should submit “briefing designed to supplement and assist in cases of general
16 public interest, supplement the efforts of counsel, and draw the court’s attention to
17 law that might otherwise escape consideration.” *Id.* at 975 (citing *Miller-Wohl Co.*
18 *v. Commissioner of Labor & Indus.*, 694 F.2d 203, 204 (9th Cir. 1982)). For the
19 reasons explained below, Policy Integrity’s motion satisfies these criteria.

20 **II. INTEREST OF AMICUS CURIAE**

21 Policy Integrity has a strong interest in this case. Policy Integrity is a
22 nonpartisan, not-for-profit think tank dedicated to improving the quality of
23 government decisionmaking through advocacy and scholarship in the fields of

1 administrative law, economics, and public policy. Policy Integrity’s legal and
2 economic experts have produced extensive scholarship on the best practices for
3 regulatory impact analysis and the proper valuation of regulatory costs and
4 benefits. Most notably, our director, Richard L. Revesz, has published more than
5 eighty articles and books on administrative law, including on the legal and
6 economic principles that inform rational regulatory decisions. *See, e.g.*, Richard L.
7 Revesz & Michael A. Livermore, *Retaking Rationality: How Cost-Benefit Analysis*
8 *Can Better Protect the Environment and Our Health* (2008).¹

9 In furtherance of its mission to promote rational decisionmaking, Policy
10 Integrity has filed *amicus curiae* briefs addressing agency analysis of costs and
11 benefits in many recent cases. *See, e.g.*, Br. for Inst. for Policy Integrity as Amicus
12 Curiae, *California v. U.S. Bureau of Land Mgmt.*, 277 F. Supp. 3d 1106 (N.D. Cal.
13 2017) (No. 17–cv–3804) (Laporte, M.J.) (arguing that agency’s failure to consider
14 forgone benefits that would result from a delay in implementation of methane
15 standards was arbitrary); Br. for Inst. for Policy Integrity as Amicus Curiae in
16 Support of Plaintiffs’ Motion for Summary Judgment, *California v. U.S. Dep’t of*
17 *the Interior*, No. C 17-56948, 2019 WL 2223804 (N.D. Cal. Mar. 29, 2019)
18 (Armstrong, J.) (arguing that repeal of procedural reforms for mineral valuation

19
20 ¹ A full list of publications can be found in Revesz’s online faculty profile,
21 *available at*
22 [https://its.law.nyu.edu/facultyprofiles/index.cfm?fuseaction=profile.overview&per](https://its.law.nyu.edu/facultyprofiles/index.cfm?fuseaction=profile.overview&personid=20228)
23 [sonid=20228](https://its.law.nyu.edu/facultyprofiles/index.cfm?fuseaction=profile.overview&personid=20228).

1 was unreasonable due to agency’s inaccurate assessment of repeal’s economic
2 impact). In those cases, courts have agreed that the agency analyses—and, in turn,
3 the rules issued in reliance on those analyses—were arbitrary and capricious.
4 *California v. BLM*, 277 F. Supp. 3d at 1123 (holding failure to consider forgone
5 benefits arbitrary); *California v. Interior*, 2019 WL 2223804, at *8-13 (finding
6 repeal arbitrary due in part to agency’s flawed economic impact assessment).

7 Policy Integrity has particular expertise on the regulatory impact analysis
8 that the Department of Health and Human Services (“HHS”) conducted in support
9 of the rule at issue in this case, Protecting Statutory Conscience Rights in Health
10 Care; Delegations of Authority, 84 Fed. Reg. 23,170 (May 21, 2019) (“Final
11 Rule”). In 2008, we submitted an expert report on the defective analysis HHS
12 prepared to support a previous effort to expand statutory conscience rights through
13 rulemaking. *See* Inst. for the Study of Regulation, Comments on Ensuring That
14 Department of Health and Human Services Funds Do Not Support Coercive or
15 Discriminatory Policies or Practices in Violation of Federal Law (Sept. 16, 2008).²
16 That 2008 rule was repealed in 2011, but the Final Rule is similar in many respects
17 and has similar fundamental deficiencies in its cost-benefit analysis, as Policy
18 Integrity pointed out in a March 2018 comment letter to HHS. Inst. for Policy
19 Integrity, Comment Letter on Protecting Statutory Conscience Rights in Health

20
21 ² Available at [https://www.regulations.gov/document?D=HHS-OS-2008-0011-](https://www.regulations.gov/document?D=HHS-OS-2008-0011-4969)
22 [4969](https://www.regulations.gov/document?D=HHS-OS-2008-0011-4969). The Institute for Policy Integrity was formerly called the Institute for the
23 Study of Regulation.

1 Care (Mar. 27, 2018).³ We also presented these critiques to the White House Office
2 of Information and Regulatory Affairs in an April 2019 teleconference.

3 Policy Integrity seeks to provide this court with information about the legal
4 and economic standards for good regulatory impact analysis, which HHS failed to
5 satisfy in its analysis of the Final Rule's costs and benefits. Policy Integrity's
6 general interest in this case is to ensure that agencies comply with their obligation
7 to accurately assess the positive and negative impacts of regulatory decisions.

8 **III. POLICY INTEGRITY'S EXPERTISE WILL BENEFIT THE** 9 **COURT**

10 Policy Integrity's proposed amicus brief is also useful to the Court. As noted
11 above, Policy Integrity has experience with the Final Rule at issue in this case,
12 having submitted comments on the proposed version of the Final Rule and having
13 prepared an expert report on the defective analysis HHS prepared to support a
14 similar regulatory expansion of statutory conscience rights in 2008. Policy
15 Integrity has made use of that experience, as well as its expertise in cost-benefit
16 analysis, to explain why HHS's regulatory impact analysis is badly flawed and its
17 Final Rule arbitrary and capricious. While Plaintiff has made a variety of
18 arguments regarding HHS's failure to provide a reasoned explanation for the Final
19 Rule, Policy Integrity's brief is uniquely focused on the agency's economic
20 analysis. The brief can serve as a resource for the Court as it analyzes Plaintiff's

21
22 ³ Available at [https://www.regulations.gov/document?D=HHS-OCR-2018-0002-](https://www.regulations.gov/document?D=HHS-OCR-2018-0002-72071)
23 [72071](https://www.regulations.gov/document?D=HHS-OCR-2018-0002-72071).

1 claim that the Final Rule does not satisfy the requirements of the Administrative
2 Procedure Act. In particular, Policy Integrity’s discussion of the shortcomings in
3 HHS’s regulatory impact analysis can help the Court as it engages with the
4 question of whether the agency’s decisionmaking was arbitrary and capricious.

5 **IV. MEET AND CONFER AND TIMELINESS**

6 Policy Integrity has conferred with the parties concerning the filing of this
7 motion. Plaintiff and Defendants have consented to this motion.

8 This motion is timely. Though this Court does not have rules governing the
9 timing of amicus briefs, the Court may look for guidance to the rules of other
10 district courts. In the U.S. District Court for the District of Columbia, the Local
11 Rules require an amicus motion to be filed “in a timely manner such that it does
12 not unduly delay the Court’s ability to rule on any pending matter.” Rules of the
13 U.S. District Court for the District of Columbia, Local Rule 7(o)(2) at 31 (June
14 2018).⁴ In this case, there is time for the Court to decide Policy Integrity’s motion
15 without unduly delaying the decision on the pending matter. Defendants’
16 opposition is due July 8, 2019, and Plaintiff’s reply is due July 15.

17 **CONCLUSION**

18 For the forgoing reasons, Policy Integrity respectfully requests that the Court
19 grant this motion and accept for filing the accompanying *amicus curiae* brief.
20
21

22 _____
23 ⁴ Available at
<https://www.dcd.uscourts.gov/sites/dcd/files/LocalRulesJune2018.pdf>.

1 Dated: July 1, 2019

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19 *Counsel for Institute for Policy Integrity*

DECLARATION OF SERVICE

I hereby declare that on this day I caused the foregoing document to be electronically filed with the Clerk of the Court using the Court’s CM/ECF System which will serve a copy of this document upon all counsel of record.

DATED this 1st day of July, 2019, at Seattle, Washington.

/s/ Deborah Strayer
Deborah Strayer, Legal Assistant

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8 *Counsel for Institute for Policy Integrity*

9 **UNITED STATES DISTRICT COURT**
10 **FOR THE EASTERN DISTRICT OF WASHINGTON**
11 **AT YAKIMA**

12 STATE OF WASHINGTON,

No. 2:19-cv-00183-SAB

13 Plaintiff,

BRIEF OF THE INSTITUTE FOR
POLICY INTEGRITY AT NEW
YORK UNIVERSITY SCHOOL OF
LAW AS *AMICUS CURIAE* IN
SUPPORT OF PLAINTIFF’S
MOTION FOR PRELIMINARY
INJUNCTION

14 v.

15 ALEX M. AZAR II, in his official
16 capacity as Secretary of the United
States Department of Health and
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17 STATES DEPARTMENT OF
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18 SERVICES,

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19 Defendants.
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Cases	Page(s)
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<i>Bus. Roundtable v. SEC</i> , 647 F.3d 1144 (D.C. Cir. 2011)	5
<i>California v. U.S. Bureau of Land Mgmt.</i> , 277 F. Supp. 3d 1106 (N.D. Cal. 2017)	2, 20
<i>California v. U.S. Dep’t of the Interior</i> , No. C 17-56948 SBA, 2019 WL 2223804 (N.D. Cal. Mar. 29, 2019)	2
<i>Chem. Mfrs. Ass’n v. EPA</i> , 28 F.3d 1259 (D.C. Cir. 1994)	18
<i>Competitive Enter. Inst. v. Nat’l Highway Traffic Safety Admin.</i> , 956 F.2d 321 (D.C. Cir. 1992)	8
<i>Corrosion Proof Fittings v. EPA</i> , 947 F.2d 1201 (5th Cir. 1991)	8
<i>Council of Parent Attorneys and Advocates, Inc. v. DeVos</i> , 365 F. Supp. 3d 28 (D.D.C. 2019)	5
<i>Ctr. for Biological Diversity v. Nat’l Highway Traffic Safety Admin.</i> , 538 F.3d 1172 (9th Cir. 2008)	5, 15
<i>FCC v. Fox Television Stations, Inc.</i> , 556 U.S. 502 (2009)	6, 9
<i>Gen. Chem. Corp. v. United States</i> , 817 F.2d 844 (D.C. Cir. 1987)	13
<i>Michigan v. EPA</i> , 135 S. Ct. 2699 (2015)	8
<i>Mingo Logan Coal Co. v. EPA</i> , 829 F.3d 710 (D.C. Cir. 2016)	7, 18
<i>Motor Vehicle Mfrs. Ass’n v. State Farm Mut. Auto. Ins. Co.</i> , 463 U.S. 29 (1983)	5, 14, 22, 27
<i>Nat’l Ass’n of Home Builders v. EPA</i> , 682 F.3d 1032, 1040 (D.C. Cir. 2012)	4, 5

TABLE OF AUTHORITIES (cont.)

Cases (cont.)	Page(s)
<i>Nat’l Fuel Gas Supply Corp. v. Fed. Energy Reg’y Comm’n.</i> , 468 F.3d 831 (D.C. Cir. 2006)	22
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Exec. Order No. 12,866 § 6(a)(3)(C)(ii), 58 Fed. Reg. 51,735 (Oct. 4, 1993)	7
Statutes	
5 U.S.C. § 706(2)	5
Other Authorities	
American Medical Association, Comment Letter on Protecting Statutory Conscience Rights in Health Care (Mar. 27, 2018)	20
Ascension, Comment Letter on Protecting Statutory Conscience Rights in Health Care (Mar. 26, 2018)	25
Br. for Inst. for Policy Integrity as Amicus Curiae in Support of Plaintiffs’ Motion for Summary Judgment, <i>California v. U.S. Dep’t of the Interior</i> , No. C 17-56948 (N.D. Cal. Mar. 29, 2019)	2
Br. for Inst. for Policy Integrity as Amicus Curiae, <i>California v. U.S. Bureau of Land Mgmt.</i> , 277 F. Supp. 3d 1106 (N.D. Cal. 2017) (No. 17–cv–3804)	2
Christy A. Rentmeester, <i>Moral Damage to Health Care Professionals and Trainees: Legalism and Other Consequences for Patients and Colleagues</i> , 33 J. Med. & Philosophy (2008)	26

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Other Authorities (cont.)	Page(s)
Fariba Borhani et al., <i>The Relationship Between Moral Distress, Professional Stress, and Intent to Stay in the Nursing Profession</i> , 7 J. Med. Ethics & Hist. Med. (2014)	27
Hearing Transcript, <i>Danquah v. Univ. of Med. & Dentistry of New Jersey</i> , Case No. 11-cv-06377 (D.N.J. Dec 16, 2011)	20
HHS, <i>Guidelines for Regulatory Impact Analysis</i> (2016)	19, 27
Institute for Policy Integrity, Comment Letter on Protecting Statutory Conscience Rights in Health Care (Mar. 27, 2018)	3, 9
Inst. for the Study of Regulation, Comments on Ensuring That Department of Health and Human Services Funds Do Not Support Coercive or Discriminatory Policies or Practices in Violation of Federal Law (Sept. 16, 2008)	3
Joan McCarthy & Chris Gastmans, <i>Moral Distress: A Review of the Argument-Based Nursing Ethics Literature</i> , 22 Nursing Ethics (2015)	26
K. Morrell & W. Chavkin, <i>Conscientious Objection to Abortion and Reproductive Healthcare: A Review of Recent Literature and Implications for Adolescents</i> , 27 Curr. Opin. Obstet. Gynecol. (2015)	14
Lambda Legal, <i>When Health Care Isn't Caring: Lambda Legal's Survey on Discrimination Against LGBT People and People Living with HIV</i> (2010)	11
ModernMedicine Network, <i>ACOG Releases New Study on Ob/Gyn Workforce</i> (July 1, 2017)	24
Nat'l Women's Law Ctr., <i>Refusals to Provide Health Care Threaten the Health and Lives of Patients Nationwide</i> (Aug. 30, 2017)	10, 12
Office of Mgmt. & Budget, <i>Circular A-4 on Regulatory Analysis</i> (2003)	7, 16, 27
Richard L. Revesz & Michael A. Livermore, <i>Retaking Rationality: How Cost-Benefit Analysis Can Better Protect the Environment and Our Health</i> (2008)	1
Sari L. Reisner et al., <i>Legal Protections in Public Accommodations Settings: A Critical Public Health Issue for Transgender and Gender-Nonconforming People</i> , 93 Milbank Q. (2015)	12
The Public Rights/Private Conscience Project, Comment Letter on Protecting Statutory Conscience Rights in Health Care (Mar. 27, 2018)	28

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Other Authorities (cont.)	Page(s)
W. Chavkin et al., <i>Conscientious Objection and Refusal to Provide Reproductive Healthcare: A White Paper Examining Prevalence, Health Consequences, and Policy Responses</i> , 123 Int’l J. Gynecol. & Obstet. S41 (2013)	14

1 The Institute for Policy Integrity at New York University School of Law
2 (“Policy Integrity”)¹ submits this brief as *amicus curiae* in support of Plaintiff’s
3 motion for an order enjoining the Department of Health and Human Services’
4 (“HHS” or the “Department”) final rule, Protecting Statutory Conscience Rights in
5 Health Care; Delegations of Authority, 84 Fed. Reg. 23,170 (May 21, 2019)
6 (“Final Rule”).

7 **INTEREST OF AMICUS CURIAE**

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9 improving the quality of government decisionmaking through advocacy and
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12 practices for regulatory impact analysis and the proper valuation of regulatory
13 costs and benefits. Most notably, our director, Richard L. Revesz, has published
14 more than eighty articles and books on environmental and administrative law,
15 including works on the legal and economic principles that inform rational
16 regulatory decisions. *See, e.g.*, Richard L. Revesz & Michael A. Livermore,

17
18 ¹ This brief does not purport to represent the views of New York University School
19 of Law, if any. Policy Integrity states that no party’s counsel authored this brief in
20 whole or in part, and no party or party’s counsel contributed money intended to
21 fund the preparation or submission of this brief. No person—other than the *amicus*
22 *curiae*, its members, or its counsel—contributed money intended to fund the
23 preparation of this brief.

1 *Retaking Rationality: How Cost-Benefit Analysis Can Better Protect the*
2 *Environment and Our Health* (2008).²

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15 the rules issued in reliance on those analyses—were arbitrary and capricious.
16 *California v. BLM*, 277 F. Supp. 3d at 1123 (holding failure to consider forgone
17 benefits arbitrary); *California v. Interior*, 2019 WL 2223804, at *8-13 (finding
18 repeal arbitrary due in part to agency’s flawed economic impact assessment).

19
20 ² A full list of publications can be found in Revesz’s online faculty profile,
21 available at
22 [https://its.law.nyu.edu/facultyprofiles/index.cfm?fuseaction=profile.overview&per](https://its.law.nyu.edu/facultyprofiles/index.cfm?fuseaction=profile.overview&personid=20228)
23 [sonid=20228](https://its.law.nyu.edu/facultyprofiles/index.cfm?fuseaction=profile.overview&personid=20228).

1 Policy Integrity has particular expertise on the regulatory impact analysis
2 that HHS conducted in support of the Final Rule. In 2008, we submitted an expert
3 report on the defective analysis HHS prepared to support a previous effort to
4 expand statutory conscience rights through rulemaking. *See* Inst. for the Study of
5 Regulation, Comments on Ensuring That Department of Health and Human
6 Services Funds Do Not Support Coercive or Discriminatory Policies or Practices in
7 Violation of Federal Law (Sept. 16, 2008).³ That 2008 rule was repealed in 2011,
8 but the Final Rule is similar in many respects and has similar fundamental
9 deficiencies in its cost-benefit analysis, as Policy Integrity pointed out in a March
10 2018 comment letter. Inst. for Policy Integrity, Comment Letter on Protecting
11 Statutory Conscience Rights in Health Care (Mar. 27, 2018) (“Policy Integrity
12 Comments”).⁴ We also presented these critiques to the White House Office of
13 Information and Regulatory Affairs in an April 2019 teleconference.

14 Plaintiff argues that the Final Rule is arbitrary and capricious in part because
15 HHS relied on a “fatally flawed” regulatory impact analysis. State of Washington’s
16 Motion for Preliminary Injunction at 34. Policy Integrity’s expertise in cost-benefit
17

19 ³ Available at [https://www.regulations.gov/document?D=HHS-OS-2008-0011-](https://www.regulations.gov/document?D=HHS-OS-2008-0011-4969)
20 [4969](https://www.regulations.gov/document?D=HHS-OS-2008-0011-4969). The Institute for Policy Integrity was formerly called the Institute for the
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23 [72071](https://www.regulations.gov/document?D=HHS-OCR-2018-0002-72071).

1 analysis and experience with the Final Rule give it a unique perspective from
2 which to evaluate Plaintiff’s claim that the Final Rule is arbitrary and capricious.

3 **SUMMARY OF ARGUMENT**

4 When an agency relies on a cost-benefit analysis to support its rulemaking,
5 “a serious flaw undermining that analysis can render the rule unreasonable.” *Nat’l*
6 *Ass’n of Home Builders v. EPA*, 682 F.3d 1032, 1040 (D.C. Cir. 2012). HHS has
7 prepared a regulatory impact analysis for the Final Rule in which it concludes that
8 “the benefits of this rule, although not always quantifiable or monetized, justify the
9 burdens.” 84 Fed. Reg. at 23,228. But the analysis underlying that assertion is
10 fundamentally flawed in at least two respects.

11 First, although HHS acknowledges that the Final Rule will increase the
12 frequency with which conscience rights are invoked as grounds for refusing to
13 provide healthcare, the Department does not meaningfully assess—qualitatively or
14 quantitatively—the costs of such refusals. Specifically, the Department fails to
15 consider the financial, physical, and psychological harms that increased refusals
16 will impose on women in need of reproductive services; lesbian, gay, bisexual, and
17 transgender (LGBT) patients; and patients living with HIV or seeking HIV-
18 preventive services. HHS also ignores staffing costs that provider organizations
19 will incur to accommodate increased refusals of care by their employees.

20 Second, the claimed benefits of the rule are entirely speculative. The
21 Department claims the Final Rule will increase the ranks of healthcare
22 professionals, improve the quality of doctor-patient relationships, reduce individual
23 healthcare professionals’ degree of “moral distress,” and promote the “societal

1 good” of personal freedom for individuals to conduct themselves based on their
2 religious beliefs and moral convictions. 84 Fed. Reg. at 23,246. But these claims
3 are unsupported by—and in some instances contradicted by—evidence in the
4 record.

5 By dismissing reasonably foreseeable costs and touting wholly speculative
6 benefits, HHS “inconsistently and opportunistically frame[s]” the Final Rule’s
7 effects, *Bus. Roundtable v. SEC*, 647 F.3d 1144, 1148-49 (D.C. Cir. 2011), and
8 “put[s] a thumb on the scale” in favor of its adoption, *Ctr. for Biological Diversity*
9 *v. Nat’l Highway Traffic Safety Admin.*, 538 F.3d 1172, 1198 (9th Cir. 2008). The
10 Department’s reliance on this rigged analysis renders the Final Rule arbitrary and
11 capricious.

12 ARGUMENT

13 Final agency actions like the Final Rule are arbitrary and capricious under
14 the Administrative Procedure Act, 5 U.S.C. § 706(2), if the agency fails to
15 “examine the relevant data,” “consider an important aspect of the problem,” or
16 “articulate a satisfactory explanation for its action, including a rational connection
17 between the facts found and the choice made.” *Motor Vehicle Mfrs. Ass’n v. State*
18 *Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) (internal quotation marks
19 omitted). When the justifications for the action include the results of a cost-benefit
20 analysis, “a serious flaw undermining the analysis can render the rule
21 unreasonable.” *Nat’l Ass’n of Home Builders*, 682 F.3d at 1040. This is true even
22 when the agency was not statutorily obligated to conduct the analysis in the first
23 place. *Id.* at 1039-40; *Council of Parent Attorneys and Advocates, Inc. v. DeVos*,

1 365 F. Supp. 3d 28, 54 n.11 (D.D.C. 2019) (rejecting government’s contention that
2 a regulatory impact analysis “conducted pursuant to Executive Orders” rather than
3 a statutory mandate was “not subject to judicial review”). Finally, if the agency’s
4 action represents a change of position on a particular issue, the agency must
5 provide a “reasoned explanation . . . for disregarding facts and circumstances that
6 underlay or were engendered by the prior policy.” *FCC v. Fox Television Stations,*
7 *Inc.*, 556 U.S. 502, 515-16 (2009); *see also Organized Vill. of Kake v. U.S. Dep’t of*
8 *Agric.*, 795 F.3d 956, 968 (9th Cir. 2015) (“[E]ven when reversing a policy after an
9 election, an agency may not simply discard prior factual findings without a
10 reasoned explanation.”).

11 Here, in assessing the likely impacts of the Final Rule, HHS failed to
12 consider relevant information regarding the harms that more frequent conscience-
13 related denials of healthcare would impose on patients and providers, failed to
14 provide a reasoned explanation for disregarding its prior conclusions regarding
15 these harms, and failed to provide any evidence to support its determination that
16 the Final Rule would generate sufficient benefits to offset its negative effects. As a
17 result, the Final Rule is arbitrary and capricious under the Administrative
18 Procedure Act and should be vacated.

19
20 **I. HHS Does Not Adequately Assess the Final Rule’s Significant
Indirect Costs to Patients and Provider Organizations**

21 As required under Executive Orders 12,866 and 13,563, HHS prepared an
22 analysis of the Final Rule’s “economic implications.” 84 Fed. Reg. at 23,228.

23 While this analysis tallies the Final Rule’s direct compliance costs for providers, in

1 the form of familiarization and paperwork-related expenses, *see* 84 Fed. Reg. at
2 23,240, tbl.6, it fails to assess the new policy’s *indirect* costs, in the form of harms
3 to patients who are refused care on conscience grounds and additional staffing
4 burdens for medical employers who must accommodate such refusals. Indeed,
5 these effects are not even listed in the Department’s summary of unquantified
6 costs. *See* 84 Fed. Reg. at 23,227, tbl.1 (listing quantified and non-quantified costs
7 that HHS considered).

8 HHS’s failure to assess indirect costs is, first, flatly contrary to the
9 requirements of Executive Order 12,866, which instructs agencies to consider not
10 just “direct cost . . . to businesses and others in complying with the regulation,” but
11 also “any adverse effects” the rule might have on “the efficient functioning of the
12 economy, private markets . . . health, safety, and the natural environment.” Exec.
13 Order No. 12,866 § 6(a)(3)(C)(ii), 58 Fed. Reg. 51,735 (Oct. 4, 1993).

14 Longstanding guidance on regulatory impact analysis from the Office of
15 Management & Budget similarly directs agencies to “look beyond the direct
16 benefits and direct costs of [their] rulemaking and consider any important ancillary
17 [i.e., indirect] benefits and countervailing risks.” Office of Mgmt. & Budget,
18 *Circular A-4 on Regulatory Analysis* 26 (2003) [hereinafter *Circular A-4*].

19 More importantly, ignoring indirect costs violates HHS’s duties under the
20 Administrative Procedure Act. “As a general rule, the costs of an agency’s action
21 are a relevant factor that the agency must consider before deciding whether to act,”
22 and “consideration of costs is an essential component of reasoned decisionmaking
23 under the Administrative Procedure Act.” *Mingo Logan Coal Co. v. EPA*, 829 F.3d

1 710, 732–33 (D.C. Cir. 2016) (Kavanaugh, J., dissenting); *see also Michigan v.*
2 *EPA*, 135 S. Ct. 2699, 2707–08 (2015) (“Agencies have long treated cost as a
3 centrally relevant factor when deciding whether to regulate.”).

4 Legally relevant costs “include[] more than the expense of complying with
5 regulations”; instead, “any disadvantage could be termed a cost.” *Id.* at 2707.
6 Accordingly, courts have repeatedly struck down rules that fail to consider
7 potentially significant indirect costs. *See, e.g., Competitive Enter. Inst. v. Nat’l*
8 *Highway Traffic Safety Admin.*, 956 F.2d 321, 326-27 (D.C. Cir. 1992) (remanding
9 fuel-efficiency rule due to agency’s failure to consider indirect safety costs);
10 *Corrosion Proof Fittings v. EPA*, 947 F.2d 1201, 1225 (5th Cir. 1991) (striking
11 down rule for failure to consider indirect safety effects of substituting asbestos-free
12 car brakes).

13 HHS’s failure to consider indirect costs to patients would be impermissible
14 in any rulemaking but is particularly arbitrary here, because the Department
15 already recognized the existence of these costs in a prior rulemaking. In 2011,
16 HHS cited indirect costs to justify repealing a 2008 conscience rule that purported
17 to implement many of the same statutory provisions as the Final Rule, in very
18 similar ways. *See* 76 Fed. Reg. 9968, 9974 (Feb. 23, 2011) (“2011 Rescission”)
19 (agreeing with commenter concerns that the 2008 rule “could limit access to
20 reproductive health services and information, including contraception, and could
21 impact a wide range of medical services, including care for sexual assault victims,
22 provision of HIV/AIDS treatment, and emergency services”); *see also* 73 Fed.
23 Reg. 78,072, 78,078 (Dec. 19, 2008) (“2008 Rule”). The APA obligates HHS to

1 provide a “reasoned explanation” for disregarding the findings underlying the 2011
2 Rescission, *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515-16 (2009), and
3 the Department has not done so. *See also Kake*, 795 F.3d at 968.

4
5 **A. HHS Does Not Adequately Consider Costs to Patients Denied Care
as a Result of the Final Rule**

6 HHS expects that, as a result of the Final Rule, “more individuals, having
7 been apprised of [conscience] rights, will assert them.” 84 Fed. Reg. at 23,250. Put
8 another way, the Final Rule will lead more healthcare workers to decline to
9 provide services or information about services on moral or religious grounds. It
10 follows that patient populations who already experience costs associated with
11 conscience-related refusals of care—like women in need of reproductive health
12 services; lesbian, gay, bisexual, and transgender patients; and patients living with
13 HIV or seeking HIV-preventive services—will see those costs increase as a result
14 of the Final Rule. But in its regulatory impact analysis, HHS refuses to assess these
15 costs appropriately, in either quantitative or qualitative terms.

16 **1. Conscience-Based Refusals of Care Impose Costs on Patients**

17 As Policy Integrity emphasized to HHS in comments on the proposed
18 version of the Final Rule, conscience-related refusals of care can impose a variety
19 of costs—financial, physical, and psychological—on patients. Policy Integrity
20 Comments at 5. At minimum, a patient denied care must incur the cost of seeking
21 out an alternative provider. Furthermore, some patients denied care may be too
22 discouraged to seek out alternative sources of care and decide to forgo treatment
23 altogether, leading to negative health consequences. Or, if the care is denied in an

1 urgent or emergency situation, there may not be adequate time to find an
2 alternative, leading in some cases to catastrophic health consequences.

3 This fundamental point—that conscience-related refusals of care impose real
4 and significant costs on patients—was reinforced by numerous other commenters
5 who submitted evidence to HHS regarding the types of patients who are most often
6 denied care on conscience grounds and the nature of the resulting harms. Evidence
7 in the record shows that women, for example, already suffer significant physical,
8 psychological, and financial harms from conscience-related denials of reproductive
9 health services, including refusals by religiously affiliated hospitals to provide
10 sterilization treatment at the time of cesarean delivery, even though is the safest
11 and most cost-effective time at which to undergo the procedure and even in cases
12 where a subsequent pregnancy would severely threaten the health or life of the
13 mother; refusals by pharmacies to fill prescriptions for emergency contraception or
14 to transfer the prescription to a pharmacy that that will, even for rape survivors;
15 and refusals by insurance plans to cover birth control. Nat’l Women’s Law Ctr.,
16 *Refusals to Provide Health Care Threaten the Health and Lives of Patients*
17 *Nationwide* 1 (Aug. 30, 2017).⁵

18 LGBT people and individuals living with HIV also contend with denials of a
19

20 ⁵ Available at <https://perma.cc/6SZU-W5TV>. This report was cited in 43 sets of
21 comments on the Final Rule, according to a search of the docket. *See*
22 <https://www.regulations.gov/docket?D=HHS-OCR-2018-0002> (last visited on June
23 12, 2019).

1 variety of health services, including those unrelated to their sexual orientation,
2 gender identity, and HIV status. *Id.* A rigorously conducted, nationwide survey
3 found in 2010 that nearly eight percent of lesbian, gay, and bisexual respondents
4 and almost twenty-seven percent of transgender respondents reported being refused
5 necessary healthcare because of their sexual orientation and gender identity,
6 respectively. Lambda Legal, *When Health Care Isn't Caring: Lambda Legal's*
7 *Survey on Discrimination Against LGBT People and People Living with HIV* 10
8 (2010).⁶ Just as they do for women in need of reproductive health services, these
9 conscience-related denials of care can carry substantial costs for affected LGBT
10 and HIV-positive patients. In one example in the record, an HIV-positive patient
11 denied treatment for chest pain ended up “admitted to the hospital” a week later,
12

13 ⁶ Available at <https://perma.cc/6SJU-Q9WB>. That survey's findings were echoed
14 in the Institute of Medicine's 2011 report, *The Health of Lesbian, Gay, Bisexual,*
15 *and Transgender People: Building a Foundation for Better Understanding* (2011),
16 [https://www.nap.edu/catalog/13128/the-health-of-lesbian-gay-bisexual-and-](https://www.nap.edu/catalog/13128/the-health-of-lesbian-gay-bisexual-and-transgender-people-building/)
17 [transgender-people-building/](https://www.nap.edu/catalog/13128/the-health-of-lesbian-gay-bisexual-and-transgender-people-building/), and were largely reproduced by a survey of LGBT
18 people conducted in 2016. Shabab Ahmed Mirza & Caitlin Rooney, Ctr. for Am.
19 Progress, *Discrimination Prevents LGBTQ People from Accessing Health Care*
20 (2016), <https://perma.cc/S3BR-F3WW>. Each of these documents was cited by
21 dozens of commenters on the Final Rule, according to a search of the docket. *See*
22 <https://www.regulations.gov/docket?D=HHS-OCR-2018-0002> (last visited on June
23 12, 2019).

1 “with gastrointestinal hemorrhaging and was diagnosed with pneumonia, a staph
2 infection, and AIDS.” Nat’l Women’s Law Ctr. at 2. On a more general level,
3 nearly twenty percent of transgender respondents to a Massachusetts-based survey
4 indicated that prior mistreatment by healthcare providers had led them to postpone
5 or forgo treatment when sick or injured. Sari L. Reisner et al., *Legal Protections in*
6 *Public Accommodations Settings: A Critical Public Health Issue for Transgender*
7 *and Gender-Nonconforming People*, 93 *Milbank Q.* 484, 494 (2015).

8 **2. The Final Rule Will Lead to an Increase in Refusals of Care**

9 HHS recognizes that refusals of care can carry costs for patients. 84 Fed.
10 Reg. at 23,251 (“Different types of harm can result from denial of a particular
11 procedure based on an exercise of [a religious or moral] belief or conviction.”).
12 The Department will not concede, however, that such refusals will increase under
13 the Final Rule, instead arguing that commenters claiming “that the rule would
14 result in harm” failed to “establish[] a causal relationship between this rule and
15 how it would affect health care access.” *Id.* at 23,250. This professed uncertainty as
16 to whether the Final Rule will lead to more refusals of care is inconsistent with the
17 Department’s claims regarding the benefits of the Final Rule, with findings the
18 Department made in the 2011 Rescission, and with the findings of studies that the
19 Department relies upon in the current proceeding.

20 As noted earlier, in its description of the Final Rule’s *benefits*, the
21 Department claims that “as a result of this rule, more individuals, having been
22 apprised of [their conscience] rights, will assert them.” *Id.* It is difficult to imagine
23 how a rule could cause more workers to assert a right to deny care without *also*

1 causing an increase in denials of care. HHS cannot have it both ways, arguing that
2 the Final Rule will affect the behavior of providers without altering the experiences
3 of their patients. The Department’s logical inconsistency on this point renders the
4 Final Rule arbitrary and capricious. *See Gen. Chem. Corp. v. United States*, 817
5 F.2d 844, 857 (D.C. Cir. 1987) (deeming agency conclusion arbitrary and
6 capricious where supporting analysis was “internally inconsistent”).

7 HHS’s unwillingness to concede that the Final Rule will result in increased
8 refusals of care is particularly unreasonable in light of its findings to the contrary
9 in the 2011 Rescission. In that proceeding, HHS agreed with commenters that the
10 2008 Rule “could limit access to reproductive health services and information,
11 including contraception, and could impact a wide range of medical services,
12 including care for sexual assault victims, provision of HIV/AIDS treatment, and
13 emergency services.” 76 Fed. Reg. at 9974. Because the Final Rule “generally
14 reinstates the structure of the 2008 Rule,” 84 Fed. Reg. at 23,179, one would
15 expect it to pose the same threat to access to care for sexual assault victims and
16 those living with HIV. If HHS disagrees, it must provide a “reasoned explanation”
17 for reaching a different conclusion than it did in the 2011 Rescission—for
18 example, by citing evidence suggesting that, contrary to the Department’s previous
19 findings, an expansive conscience rule will *not* reduce access to care for these
20 populations. *Fox*, 556 U.S. at 515-16.

21 The Department does cite two studies that it claims found “insufficient
22 evidence to conclude that conscience protections have negative effects on access to
23 care.” 84 Fed. Reg. at 23,251 (citing W. Chavkin et al., *Conscientious Objection*

1 *and Refusal to Provide Reproductive Healthcare: A White Paper Examining*
2 *Prevalence, Health Consequences, and Policy Responses*, 123 Int’l J. Gynecol. &
3 Obstet. S41 (2013); K. Morrell & W. Chavkin, *Conscientious Objection to*
4 *Abortion and Reproductive Healthcare: A Review of Recent Literature and*
5 *Implications for Adolescents*, 27 Curr. Opin. Obstet. Gynecol. 333 (2015)). But
6 those studies actually show that conscience-based refusals *are* a material barrier to
7 care and that the only open empirical question is the extent to which such refusals
8 negatively affect patient health. HHS’s quotations from the studies are misleading
9 reflections of their true points—namely, that “it is difficult to disentangle the
10 impact of conscientious objection when *it is one of many barriers* to reproductive
11 healthcare,” Chavkin at S42 (emphasis added), and that “[c]onscientious objection
12 is understudied, complicated, and *appears to constitute a barrier to care*,
13 especially for certain subgroups,” Morrell & Chavkin at 334 (emphasis added).
14 Thus, HHS’s conclusion that the Final Rule will not negatively affect access to
15 care “runs counter to the evidence before the agency.” *State Farm*, 463 U.S. at 43.

16 **3. Uncertainty Does Not Excuse HHS’s Failure to Estimate the** 17 **Final Rule’s Effects on the Rate and Nature of Conscience-** 18 **Related Refusals of Care**

19 In addition to suggesting that the Final Rule may have *no* negative effects on
20 patients’ access to care, HHS claims that estimating the magnitude of such effects
21 is simply too difficult. 84 Fed. Reg. at 23,252 (“The Department attempted to
22 quantify the impact of this rule on access to care but determined that there is not
23 enough reliable data, and that the analysis was subject to too many confounding
variables, for the Department to arrive at a useful estimate.”). But uncertainty

1 about the precise magnitude of a regulatory effect does not justify assigning that
2 effect no value in a cost-benefit analysis. *Ctr. for Biological Diversity v. Nat'l*
3 *Highway Traffic Safety Admin.*, 538 F.3d 1172, 1190, 1200 (9th Cir. 2008) (finding
4 agency reasoning arbitrary and capricious where agency argued that benefits of
5 carbon dioxide reductions were “too uncertain to support their explicit valuation
6 and inclusion” in a regulatory cost-benefit analysis). Ultimately, while there may
7 be “a range of values” for the costs to patients of the Final Rule, that value “is
8 certainly not zero.” *Id.* at 1200. Thus, the costs must be “accounted for in the
9 agency’s analysis.” *Id.*

10 HHS repeatedly complains that it lacks the necessary data to consider costs
11 to patients. *See, e.g.*, 84 Fed. Reg. at 23,252 (“The Department is not aware of a
12 source for data on the percentages of providers who have religious beliefs or moral
13 convictions against each particular service or procedure that is the subject of this
14 rule.”); *id.* (“[T]he Department lacks the predicate for estimating the impact on
15 health outcomes of any change in the availability of services.”). But the
16 Department is perfectly capable of *generating* such data by conducting its own
17 surveys. Indeed, White House guidance on regulatory impact analysis urges
18 agencies to do just that when confronted with significant uncertainties about
19 regulatory effects. *Circular A-4* at 39 (“When uncertainty has significant effects on
20 the final conclusion about net benefits, your agency should consider additional
21 research prior to rulemaking. The costs of being wrong may outweigh the benefits
22 of a faster decision.”). An agency does not prove that it is impossible to ascertain
23 the answer to a question by refusing to ask it.

1 Ultimately, even if HHS cannot fully quantify and monetize the expected
2 costs of the rule for patients, the Department should at least engage in a rigorous
3 qualitative analysis, in which it lists the types of procedures that might be denied as
4 a result of the rule and the potential consequences of such denials for patients,
5 assigning dollar values to these consequences wherever possible. Circular A-4 at
6 39 (“In some cases, the level of scientific uncertainty may be so large that you can
7 only present discrete alternative scenarios without assessing the relative likelihood
8 of each scenario quantitatively.”); *id.* at 27 (“If you are not able to quantify the
9 effects, you should present any relevant quantitative information along with a
10 description of the unquantified effects . . .”).

11 Instead, HHS blames commenters for failing to do the Department’s work
12 for it. 84 Fed. Reg. at 23,250 (arguing that commenters failed “to answer the
13 difficult question of how this rule would affect access to care and health outcomes,
14 and how to quantify those effects”); *id.* at 23,252 (“No comment attempted a
15 detailed description of the actual impact expected from the rule on access to care,
16 health outcomes, and associated concerns.”). But while commenters can supply
17 useful information to inform an agency’s analysis—and, as discussed in Section
18 I.A.1, did so here—the agency bears the ultimate burden of supplying “a
19 satisfactory explanation for its action,” including due consideration of “relevant
20 factors” like cost. *Fox*, 556 U.S. at 513, 549.

21 HHS’s criticism of commenters for not providing it with a complete
22 assessment of the Final Rule’s effects on access to care is particularly galling given
23 that the uncertainty surrounding those effects is largely of the Department’s own

1 making. Repeatedly in the preamble to the Final Rule, HHS declines opportunities
2 to provide guidance on the circumstances under which the Final Rule protects
3 refusals of care. For example, in response to comments warning that that the Final
4 Rule could negatively “impact counseling or referrals for LGBT persons,” the
5 Department could easily have clarified that the Final Rule’s protections do not
6 apply to providers who deny care based on objections to a patient’s sexual
7 orientation or gender identity. 84 Fed. Reg. at 23,189. Instead, HHS says only that
8 it “does not pre-judge matters without the benefit of specific facts and
9 circumstances” and that any invocations of conscience rights “will be evaluated on
10 a case-by-case basis.” *Id.* Similarly, in response to concerns that that the Final Rule
11 will promote denials of HIV or infertility treatment, HHS again fails to specify
12 whether and when a refusal to provide such treatment might fall within the scope
13 of protected conduct, noting only that, if it received a complaint from a healthcare
14 worker who felt coerced into providing such treatments, the Department “would
15 examine the facts and circumstances of the complaint to determine whether it falls
16 within the scope of the statute in question and these regulations.” *Id.* at 23,188. If
17 HHS will not explain how its Final Rule changes the legal status quo, it cannot
18 reasonably expect commenters to independently assess the costs of that change.

19 **4. HHS Cannot Excuse Its Failure to Assess Patient Costs by**
20 **Making a Conclusory Assertion That Any Such Costs Are**
21 **Justified**

22 HHS attempts to excuse its failure to assess the Final Rule’s costs to patients
23 by asserting that “the Department expects any decreases in access to care to be
outweighed by significant overall increases in access generated by this rule.” 84

1 Fed. Reg. at 23,252. In other words, HHS claims that any costs to patients
2 associated with the Final Rule are functionally irrelevant because they are
3 outweighed by benefits.

4 But even if it were true that any increase in refusals of specific types of care
5 under the Final Rule would be outweighed by an increase in access to other types
6 of care—and, as discussed in Section II, HHS has provided no credible evidence
7 that this is the case—a conclusion regarding the Final Rule’s *net* effects does not
8 substitute for a discussion of the “relevant factor” of cost. *Mingo Logan*, 829 F.3d
9 at 732–33. The Department remains obligated to specify who will be harmed by
10 the Final Rule and in what ways they will be harmed, even if it believes those costs
11 are justified by benefits to others. For example, elsewhere in the preamble to the
12 Final Rule, HHS suggests conscience protections under the Final Rule might, in
13 some circumstances, extend to ambulance drivers who refuse “emergency
14 transportation of persons with conditions such as an ectopic pregnancy, where the
15 potential procedures performed at the hospital may include abortion.” 84 Fed. Reg.
16 at 23,187. The health consequences of such a refusal could be severe, yet they are
17 not mentioned in the regulatory impact analysis for the Final Rule.

18 In the absence of an acknowledgement of these costs, HHS’s conclusory
19 assertion that the Final Rule will have a *net* positive effect on healthcare access
20 “adds nothing to the agency’s defense of its thesis except perhaps the implication
21 that it was committed to its position regardless of any facts to the contrary.” *Chem.*
22 *Mfrs. Ass’n v. EPA*, 28 F.3d 1259, 1266 (D.C. Cir. 1994). As the Department’s
23 own *Guidelines for Regulatory Impact Analysis* warn, “[i]n the absence of

1 information, decision-makers and others may weight nonquantified effects in a
2 manner consistent with their own (unarticulated and perhaps unconscious) beliefs,
3 without sufficiently probing the rationale or the weighting.” HHS, *Guidelines for*
4 *Regulatory Impact Analysis* 47 (2016) [hereinafter *HHS Guidelines*]. To
5 “counterbalance this tendency,” HHS’s *Guidelines* require “[c]lear presentation of
6 the available evidence,” *id.*, which the Department utterly fails to provide in its
7 analysis for the Final Rule.

8 **5. HHS Cannot Excuse Its Failure to Assess Patient Costs by**
9 **Claiming That the Costs Are Attributable to Congressional**
10 **Decisions**

11 HHS’s final excuse for inadequately assessing the Final Rule’s costs for
12 patients is that any objections to the Final Rule “based on potential (often
13 temporary) lack of access to particular procedures as a result of enforcement of the
14 law are really objections to policy decisions made by the people’s representatives
15 in Congress in enacting the Federal conscience and anti-discrimination laws in the
16 first place.” 84 Fed. Reg. at 23,251. This argument, too, is unavailing. While the
17 statutory provisions underlying the Final Rule were indeed passed by Congress,
18 HHS has made a discretionary decision to adopt new, unprecedentedly expansive
19 definitions of terms in those provisions and new procedures for enforcing the
20 provisions. That discretionary decision has costs relative to the status quo, which
21 the Administrative Procedure Act obligates the Department to consider.
22 Furthermore, if it *were* true that no patient costs associated with invocations of
23 conscience rights could be attributed to the Final Rule, it would necessarily *also* be
true that the Final Rule could claim no credit for patient or provider *benefits*

1 associated with such invocations. HHS, in short, cannot rationally claim that the
2 Final Rule has incremental benefits without acknowledging corresponding
3 incremental costs. *See California v. U.S. Bureau of Land Mgmt.*, 277 F. Supp. 3d
4 1106, 1123 (N.D. Cal. 2017) (agencies cannot consider only “one side of the
5 equation” by calculating benefits and ignoring costs).

6
7 **B. HHS Completely Ignores Costs to Provider Organizations of
Accommodating Increased Refusals of Care**

8 In addition to failing to adequately assess costs that more frequent
9 conscience-related refusals of care will impose on patients, HHS completely
10 ignores the costs that provider organization will incur in accommodating such
11 refusals. As the American Medical Association warned in comments, increased
12 invocations of conscience rights by individual healthcare workers “could
13 significantly impact the smooth flow of health care operations for physicians,
14 hospitals, and other health care institutions and could be unworkable in many
15 circumstances.” American Medical Association, Comment Letter on Protecting
16 Statutory Conscience Rights in Health Care 4–5 (Mar. 27, 2018).

17 While the Final Rule authorizes employers to request some advance notice
18 of objections, 84 Fed. Reg. at 23,191–92, employers may make such requests only
19 after hiring an employee, and cannot then fire that employee for conscience-based
20 refusals to provide care. Thus, even large, urban hospitals will likely bear
21 significant costs when accommodating employees who refuse to provide or assist
22 with certain forms of care. *See, e.g.*, Hearing Transcript, *Danquah v. Univ. of Med.*
23 *& Dentistry of New Jersey*, Case No. 11-cv-06377, (D.N.J. Dec 16, 2011)

1 (indicating that hospital hired team of nurses to fill staffing gap left by nurses who
2 refused to assist with provision of abortion or related procedures).⁷ For provider
3 organizations with access to fewer resources, such as those in remote locations, the
4 costs of finding replacement staff and adjusting patient and provider schedules to
5 accommodate increased invocation of conscience rights could be greater still. But
6 such costs are mentioned nowhere in HHS’s regulatory impact analysis. HHS’s
7 failure to consider these costs is particularly egregious given that elsewhere in the
8 preamble to the Final Rule the Department expressly contemplates “the use [of]
9 alternate staff” and other staffing adjustments to accommodate objections and
10 refusals on conscience grounds. 84 Fed. Reg. at 23,191–92, 23,202, 23,263.

11 **II. The Final Rule’s Purported Benefits Are Speculative and** 12 **Unsupported by Evidence**

13 Courts have explained that, while an agency’s predictive judgments about
14 the likely economic effects of a rule are entitled to deference,” those judgments
15 “must be based on some logic and evidence, not sheer speculation.” *Sorenson*
16 *Commc’ns Inc. v. F.C.C.*, 755 F.3d 702, 708 (D.C. Cir. 2014) (citations and
17 internal quotation marks omitted). In its regulatory impact analysis, HHS claims
18 the Final Rule will yield three types of benefits: a net increase in access to
19 healthcare, better quality of care, and “societal goods that extend beyond health
20 care.” 84 Fed. Reg. at 23,246. HHS explains further that the Final Rule will deliver
21

22 ⁷ HHS cites *Danquah*—but not this particular hearing transcript—in the Final Rule.
23 84 Fed. Reg. at 3888.

1 these benefits through four mechanisms: first, it will increase “the availability of
2 qualified health care professionals,” in part by preventing exits from the field;
3 second, it will improve the quality of doctor-patient relationships; third, it will
4 reduce “moral distress” among providers; and, fourth, it will promote the “societal
5 good” of “protection of religious beliefs and moral convictions” by giving
6 providers greater “personal freedom” to act in accordance with their beliefs. 84
7 Fed. Reg. at 23,246. But HHS’s analysis of these beneficial effects is grounded
8 only in “sheer speculation,” *see Sorenson*, 755 F.3d at 708, and in at least one
9 instance is contradicted by evidence HHS itself added to the record, *see State*
10 *Farm*, 463 U.S. at 56–57 (action is arbitrary and capricious if explanation “runs
11 counter to the evidence before the agency”). The Final Rule is, as a result, arbitrary
12 and capricious. *Nat’l Fuel Gas Supply Corp. v. Fed. Energy Reg’y Comm’n.*, 468
13 F.3d 831, 839 (D.C. Cir. 2006) (agency action found arbitrary and capricious
14 where agency “provided no evidence of a real problem” the action would solve);
15 *Arizona Cattle Growers’ Ass’n v. U.S. Fish & Wildlife, Bureau of Land Mgmt.*, 273
16 F.3d 1229, 1244 (9th Cir. 2001) (action found arbitrary and capricious where based
17 on “speculation ... not supported by the record.”).

18
19 **A. HHS Offers No Evidence That the Final Rule Will Increase the
20 Number of U.S. Healthcare Professionals**

21 HHS claims that “[n]umerous studies and comments show that the failure to
22 protect conscience is a barrier to careers in the health care field,” 84 Fed. Reg. at
23 23,246, but the record contains only a handful of anecdotes reporting early
retirements for reasons of conscience, and *no* data evidencing a noticeable rate of

1 professional exit. Instead, HHS refers repeatedly to the results of an online survey
2 of self-selecting members of five Christian medical associations conducted on
3 behalf of the Christian Medical and Dental Association in 2009, just after HHS
4 proposed to repeal the 2008 Rule.⁸ *See* 84 Fed. Reg. at nn.15, 38, 309, 316–18,
5 322, 340, 347, 349. HHS highlights repeatedly that ninety-one percent of
6 respondents said that they “would rather stop practicing medicine altogether than
7 be forced to violate [their] conscience.” *See id.* at 23,191 nn.46 & 48, 23,246-47.
8 At one point, it pairs this point with a reference to the claim, submitted by the
9 American Association of Pro-Life Obstetricians and Gynecologists (AAPLOG) to
10 HHS in 2009, that its members “overwhelmingly would leave the medical
11 profession—or relocate to a conscience-friendly jurisdiction—before they would
12 accept coercion to participate or assist in procedures that violate their
13 consciences.” 84 Fed. Reg. at 23,247.

14 But HHS conducted no follow-up survey of any sort and supplies no
15 quantitative information in its analysis about actual exits from the profession or
16

17 ⁸ Notably, though the headline of the 2009 survey was “Online Survey of 2,852
18 Members of *Faith-Based* Medical Associations,” all respondents were members of
19 a *Christian* medical association. Memorandum from Kellyanne Conway, President
20 & CEO, the polling companyTM, inc./WomanTrend, to Interested parties 4 (Apr. 8,
21 2009), available at <https://perma.cc/PC6K-5SML> (describing survey methodology)
22 (emphases added). The surveys’ results are available at: [https://perma.cc/WP7R-](https://perma.cc/WP7R-ARXV)
23 [ARXV](https://perma.cc/WP7R-ARXV) and <https://perma.cc/X2YS-CZFT>.

1 relocations from one jurisdiction to another in response to the 2011 Rescission. In
2 other words, it makes no effort to confirm whether the post-survey elimination of
3 the expansive protections in the 2008 Rule prompted any survey respondents to
4 follow through on their threat to leave the medical profession.

5 Furthermore, HHS fails to mention that the ranks of the very providers it
6 claims were most likely to leave the profession after the 2011 Rescission seem to
7 have been growing. Not only has the number of obstetricians and gynecologists
8 grown by almost nine percent nationwide from 2011 to 2017, ModernMedicine
9 Network, *ACOG Releases New Study on Ob/Gyn Workforce* (July 1, 2017),⁹ but
10 the pro-life group AAPLOG's ranks have grown by fourteen percent since 2009.¹⁰
11 This pattern is at odds with AAPLOG's 2009 prediction and the organization's
12 current arguments that its members would leave the profession without the
13 protections provided by the Final Rule. *See* 84 Fed. Reg. at 23,247. In short, HHS
14 provides no credible evidence to support its claim that people are leaving the
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16 ⁹ Available at <https://perma.cc/65FD-QRES>.

17 ¹⁰ *Compare* American Association of Pro-Life Obstetricians and Gynecologists,
18 *About Us*, <http://aaplog.org/about-us> [<https://perma.cc/BBV7-T2YP>] (accessed
19 May 18, 2019) (reporting 2,500 members and associates), *with* Letter from
20 Lawrence J. Joseph, on behalf of the American Association of Pro-Life
21 Obstetricians & Gynecologists, to the Office of Public Health & Science, Dep't of
22 Health & Human Servs. (Apr. 9, 2009), <https://perma.cc/UL8C-PSSU> (reporting
23 2,100 members and associates).

1 healthcare profession in material numbers for lack of provisions like those in the
2 Final Rule.

3
4 **B. HHS Offers No Evidence That the Final Rule Will Improve
Healthcare Quality**

5 The lynchpin of HHS’s argument that its Final Rule will improve patient
6 care is that the rule will induce religious provider organizations to expand the
7 scope of their operations in terms of both service provision and geography. 84 Fed.
8 Reg. at 23,248. But *no commenter* indicated to HHS that it had confined either the
9 scope or geographic footprint of its services as a result of the repeal of the 2008
10 Rule, that the “status quo risks driving [it] out of underserved communities
11 altogether,” *see id.*, or that it had plans to expand in any way should the Final Rule
12 be adopted. Given that HHS pointed to organizations like Ascension as potentially
13 curtailing charity care without the Final Rule, *id.*, the absence of substantiating
14 statements from these organizations in their comments weighs against HHS’s
15 claim, *see, e.g.*, Ascension, Comment Letter on Protecting Statutory Conscience
16 Rights in Health Care (Mar. 27, 2018).

17
18 **C. HHS Offers No Evidence That the Final Rule Will Reduce the
Prevalence of Moral Distress**

19 HHS contends that the Final Rule “will reduce the incidence of the harm that
20 being forced to violate one's conscience inflicts on providers.” 84 Fed. Reg. at
21 23,249. In making this assertion, the Department claims to rely on “[s]ubstantial
22 academic literature [that] documents the existence among health care providers of
23 ‘moral distress,’” *Id.* But while the literature HHS cites does recognize the

1 existence of moral distress among some medical providers, it rarely if ever
2 specifically links that distress to the type of conduct addressed by the Final Rule
3 (i.e., performing or assisting in the performance of particular procedures to which a
4 provider has a religious or moral objection). One article cited by HHS suggests that
5 moral distress has been generated by “broad systemic changes . . . in how health
6 care institutions are organized, how health care is financed, and how health care
7 resources are managed,” which “reduce[d] the amount of time caregivers are
8 allotted to spend with patients.” Christy A. Rentmeester, *Moral Damage to Health
9 Care Professionals and Trainees: Legalism and Other Consequences for Patients
10 and Colleagues*, 33 J. Med. & Philosophy 27, 37 (2008). Another article lists the
11 following sources of distress:

12 aggressive and futile treatment, the carrying out of unnecessary tests, lack of
13 treatment, poor pain management, incompetent or inadequate care, deception
14 and inadequate consent for treatment[,] . . . the increased corporatization of
15 healthcare, administrative, organizational and legal policies, lack of policies
and guidelines, the shift in focus from patients and families to organizations,
poor staffing, cost cuts, economic efficiencies and increased workloads.

16 Joan McCarthy & Chris Gastmans, *Moral Distress: A Review of the Argument-
17 Based Nursing Ethics Literature*, 22 Nursing Ethics 131, 148–49 (2015); *see also*
18 84 Fed. Reg. at 23,249 n.337 (citing McCarthy & Gastmans). Notably, under this
19 broad conception of the term, the Final Rule might *increase* rather than reduce
20 moral distress among some providers, insofar as it leads to lack of treatment,
21 inadequate care, and inadequate consent for treatment (when patients are denied
22 information about certain treatment options due to a provider’s religious or moral
23 beliefs).

1 Finally, a third study cited by HHS finds, based on a survey of 250 nurses,
2 that the most frequent and intense source of moral distress “related to concern for
3 patients’ feelings and emotions”—again suggesting that the Final Rule might
4 actually increase such distress by causing more refusals of care for certain patients.
5 Fariba Borhani et al., *The Relationship Between Moral Distress, Professional*
6 *Stress, and Intent to Stay in the Nursing Profession*, 7 J. Med. Ethics & Hist. Med.
7 1, 5 (2014); 84 Fed. Reg. at 23,249 n.330 (citing Borhani et al.). What is more, the
8 study finds no correlation between the moral distress levels reported by
9 respondents and their stated intention to leave the profession of nursing. Borhani,
10 *supra*, at 4. Thus, it directly contradicts the Department’s assertion that alleviating
11 moral distress will prevent exits from the medical profession. *See State Farm*, 463
12 U.S. at 56-57 (action is arbitrary and capricious if explanation “runs counter to the
13 evidence before the agency”).

14 In addition to misrepresenting the *causes* of moral distress as described in
15 the academic literature, HHS fails to provide even a minimal amount of evidence
16 or information to support its claim that the Final Rule will reduce the *prevalence* of
17 moral distress. The *HHS Guidelines* explain that when the effects of a rule are less
18 tangible and difficult to quantify—because, for instance, the rule implicates
19 “important human values, such as dignity, equity, and privacy”—HHS should
20 attempt to “count the number of people affected.” *HHS Guidelines* at 48. Similarly,
21 “[w]here some data exist, but are not sufficient to reasonably quantify the effect,
22 HHS should, if possible, report “[i]ntermediate measures, such as the number of
23 individuals affected.” *Id.* at 51; *see also Circular A-4* at 27 (“If you are not able to

1 quantify the effects, you should present any relevant quantitative information along
2 with a description of the unquantified effects You should provide a discussion
3 of the strengths and limitations of the qualitative information.”). But HHS has not
4 quantified, in exact or approximate terms, the number of medical practitioners
5 whose moral distress will be alleviated under the Final Rule, nor any of the
6 following antecedent quantities of individuals: (1) those experiencing moral
7 distress for any reason; (2) those experiencing moral distress for the reasons of
8 concern to HHS; or (3) those who would refuse to assist in or conduct medical
9 procedures that prompt their moral distress.

10 HHS’s failure to support its assertions regarding the effects of the Final Rule
11 on healthcare professionals’ moral distress undermines the analytical validity of
12 HHS’s regulatory impact analysis and the legal validity of the Final Rule as a
13 whole.

14 **D. HHS Offers No Evidence That the Final Rule Will Cause a Net**
15 **Increase in Freedom of Conscience for Healthcare Professionals**

16 Contrary to the directives in Circular A-4 and the *HHS Guidelines* mentioned
17 above, HHS has not estimated the number of healthcare professionals who would
18 find that the Final Rule increased their freedom of conscience. Furthermore, HHS
19 uses this departure from analytic norms to avoid acknowledging a vitally important
20 fact: the Final Rule would likely *constrain* the freedom of many individuals whose
21 religious or moral beliefs compel them to offer patients a full range of treatment
22 options. *See* The Public Rights/Private Conscience Project Comment Letter on
23 Protecting Statutory Conscience Rights in Health Care 1 (Mar. 27, 2018)

1 (explaining that where a provider organization bars employees from providing
2 some services on religious grounds, “medical professionals whose religious or
3 moral beliefs require them to provide patients with the full range of reproductive
4 health services may be prohibited by their employer from acting on this belief”);
5 *see also id.* at 2–6 (describing diverse views of religious communities on morality
6 of reproductive healthcare services, including abortion).¹¹ HHS asserts that “[t]he
7 rule will promote protection of religious beliefs and moral convictions,” but it has
8 made no apparent effort to determine the relative numbers of people who would
9 experience the Final Rule as supporting or interfering with their religious beliefs
10 and moral convictions. As a result, the assertion is entirely conclusory and thus
11 arbitrary and capricious.

12 CONCLUSION

13 This Court should grant Plaintiff’s Motion for Preliminary Injunction.¹²
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19 ¹¹ Available at <https://www.regulations.gov/document?D=HHS-OCR-2018-0002-70101>.

21 ¹² Policy Integrity gratefully acknowledges James Meresman and Cris Ray, students
22 in New York University School of Law’s Regulatory Policy Clinic, for assisting in
23 the preparation of this brief.

1 Dated: July 1, 2019

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JUDGE STANLEY A. BASTIAN

**UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF WASHINGTON
AT YAKIMA**

STATE OF WASHINGTON,

Plaintiff,

v.

ALEX M. AZAR II, in his official
capacity as Secretary of the United
States Department of Health and
Human Services; and UNITED
STATES DEPARTMENT OF
HEALTH AND HUMAN
SERVICES,

Defendants.

NO. 2:19-cv-00183-SAB

[PROPOSED] ORDER GRANTING
UNOPPOSED MOTION FOR LEAVE
TO FILE AS *AMICUS CURIAE*

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[PROPOSED] ORDER

On July 1, 2019, the Institute for Policy Integrity at New York University School of Law filed an Unopposed Motion for Leave to File as *Amicus Curiae* in Support of Plaintiff’s Motion for Preliminary Injunction. Having considered the pleadings and papers filed in connection therewith, and all other matters presented to the Court, and good cause having been shown:

It is hereby ORDERED that Institute for Policy Integrity’s Motion is GRANTED. The *Amicus* Brief filed with Institute for Policy Integrity’s Motion is deemed filed and served as of this date.

IT IS SO ORDERED this _____ day of _____, 2019.

HON. STANLEY A. BASTIAN
UNITED STATES DISTRICT JUDGE

Presented by:

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