

1 Taylor Washburn, WSBA #51524
LANE POWELL PC

JUDGE STANLEY A. BASTIAN

2 1420 Fifth Avenue, Suite 4200
Seattle, WA 98101-2375
3 washburnt@lanepowell.com; T: (206) 223-7000

4 Jack Lienke, N.Y. State Bar #5066386 (admitted *pro hac vice*)
Justin Gundlach, N.Y. State Bar #4915468 (admitted *pro hac vice*)

5 INSTITUTE FOR POLICY INTEGRITY
NEW YORK UNIVERSITY SCHOOL OF LAW

6 139 MacDougal Street, 3rd Floor
New York, NY 10012
7 jack.lienke@nyu.edu; T: (212) 992-8932

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

11 STATE OF WASHINGTON,

No. 2:19-cv-00183-SAB

12 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 CROSS-MOTION
FOR SUMMARY JUDGMENT**

13 v.

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

11/7/2019
With Oral Argument: 10:00 a.m.
Spokane Courtroom 755

17 Defendants.

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 Cross-
4 Motion for Summary Judgment, calendared for hearing before this Court on
5 November 7, 2019, at 10:00 a.m. Policy Integrity has conferred with the parties
6 concerning the filing of this motion. Counsel for Plaintiff and Defendants have
7 consented to this motion.

8 I. LEGAL STANDARD

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

21 II. INTEREST OF AMICUS CURIAE

22 Policy Integrity has a strong interest in this case. Policy Integrity is a
23 nonpartisan, not-for-profit think tank dedicated to improving the quality of

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

10 In furtherance of its mission to promote rational decisionmaking, Policy
11 Integrity has filed *amicus curiae* briefs addressing agency analysis of costs and
12 benefits in many recent cases. *See, e.g.,* Br. for Inst. for Policy Integrity as Amicus
13 Curiae, *California v. U.S. Bureau of Land Mgmt.*, 277 F. Supp. 3d 1106 (N.D. Cal.
14 2017) (No. 17–cv–3804-EDL) (arguing that agency’s failure to consider forgone
15 benefits that would result from a delay in implementation of methane standards was
16 arbitrary); Br. for Inst. for Policy Integrity as Amicus Curiae, *California v. U.S.*
17 *Dep’t of the Interior*, 381 F. Supp. 3d 1153 (N.D. Cal. 2019) (No. 17-cv-5948-SBA)
18 (arguing that repeal of procedural reforms for mineral valuation was unreasonable
19 due to agency’s inaccurate assessment of repeal’s economic impact). In those cases,
20 courts have agreed that the agency analyses—and, in turn, the rules issued in reliance
21 on those analyses—were arbitrary and capricious. *California v. BLM*, 277 F. Supp.
22 3d at 1123 (holding failure to consider forgone benefits arbitrary); *California v.*

1 *Interior*, 381 F. Supp. 3d at 1170 (finding repeal arbitrary due in part to agency’s
2 flawed economic impact assessment).

3 Policy Integrity has particular expertise on the regulatory impact analysis that
4 the United States Department of Health and Human Services (“HHS”) conducted in
5 support of the rule at issue in this case, Protecting Statutory Conscience Rights in
6 Health Care; Delegations of Authority, 84 Fed. Reg. 23,170 (May 21, 2019) (“Final
7 Rule”). In 2008, we submitted an expert report on the defective analysis HHS
8 prepared to support a previous effort to expand statutory conscience rights through
9 rulemaking. See Inst. for the Study of Regulation, Comments on Ensuring That
10 Department of Health and Human Services Funds Do Not Support Coercive or
11 Discriminatory Policies or Practices in Violation of Federal Law (Sept. 16, 2008).
12 That 2008 rule was repealed in 2011, but the Final Rule is similar in many respects
13 and has similar fundamental deficiencies in its cost-benefit analysis, as Policy
14 Integrity pointed out in a March 2018 comment letter to HHS. Inst. for Policy
15 Integrity, Comment Letter on Protecting Statutory Conscience Rights in Health Care
16 (Mar. 27, 2018). We also presented these critiques to the White House Office of
17 Information and Regulatory Affairs in an April 2019 teleconference.

18 Policy Integrity seeks to provide this court with information about the legal
19 and economic standards for good regulatory impact analysis, which HHS failed to
20 satisfy in its assessment of the Final Rule’s costs and benefits. Policy Integrity’s
21
22
23

1 general interest in this case is to ensure that agencies comply with their obligation to
2 accurately assess the positive and negative impacts of regulatory decisions.

3 **III. POLICY INTEGRITY'S EXPERTISE WILL BENEFIT THE**
4 **COURT**

5 Policy Integrity's proposed amicus brief is also useful to the Court. As noted
6 above, Policy Integrity has experience with the Final Rule at issue in this case,
7 having submitted comments on the proposed version of the Final Rule and having
8 prepared an expert report on the defective analysis HHS prepared to support a similar
9 regulatory expansion of statutory conscience rights in 2008. Policy Integrity has
10 made use of that experience, as well as its expertise in cost-benefit analysis, to
11 explain why HHS's regulatory impact analysis is badly flawed and its Final Rule
12 arbitrary and capricious. While Plaintiff has made a variety of arguments regarding
13 HHS's failure to provide a reasoned explanation for the Final Rule, Policy Integrity's
14 brief is uniquely focused on the agency's economic analysis. The brief can serve as
15 a resource for the Court as it analyzes Plaintiff's claims that the Final Rule does not
16 satisfy the requirements of the Administrative Procedure Act. In particular, Policy
17 Integrity's discussion of the shortcomings in HHS's regulatory impact analysis can
18 help the Court as it engages with the question of whether the agency's
19 decisionmaking was arbitrary and capricious.

20 **IV. MEET AND CONFER AND TIMELINESS**

21 Policy Integrity has conferred with the parties concerning the filing of this
22 motion. Counsel for Plaintiff and Defendants have consented to this motion.
23

1 This motion is timely. Though this Court does not have rules governing the
2 timing of amicus briefs, the Court may look for guidance to the rules of other district
3 courts. In the U.S. District Court for the District of Columbia, the Local Rules
4 require an amicus motion to be filed “in a timely manner such that it does not unduly
5 delay the Court’s ability to rule on any pending matter.” Rules of the U.S. District
6 Court for the District of Columbia, Local Rule 7(o)(2) at 31 (June 2018).¹ In this
7 case, there is time for the Court to decide Policy Integrity’s motion without unduly
8 delaying the decision on the pending matter. Plaintiff’s cross-motion is due
9 September 20, Defendants’ opposition is due October 4, and Plaintiff’s reply is due
10 October 18. *See* Order Setting Briefing Schedule (Doc. No. 35).

11 **V. CONCLUSION**

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

14 DATED: September 20, 2019

15 LANE POWELL PC

16 *s/ Taylor Washburn*

17 Taylor Washburn, WSBA #51524

18 washburn@lanepowell.com

19 1420 Fifth Avenue, Suite 4200

20 Seattle, WA 98101-2375

21 T: (206) 223-7000

22 ¹ Available at

23 <https://www.dcd.uscourts.gov/sites/dcd/files/LocalRulesJune2018.pdf>.

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INSTITUTE FOR POLICY INTEGRITY
NEW YORK UNIVERSITY SCHOOL OF LAW

Jack Lienke, N.Y. State Bar #5066386
jack.lienke@nyu.edu (admitted *pro hac vice*)
Justin Gundlach, N.Y. State Bar #4915468
justin.gundlach@nyu.edu (admitted *pro hac vice*)
139 MacDougal Street, 3rd Floor
New York, NY 10012
T: (212) 992-8932

*Counsel for Amicus Curiae Institute for Policy
Integrity*

DECLARATION OF SERVICE

1 I hereby declare that on this day I caused the foregoing document to be
2 electronically filed with the Clerk of the Court using the Court’s CM/ECF System
3 which will serve a copy of this document upon all counsel of record.
4

5 DATED this 20th day of September, 2019, at Seattle, Washington.

6
7 s/ Peter Elton
8 Peter Elton
9 Legal Assistant
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15
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17
18
19
20
21
22
23

1 Taylor Washburn, WSBA #51524
LANE POWELL PC

JUDGE STANLEY A. BASTIAN

2 1420 Fifth Avenue, Suite 4200
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9 **FOR THE EASTERN DISTRICT OF WASHINGTON**
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11 STATE OF WASHINGTON,

No. 2:19-cv-00183-SAB

12 Plaintiff,

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POLICY INTEGRITY AT NEW
YORK UNIVERSITY SCHOOL OF
LAW AS *AMICUS CURIAE* IN
SUPPORT OF PLAINTIFF'S
CROSS-MOTION FOR SUMMARY
JUDGMENT**

13 v.

14 ALEX M. AZAR II, in his official
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15 STATES DEPARTMENT OF
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With Oral Argument: 10:00 a.m.
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17 Defendants.

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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 to vacate the Department of Health and Human Services’ (“HHS” or the
4 “Department”) final rule, Protecting Statutory Conscience Rights in Health Care;
5 Delegations of Authority, 84 Fed. Reg. 23,170 (May 21, 2019) (“Final Rule”).

6 **INTEREST OF AMICUS CURIAE**

7 Policy Integrity is a nonpartisan, not-for-profit think tank dedicated to
8 improving the quality of government decisionmaking through advocacy and
9 scholarship in the fields of administrative law, economics, and public policy. Our
10 legal and economic experts have produced extensive scholarship on the best
11 practices for regulatory impact analysis and the proper valuation of regulatory costs
12 and benefits. Most notably, our director, Richard L. Revesz, has published more than
13 eighty articles and books on environmental and administrative law, including works
14 on the legal and economic principles that inform rational regulatory decisions. *See*,

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16
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 fund
21 the preparation or submission of this brief. No person—other than the *amicus curiae*,
22 its members, or its counsel—contributed money intended to fund the preparation of
23 this brief.

1 e.g., Richard L. Revesz & Michael A. Livermore, *Retaking Rationality: How Cost-*
2 *Benefit Analysis Can Better Protect the Environment and Our Health* (2008).²

3 In furtherance of its mission to promote rational decisionmaking, Policy
4 Integrity has filed *amicus curiae* briefs addressing agency analysis of costs and
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11 SBA) (arguing that repeal of procedural reforms for mineral valuation was
12 unreasonable due to agency's inaccurate assessment of repeal's economic impact).
13 In those cases, courts have agreed that the agency analyses—and, in turn, the rules
14 issued in reliance on those analyses—were arbitrary and capricious. *California v.*
15 *BLM*, 277 F. Supp. 3d at 1123 (holding failure to consider forgone benefits
16 arbitrary); *California v. Interior*, 381 F. Supp. 3d at 1170 (finding repeal arbitrary
17 due in part to agency's flawed economic impact assessment).

18 Policy Integrity has particular expertise on the regulatory impact analysis that
19 HHS conducted in support of the Final Rule. In 2008, we submitted an expert report

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

12 Plaintiff argues that the Final Rule is arbitrary and capricious in part because
13 HHS relied on a “fatally flawed” regulatory impact analysis. State of Washington’s
14 Motion for Preliminary Injunction (Doc. No. 8) at 34. Policy Integrity’s expertise in
15 cost-benefit analysis and experience with the Final Rule give it a unique perspective
16 from which to evaluate this claim.

17
18
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 Study
21 of Regulation.

22 ⁴ 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 **SUMMARY OF ARGUMENT**

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

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

18 Second, the alleged benefits of the Final Rule are entirely speculative. The
19 Department claims that the rule will increase the ranks of healthcare professionals,
20 improve the quality of doctor-patient relationships, reduce “moral distress” among
21 healthcare professionals, and promote the “societal good” of personal freedom for
22 individuals to conduct themselves based on their religious beliefs and moral
23

1 convictions. 84 Fed. Reg. at 23,246. But these findings are unsupported by—and in
2 some instances contradicted by—evidence in the record.

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

10 **ARGUMENT**

11 Final agency actions like the Final Rule are arbitrary and capricious under the
12 Administrative Procedure Act, 5 U.S.C. § 706(2), if the agency fails to “examine the
13 relevant data,” “consider an important aspect of the problem,” or “articulate a
14 satisfactory explanation for its action including a rational connection between the
15 facts found and the choice made.” *Motor Vehicle Mfrs. Ass’n v. State Farm Mut.*
16 *Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) (internal quotation marks omitted). When the
17 justifications for the action include the results of a cost-benefit analysis, “a serious
18 flaw undermining that analysis can render the rule unreasonable.” *Nat’l Ass’n of*
19 *Home Builders*, 682 F.3d at 1040. This is true even when the agency was not
20 statutorily obligated to conduct the analysis in the first place. *Id.* at 1039–40; *Council*
21 *of Parent Attorneys & Advocates, Inc. v. DeVos*, 365 F. Supp. 3d 28, 54 n.11 (D.D.C.
22 2019) (rejecting government’s contention that a regulatory impact analysis
23 “conducted pursuant to Executive Orders” rather than a statutory mandate was “not

1 subject to judicial review”). Finally, if the agency’s action represents a change of
2 position on a particular issue, the agency must provide a “reasoned explanation . . .
3 for disregarding facts and circumstances that underlay or were engendered by the
4 prior policy.” *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515–16 (2009);
5 *see also Organized Vill. of Kake v. U.S. Dep’t of Agric.*, 795 F.3d 956, 968 (9th Cir.
6 2015) (“[E]ven when reversing a policy after an election, an agency may not simply
7 discard prior factual findings without a reasoned explanation.”).

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

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

18 HHS’s analysis of the Final Rule’s “economic implications,” 84 Fed. Reg. at
19 23,228—prepared pursuant to Executive Orders 12,866 and 13,563—fails to
20 account for many of the Final Rule’s likely costs. While this analysis tallies the Final
21 Rule’s direct compliance costs for providers, in the form of familiarization and
22 paperwork-related expenses, *see* 84 Fed. Reg. at 23,240 tbl.6, it fails to assess the
23 new policy’s *indirect* costs, in the form of harms to patients who are refused care on

1 conscience grounds and additional staffing burdens for the medical employers who
2 must accommodate such refusals. Indeed, these effects are not even listed in the
3 Department’s summary of unquantified costs. *See* 84 Fed. Reg. at 23,227, tbl.1
4 (listing quantified and non-quantified costs that HHS considered).

5 HHS’s failure to assess indirect costs is, first, flatly contrary to the
6 requirements of Executive Order 12,866, which instructs agencies to consider not
7 just “direct cost . . . to businesses and others in complying with the regulation,” but
8 also “any adverse effects” the rule might have on “the efficient functioning of the
9 economy, private markets . . . health, safety, and the natural environment.” Exec.
10 Order No. 12,866 § 6(a)(3)(C)(ii), 58 Fed. Reg. 51,735 (Oct. 4, 1993). Longstanding
11 guidance on regulatory impact analysis from the Office of Management and Budget
12 similarly directs agencies to “look beyond the direct benefits and direct costs of
13 [their] rulemaking and consider any important ancillary [i.e., indirect] benefits and
14 countervailing risks.” Office of Mgmt. & Budget, *Circular A-4 on Regulatory*
15 *Analysis* 26 (2003) [hereinafter *Circular A-4*].⁵

16 More importantly, ignoring indirect costs violates HHS’s duties under the
17 Administrative Procedure Act. Agency decisions must be “based on consideration
18 of the relevant factors,” *State Farm*, 463 U.S. at 42, and “[a]gencies have long treated
19 cost as a centrally relevant factor when deciding whether to regulate,” *Michigan v.*
20 *EPA*, 135 S. Ct. 2699, 2707 (2015). *See also Mingo Logan Coal Co. v. EPA*, 829

22 ⁵ Available at

23 <https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/circulars/A4/a-4.pdf>.

1 F.3d 710, 732 (D.C. Cir. 2016) (Kavanaugh, J., dissenting) (“As a general rule, the
2 costs of an agency’s action are a relevant factor that the agency must consider before
3 deciding whether to act.”).

4 Legally relevant costs “include[] more than the expense of complying with
5 regulations”; instead, “any disadvantage could be termed a cost.” *Michigan*, 135 S.
6 Ct. at 2707. Accordingly, courts have repeatedly struck down rules that fail to
7 consider potentially significant indirect costs. *See, e.g., Competitive Enter. Inst. v.*
8 *Nat’l Highway Traffic Safety Admin.*, 956 F.2d 321, 326–27 (D.C. Cir. 1992)
9 (remanding fuel-efficiency rule due to agency’s failure to consider indirect safety
10 costs); *Corrosion Proof Fittings v. EPA*, 947 F.2d 1201, 1225 (5th Cir. 1991)
11 (striking down rule for failure to consider indirect safety effects of substituting
12 asbestos-free car brakes).

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

1 a “reasoned explanation” for disregarding the findings underlying the 2011
2 Rescission, *Fox Television*, 556 U.S. at 515–16, and the Department has not done
3 so. *See also Kake*, 795 F.3d at 968.

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

6 HHS expects that, as a result of the Final Rule, “more individuals, having been
7 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 provide
9 services (or information about services) on moral or religious grounds. It follows
10 that patient populations who already experience costs associated with conscience-
11 related refusals of care—like women in need of reproductive health services; LGBT
12 patients; and patients living with HIV or seeking HIV-preventive services—will see
13 those costs increase as a result of the Final Rule. But in its regulatory impact analysis,
14 HHS refuses to assess these costs appropriately, in either quantitative or qualitative
15 terms.

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

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

1 situation, there may not be adequate time to find an alternative, leading in some cases
2 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. Record
7 evidence shows that women, for example, already suffer significant physical,
8 psychological, and financial harms from conscience-related denials of reproductive
9 health services. These include refusals by religiously affiliated hospitals to provide
10 sterilization treatment at the time of cesarean delivery—despite the fact that this is
11 the safest and most cost-effective time at which to undergo the procedure—even in
12 cases 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 prescriptions to pharmacies that will, even for rape survivors; and refusals
15 by insurance plans to cover birth control. Nat’l Women’s Law Ctr., *Refusals to*
16 *Provide Health Care Threaten the Health and Lives of Patients Nationwide* 1 (Aug.
17 30, 2017).⁶

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

20 ⁶ 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 Sept.
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 8 percent of lesbian, gay, and bisexual respondents and
4 almost 27 percent of transgender respondents reported being refused necessary
5 healthcare because of their sexual orientation and gender identity, respectively.

6 Lambda Legal, *When Health Care Isn't Caring: Lambda Legal's Survey on*
7 *Discrimination Against LGBT People and People Living with HIV* 10 (2010).⁷ Just
8 as they do for women in need of reproductive health services, these conscience-
9 related denials of care can carry substantial costs for affected LGBT and HIV-
10 positive patients. In one example in the record, an HIV-positive patient denied
11 treatment for chest pain ended up “admitted to the hospital . . . with gastrointestinal
12

13 ⁷ Available at <https://perma.cc/6SJU-Q9WB>. That survey's findings were echoed in
14 a 2011 Institute of Medicine report, *The Health of Lesbian, Gay, Bisexual, and*
15 *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 Sept.
23 12, 2019).

1 hemorrhaging” a week later, and “was diagnosed with pneumonia, a staph infection,
2 and AIDS.” Nat’l Women’s Law Ctr. at 2. On a more general level, nearly 20 percent
3 of transgender respondents to a Massachusetts-based survey indicated that prior
4 mistreatment by healthcare providers had led them to postpone or forgo treatment
5 when sick or injured. Sari L. Reisner et al., *Legal Protections in Public*
6 *Accommodations Settings: A Critical Public Health Issue for Transgender and*
7 *Gender-Nonconforming People*, 93 *Milbank Q.* 484, 494 (2015).⁸

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

18
19
20 ⁸ Available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4567851>. This
21 article was cited by 71 commenters, according to a search of the docket. See
22 <https://www.regulations.gov/docket?D=HHS-OCR-2018-0002> (last visited Sept.
23 11, 2019).

1 2011 Rescission, and with the findings of studies that the Department relies upon in
2 the current proceeding.

3 As noted earlier, in its description of the Final Rule’s *benefits*, the Department
4 claims that “as a result of this rule, more individuals, having been apprised of [their
5 conscience] rights, will assert them.” *Id.* It is difficult to imagine how a rule could
6 cause more workers to assert a right to deny care without *also* causing an increase
7 in denials of care. HHS cannot have it both ways, arguing that the Final Rule will
8 affect the behavior of providers without altering the experiences of their patients.
9 The Department’s logical inconsistency on this point renders the Final Rule arbitrary
10 and capricious. *See Gen. Chem. Corp. v. United States*, 817 F.2d 844, 857 (D.C. Cir.
11 1987) (deeming agency conclusion arbitrary and capricious where supporting
12 analysis was “internally inconsistent”).

13 HHS’s unwillingness to concede that the Final Rule will result in increased
14 refusals of care is particularly unreasonable in light of its findings to the contrary in
15 the 2011 Rescission. In that proceeding, HHS agreed with commenters that the 2008
16 Rule “could limit access to reproductive health services and information, including
17 contraception, and could impact a wide range of medical services, including care for
18 sexual assault victims, provision of HIV/AIDS treatment, and emergency services.”
19 76 Fed. Reg. at 9974. Because the Final Rule “generally reinstates the structure of
20 the 2008 Rule,” 84 Fed. Reg. at 23,179, one would expect it to pose the same threat
21 to access to care for sexual assault victims and those living with HIV. If HHS
22 disagrees, it must provide a “reasoned explanation” for reaching a different
23 conclusion than it did in the 2011 Rescission—for example, by citing evidence

1 suggesting that, contrary to the Department’s previous findings, an expansive
2 conscience rule will *not* reduce access to care for these populations. *Fox Television*,
3 556 U.S. at 515–16.

4 The Department does cite two studies that it claims found “insufficient
5 evidence to conclude that conscience protections have negative effects on access to
6 care.” 84 Fed. Reg. at 23,251 (citing W. Chavkin et al., *Conscientious Objection and*
7 *Refusal to Provide Reproductive Healthcare: A White Paper Examining Prevalence,*
8 *Health Consequences, and Policy Responses*, 123 Int’l J. Gynecol. & Obstet. S41
9 (2013); K. Morrell & W. Chavkin, *Conscientious Objection to Abortion and*
10 *Reproductive Healthcare: A Review of Recent Literature and Implications for*
11 *Adolescents*, 27 Curr. Opin. Obstet. Gynecol. 333 (2015)). But those studies actually
12 show that conscience-based refusals *are* a material barrier to care and that the only
13 open empirical question is the extent to which such refusals negatively affect patient
14 health. *See* Chavkin at S42 (characterizing conscientious objection as “one of many
15 barriers to reproductive healthcare”); Morrell & Chavkin at 334 (“Conscientious
16 objection . . . appears to constitute a barrier to care, especially for certain subgroups.
17 . . .”). Thus, HHS’s conclusion that the Final Rule will not negatively affect access
18 to care “runs counter to the evidence before the agency” and is therefore arbitrary
19 and capricious. *State Farm*, 463 U.S. at 43.

20 3. **Uncertainty Does Not Excuse HHS’s Failure to Estimate the** 21 **Final Rule’s Effects on the Rate and Nature of Conscience-** 22 **Related Refusals of Care**

23 In addition to suggesting that the Final Rule may have *no* negative effects on
patients’ access to care, HHS claims that estimating the magnitude of such effects is

1 simply too difficult. 84 Fed. Reg. at 23,252 (“The Department attempted to quantify
2 the impact of this rule on access to care but determined that there is not enough
3 reliable data, and that the analysis was subject to too many confounding variables,
4 for the Department to arrive at a useful estimate.”). But uncertainty about the precise
5 magnitude of a regulatory effect does not justify assigning that effect no value in a
6 cost-benefit analysis. *Ctr. for Biological Diversity v. Nat’l Highway Traffic Safety*
7 *Admin.*, 538 F.3d 1172, 1190, 1200 (9th Cir. 2008) (finding agency reasoning
8 arbitrary and capricious where agency argued that benefits of carbon dioxide
9 reductions were “too uncertain to support their explicit valuation and inclusion” in a
10 regulatory cost-benefit analysis). Ultimately, while there may be “a range of values”
11 for the costs to patients of the Final Rule, that value “is certainly not zero.” *Id.* at
12 1200. Thus, the costs must be “accounted for in the agency’s analysis.” *Id.*

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

1 costs of being wrong may outweigh the benefits of a faster decision.”). An agency
2 does not prove that it is impossible to ascertain the answer to a question by refusing
3 to ask it.

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

14 Instead, HHS blames commenters for failing to do the Department’s work for
15 it. 84 Fed. Reg. at 23,250 (arguing that commenters failed “to answer the difficult
16 question of how this rule would affect access to care and health outcomes, and how
17 to quantify those effects”); *id.* at 23,252 (“No comment attempted a detailed
18 description of the actual impact expected from the rule on access to care, health
19 outcomes, and associated concerns.”). But while commenters can supply useful
20 information to inform an agency’s analysis—and, as discussed in Section I.A.1, did
21 so here—the agency bears the ultimate burden of supplying “a satisfactory
22 explanation for its action,” including due consideration of “relevant factors” like
23 cost. *State Farm*, 463 U.S. at 42.

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

1 **4. HHS Cannot Excuse Its Failure to Assess Patient Costs by**
2 **Making a Conclusory Assertion That Any Such Costs Are**
3 **Justified**

4 HHS attempts to excuse its failure to assess the Final Rule’s costs to patients
5 by asserting that “the Department expects any decreases in access to care to be
6 outweighed by significant overall increases in access generated by this rule.” 84 Fed.
7 Reg. at 23,252. In other words, HHS claims that any costs to patients associated with
8 the Final Rule are functionally irrelevant because they are outweighed by benefits.

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

23 In the absence of an acknowledgement of these costs, HHS’s conclusory
 assertion that the Final Rule will have a *net* positive effect on healthcare access

1 “add[s] nothing to the agency’s defense of its thesis except perhaps the implication
2 that it was committed to its position regardless of any facts to the contrary.”
3 *Chemical Mfrs. Ass’n v. EPA*, 28 F.3d 1259, 1266 (D.C. Cir. 1994). Indeed, the
4 Department’s own *Guidelines for Regulatory Impact Analysis* warn decisionmakers
5 facing an “absence of information” against “weight[ing] nonquantified effects in a
6 manner consistent with their own (unarticulated and perhaps unconscious) beliefs,
7 without sufficiently probing the rationale or the weighting.” HHS, *Guidelines for*
8 *Regulatory Impact Analysis* 47 (2016) [hereinafter *HHS Guidelines*].⁹ To
9 “counterbalance this tendency,” the *HHS Guidelines* require “[c]lear presentation of
10 the available evidence,” *id.*, which the Department utterly fails to provide in its
11 analysis of the Final Rule.

12 **5. HHS Cannot Excuse Its Failure to Assess Patient Costs by**
13 **Claiming That the Costs Are Attributable to Congressional**
14 **Decisions**

15 HHS’s final excuse for inadequately assessing the Final Rule’s costs for
16 patients is that any objections to the Final Rule “based on potential (often temporary)
17 lack of access to particular procedures as a result of enforcement of the law are really
18 objections to policy decisions made by the people’s representatives in Congress in
19 enacting the Federal conscience and anti-discrimination laws in the first place.” 84
20 Fed. Reg. at 23,251. This argument, too, is unavailing. While the statutory provisions
21 underlying the Final Rule were indeed passed by Congress, HHS has made a

22 ⁹ Available at

23 https://aspe.hhs.gov/system/files/pdf/242926/HHS_RIAGuidance.pdf.

1 discretionary decision to adopt new, unprecedentedly expansive definitions of terms
2 in those provisions and new procedures for enforcing the provisions. That
3 discretionary decision has costs relative to the status quo, which the Administrative
4 Procedure Act obligates the Department to consider. Furthermore, if it *were* true that
5 no patient costs associated with invocations of conscience rights could be attributed
6 to the Final Rule, it would necessarily also be true that the Final Rule could claim
7 no credit for patient or provider *benefits* associated with such invocations. HHS, in
8 short, cannot rationally claim that the Final Rule has incremental benefits without
9 acknowledging corresponding incremental costs. *See California v. U.S. Bureau of*
10 *Land Mgmt.*, 277 F. Supp. 3d 1106, 1123 (N.D. Cal. 2017) (agencies cannot consider
11 only “one side of the equation” by calculating benefits and ignoring costs).

12 **B. HHS Completely Ignores Costs to Provider Organizations of**
13 **Accommodating Increased Refusals of Care**

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

1 While the Final Rule authorizes employers to request some advance notice of
2 objections, 84 Fed. Reg. at 23,191–92, employers may make such requests only after
3 hiring an employee, and cannot then fire that employee for conscience-based refusals
4 to provide care. Thus, even large, urban hospitals will likely bear significant costs
5 when accommodating employees who refuse to provide or assist with certain forms
6 of care. *See, e.g.,* Hearing Transcript, *Danquah v. Univ. of Med. & Dentistry of New*
7 *Jersey*, No. 11-cv-6377 (D.N.J. Dec. 16, 2011) (indicating that hospital hired team
8 of nurses to fill staffing gap left by nurses who refused to assist with provision of
9 abortion or related procedures).¹⁰ For provider organizations with access to fewer
10 resources, such as those in remote locations, the costs of finding replacement staff
11 and adjusting patient and provider schedules to accommodate increased invocation
12 of conscience rights could be greater still. But such costs are mentioned nowhere in
13 HHS’s regulatory impact analysis. HHS’s failure to consider these costs is
14 particularly egregious given that, elsewhere in the preamble to the Final Rule, the
15 Department expressly contemplates “the use [of] alternate staff” and other staffing
16 adjustments to accommodate objections and refusals on conscience grounds. 84 Fed.
17 Reg. at 23,191–92, 23,202, 23,263.

18 **II. The Final Rule’s Purported Benefits Are Speculative and** 19 **Unsupported by Evidence**

20 In its regulatory impact analysis, HHS claims the Final Rule will yield three

22 ¹⁰ HHS cites *Danquah*—but not this particular hearing transcript—in the Final Rule.
23 84 Fed. Reg. at 3888.

1 types of benefits: a net increase in access to healthcare, better quality of care, and
2 “societal goods that extend beyond health care.” 84 Fed. Reg. at 23,246. HHS
3 explains further that the Final Rule will deliver these benefits through four
4 mechanisms: first, it will increase “the availability of qualified health care
5 professionals,” in part by preventing exits from the field; second, it will improve the
6 quality of doctor-patient relationships; third, it will reduce “moral distress” among
7 providers; and, fourth, it will promote the “societal good” of “protection of religious
8 beliefs and moral convictions” by giving providers greater “personal freedom” to act
9 in accordance with their beliefs. 84 Fed. Reg. at 23,246. But HHS cites no credible
10 evidence to support any of these assertions.

11 While “an agency’s predictive judgments . . . are entitled to particularly
12 deferential review,” that deference is given only “so long as [the predictions] are
13 reasonable.” *BNSF Ry. Co. v. Surface Transp. Bd.*, 526 F.3d 770, 781 (D.C. Cir.
14 2008) (Kavanaugh, J.) (internal quotation marks omitted). Here, the Department’s
15 wholly “conclusory [and] unsupported suppositions” of the Final Rule’s benefits are
16 unreasonable and thus “not [entitled to] defer[ence].” *United Techs. Corp. v. Dep’t*
17 *of Def.*, 601 F.3d 557, 562 (D.C. Cir. 2010) (internal quotations marks omitted). And
18 because the Department relies on these speculative and unsupported benefits to
19 justify the Final Rule, the rule is arbitrary and capricious. *Nat’l Fuel Gas Supply*
20 *Corp. v. Fed. Energy Reg’y Comm’n*, 468 F.3d 831, 839 (D.C. Cir. 2006) (agency
21 action found arbitrary and capricious where agency “provided no evidence of a real
22 problem” the action would solve); *Arizona Cattle Growers’ Ass’n v. U.S. Fish &*
23 *Wildlife, Bureau of Land Mgmt.*, 273 F.3d 1229, 1244 (9th Cir. 2001) (action found

1 arbitrary and capricious where based on “speculation . . . not supported by the
2 record”).

3 **A. HHS Does Not Adequately Support Its Conclusion That the Final**
4 **Rule Will Increase the Number of U.S. Healthcare Professionals**

5 HHS claims that “[n]umerous studies and comments show that the failure to
6 protect conscience is a barrier to careers in the health care field,” 84 Fed. Reg. at
7 23,246, but the record contains only a handful of anecdotes reporting early
8 retirements for reasons of conscience, and *no* data evidencing a noticeable rate of
9 professional exit. Instead, HHS refers repeatedly to the results of an online survey
10 of self-selecting members of five Christian medical associations conducted on behalf
11 of the Christian Medical and Dental Association in 2009, just after HHS proposed
12 to repeal the 2008 Rule. *See* 84 Fed. Reg. at 23,175–253 nn.15, 38, 309, 316–18,
13 322, 340, 347, 349. HHS highlights repeatedly that 91 percent of respondents said
14 that they “would rather stop practicing medicine altogether than be forced to violate
15 [their] conscience.” *See id.* at 23,191 nn.46 & 48, 23,246–47. At one point, it pairs
16 this point with a reference to the claim, submitted by the American Association of
17 Pro-Life Obstetricians and Gynecologists (“AAPLOG”) to HHS in 2009, that its
18 members “overwhelmingly would leave the medical profession—or relocate to a
19 conscience-friendly jurisdiction—before they would accept coercion to participate
20 or assist in procedures that violate their consciences.” 84 Fed. Reg. at 23,247.

21 But HHS conducted no follow-up survey of any sort and supplies no
22 quantitative information in its analysis about actual exits from the profession or
23 relocations from one jurisdiction to another in response to the 2011 Rescission. In

1 other words, it makes no effort to confirm whether the post-survey elimination of
2 the expansive protections in the 2008 Rule prompted any survey respondents to
3 follow through on their threat to leave the medical profession. In the absence of “a
4 conscientious effort to take into account what is known as to past experience,” the
5 Department’s “theoretical or model-based approaches” to decisionmaking are not
6 entitled to deference. *Am. Petroleum Inst. v. EPA*, 862 F.3d 50, 69 (D.C. Cir. 2017),
7 *modified on reh’g*, 883 F.3d 918 (D.C. Cir. 2018) (citation and internal quotation
8 marks omitted).

9 Furthermore, HHS fails to mention that the ranks of the very providers it
10 claims were most likely to leave the profession after the 2011 Rescission seem to
11 have been growing. Not only has the number of obstetricians and gynecologists
12 grown by almost 9 percent nationwide from 2011 to 2017, ModernMedicine
13 Network, *ACOG Releases New Study on Ob/Gyn Workforce* (July 1, 2017),¹¹ but the
14 pro-life group AAPLOG’s ranks have also grown by 14 percent since 2009.¹² This
15 pattern is at odds with AAPLOG’s 2009 prediction and the organization’s current
16 arguments that its members would leave the profession without the protections

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18 ¹¹ Available at <https://perma.cc/65FD-QRES>.

19 ¹² Compare AAPLOG, *About Us*, <http://aaplog.org/about-us>
20 [<https://perma.cc/BBV7-T2YP>] (accessed May 18, 2019) (reporting 2,500 members
21 and associates), with Letter from Lawrence J. Joseph, on behalf of AAPLOG, to the
22 Office of Public Health & Science, Dep’t of Health & Human Servs. (Apr. 9, 2009),
23 <https://perma.cc/UL8C-PSSU> (reporting 2,100 members and associates).

1 provided by the Final Rule. *See* 84 Fed. Reg. at 23,247; *see also Am. Petroleum Inst.*,
2 862 F.3d at 69 (“[W]hat we seek is some indication of a reasonable concurrence
3 between model and reality.”).

4 In sum, HHS provides no credible evidence to support its claim that people
5 are leaving or declining to enter the healthcare profession in material numbers for
6 lack of provisions like those in the Final Rule.

7 **B. HHS Does Not Adequately Support Its Conclusion That the Final**
8 **Rule Will Improve Healthcare Quality**

9 The lynchpin of HHS’s argument that its Final Rule will improve patient care
10 is that the rule will induce religious provider organizations to expand the scope of
11 their operations in terms of both service provision and geography. 84 Fed. Reg. at
12 23,248. But *no commenter* indicated to HHS that it had confined either the scope or
13 geographic footprint of its services as a result of the 2011 Rescission, that the “status
14 quo risks driving [it] out of underserved communities altogether,” *see id.*, or that it
15 had plans to expand in any way should the Final Rule be adopted. Given that HHS
16 pointed to organizations like Ascension as potentially curtailing charity care without
17 the Final Rule, *id.*, the absence of substantiating statements from these organizations
18 in their comments weighs against HHS’s claim, *see, e.g., Ascension, Comment*
19 *Letter on Protecting Statutory Conscience Rights in Health Care* (Mar. 27, 2018).

20 **C. HHS Does Not Adequately Support Its Conclusion That the Final**
21 **Rule Will Reduce the Prevalence of Moral Distress**

22 HHS contends that the Final Rule “will reduce the incidence of the harm
23 that being forced to violate one’s conscience inflicts on providers.” 84 Fed. Reg. at
23,249. In making this assertion, the Department claims to rely on “[s]ubstantial

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

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

20 Joan McCarthy & Chris Gastmans, *Moral Distress: A Review of the Argument-Based*
21 *Nursing Ethics Literature*, 22 *Nursing Ethics* 131, 148–49 (2015); *see also* 84 Fed.
22 Reg. at 23,249 n.337 (citing McCarthy & Gastmans). Notably, under this broad
23 conception of the term, the Final Rule might *increase* rather than reduce moral
distress among some providers, insofar as it leads to lack of treatment, inadequate

1 care, and inadequate consent for treatment (when patients are denied information
2 about certain treatment options due to a provider’s religious or moral beliefs).

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

16 In addition to misrepresenting the *causes* of moral distress as described in the
17 academic literature, HHS fails to provide even a minimal amount of evidence or
18 information to support its claim that the Final Rule will reduce the *prevalence* of
19 moral distress. The *HHS Guidelines* explain that when the effects of a rule are less
20 tangible and difficult to quantify—because, for instance, the rule implicates
21 “important human values, such as dignity, equity, and privacy”—HHS should
22 attempt to “count the number of people affected.” *HHS Guidelines* at 48. Similarly,
23 “[w]here some data exist, but are not sufficient to reasonably quantify the effect,”

1 HHS should, if possible, report “[i]ntermediate measures, such as the number of
2 individuals affected.” *Id.* at 51; *see also Circular A-4* at 27 (“If you are not able to
3 quantify the effects, you should present any relevant quantitative information along
4 with a description of the unquantified effects You should provide a discussion
5 of the strengths and limitations of the qualitative information.”). But HHS has not
6 quantified, in exact or approximate terms, the number of medical practitioners whose
7 moral distress will be alleviated under the Final Rule, nor any of the following
8 antecedent quantities of individuals: (1) those experiencing moral distress for any
9 reason; (2) those experiencing moral distress for the reasons of concern to HHS; or
10 (3) those who would refuse to assist in or conduct medical procedures that prompt
11 their moral distress.

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

15 **D. HHS Does Not Adequately Support Its Conclusion That the Final**
16 **Rule Will Cause a Net Increase in Freedom of Conscience for**
17 **Healthcare Professionals**

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

1 Protecting Statutory Conscience Rights in Health Care 1 (Mar. 27, 2018)¹³
2 (explaining that where a provider organization bars employees from providing some
3 services on religious grounds, “medical professionals whose religious or moral
4 beliefs require them to provide patients with the full range of reproductive health
5 services may be prohibited by their employer from acting on this belief”); *see also*
6 *id.* at 2–6 (describing diverse views of religious communities on morality of
7 reproductive healthcare services, including abortion). HHS asserts that “[t]he rule
8 will promote protection of religious beliefs and moral convictions,” but it has made
9 no apparent effort to determine the relative numbers of people who would experience
10 the Final Rule as supporting or interfering with their religious beliefs and moral
11 convictions. As a result, the assertion is entirely conclusory and thus arbitrary and
12 capricious.

13 CONCLUSION

14 This Court should grant Plaintiff’s Cross-Motion for Summary Judgment.¹⁴
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19 ¹³ Available at [https://www.regulations.gov/document?D=HHS-OCR-2018-0002-](https://www.regulations.gov/document?D=HHS-OCR-2018-0002-70101)
20 [70101](https://www.regulations.gov/document?D=HHS-OCR-2018-0002-70101).

21 ¹⁴ 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: September 20, 2019

2 LANE POWELL PC

3 s/ Taylor Washburn

4 Taylor Washburn, WSBA #51524

5 washburnt@lanepowell.com

6 1420 Fifth Avenue, Suite 4200

7 Seattle, WA 98101-2375

8 T: (206) 223-7000

9 INSTITUTE FOR POLICY INTEGRITY

10 NEW YORK UNIVERSITY SCHOOL OF LAW

11 Jack Lienke, N.Y. State Bar #5066386

12 jack.lienke@nyu.edu (admitted *pro hac vice*)

13 Justin Gundlach, N.Y. State Bar #4915468

14 justin.gundlach@nyu.edu (admitted *pro hac vice*)

15 139 MacDougal Street, 3rd Floor

16 New York, NY 10012

17 T: (212) 992-8932

18 *Counsel for Amicus Curiae Institute for Policy*
19 *Integrity*

DECLARATION OF SERVICE

1 I hereby declare that on this day I caused the foregoing document to be
2 electronically filed with the Clerk of the Court using the Court’s CM/ECF System
3 which will serve a copy of this document upon all counsel of record.
4

5 DATED this 20th day of September, 2019, at Seattle, Washington.

6
7 s/ Peter Elton
8 Peter Elton
9 Legal Assistant
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JUDGE STANLEY A. BASTIAN

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

STATE OF WASHINGTON,

NO. 2:19-cv-00183-SAB

Plaintiff,

v.

[PROPOSED]

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,

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

Defendants.

ORDER

On September 20, 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 Cross-Motion for Summary Judgment. 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.

THE HONORABLE STANLEY A. BASTIAN
UNITED STATES DISTRICT JUDGE

1 Presented by:

2 LANE POWELL PC

3 s/ Taylor Washburn

4 Taylor Washburn, WSBA #51524

5 washburnt@lanepowell.com

6 1420 Fifth Avenue, Suite 4200

Seattle, WA 98101-2375

Telephone: 206.223.7000

7 Jack Lienke, N.Y. State Bar #5066386

8 jack.lienke@nyu.edu

(admitted *pro hac vice*)

9 Justin Gundlach, N.Y. State Bar #4915468

10 justin.gundlach@nyu.edu

(admitted *pro hac vice*)

Institute for Policy Integrity

11 New York University School of Law

12 139 MacDougal Street, 3rd Floor

New York, NY 10012

13 T: (212) 992-8932

14 *Counsel for Amicus Curiae Institute for Policy Integrity*