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12 **IN THE UNITED STATES DISTRICT COURT**
13 **FOR THE NORTHERN DISTRICT OF CALIFORNIA**

14 CITY AND COUNTY OF SAN FRANCISCO,

15 *Plaintiff,*

16 v.

17 ALEX M. AZAR II, Secretary of U.S.
18 Department of Health and Human Services;
19 ROGER SEVERINO, Director, Office for Civil
20 Rights, Department of Health and Human
21 Services; U.S. DEPARTMENT OF HEALTH
22 AND HUMAN SERVICES; and DOES 1-25,

23 *Defendants.*

Case No. 3:19-cv-2405-WHA

**NOTICE OF MOTION AND
UNOPPOSED MOTION OF THE
INSTITUTE FOR POLICY
INTEGRITY AT NEW YORK
UNIVERSITY SCHOOL OF LAW TO
FILE AN AMICUS CURIAE BRIEF IN
SUPPORT OF PLAINTIFFS' MOTION
FOR PRELIMINARY INJUNCTION**

Judge: The Honorable William Alsup

24 STATE OF CALIFORNIA, by and through
25 XAVIER BECERRA, Attorney General,

26 *Plaintiff,*

27 v.

28 ALEX M. AZAR, in his OFFICIAL
CAPACITY as SECRETARY of the U.S.
DEPARTMENT of HEALTH & HUMAN
SERVICES; U.S. DEPARTMENT of HEALTH
& HUMAN SERVICES; DOES 1-100,

Defendants.

Case No. 3:19-cv-2769-WHA

COUNTY OF SANTA CLARA, TRUST WOMEN SEATTLE, LOS ANGELES LGBT CENTER, WHITMAN-WALKER CLINIC, INC. d/b/a WHITMAN-WALKER HEALTH, BRADBURY-SULLIVAN LGBT COMMUNITY CENTER, CENTER ON HALSTED, HARTFORD GYN CENTER, MAZZONI CENTER, MEDICAL STUDENTS FOR CHOICE, AGLP: THE ASSOCIATION OF LGBTQ+ PSYCHIATRISTS, AMERICAN ASSOCIATION OF PHYSICIANS FOR HUMAN RIGHTS d/b/a GLMA: HEALTH PROFESSIONALS ADVANCING LGBTQ EQUALITY, COLLEEN MCNICHOLAS, ROBERT BOLAN, WARD CARPENTER, SARAH HENN, and RANDY PUMPHREY,

Plaintiffs,

v.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES and ALEX M. AZAR, II, in his official capacity as SECRETARY OF HEALTH AND HUMAN SERVICES,

Defendants.

Case No. 3:19-cv-2916-WHA

TO ALL PARTIES AND THEIR ATTORNEYS OF RECORD:

PLEASE TAKE NOTICE THAT the Institute for Policy Integrity at New York University School of Law (“Policy Integrity”) hereby moves the Court for leave to file the accompanying *amicus curiae* brief in the above-captioned case in support of Plaintiffs’ Motion for Preliminary Injunction. Policy Integrity has conferred with the parties concerning the filing of this motion. Plaintiffs and Defendants have consented to this motion.

I. LEGAL STANDARD

The question of whether to grant permission to file an amicus brief lies solely within the discretion of the Court. *Hoptowit v. Ray*, 682 F.2d 1237, 1260 (9th Cir. 1982). In general, courts have “exercised great liberality” when determining whether to allow amicus participation. *Woodfin Suite Hotels, LLC v. City of Emeryville*, No. C-06-1254, 2007 WL 81911, at *3 (N.D.

1 Cal. Jan. 9, 2007) (Armstrong, J.); *accord Ou-Young v. Roberts*, No. C-13-4442, 2013 WL
2 6732118, at *3 (N.D. Cal. Dec. 20, 2013) (Chen, J.). “[A]n individual seeking to appear as
3 amicus must merely make a showing that his participation is useful or otherwise desirable to the
4 court.” *Woodfin Suite Hotels*, 2007 WL 81911, at *3. As such, district courts welcome amicus
5 briefs where “the amicus has unique information or perspective that can help the court beyond
6 the help that the lawyers for the parties are able to provide.” *NGV Gaming, Ltd. v. Upstream*
7 *Point Molate, LLC*, 355 F. Supp. 2d 1061, 1067 (N.D. Cal. 2005) (Conti, J.) (internal quotation
8 marks omitted). Moreover, amicus briefs should normally be allowed when the amicus has an
9 interest in the case. *See In re Heath*, 331 B.R. 424, 430 (9th Cir. B.A.P. 2005). Policy Integrity’s
10 motion satisfies all of these factors.

11 II. INTEREST OF *AMICUS CURIAE*

12 Policy Integrity has a strong interest in this case. Policy Integrity is a nonpartisan, not-
13 for-profit think tank dedicated to improving the quality of government decisionmaking through
14 advocacy and scholarship in the fields of administrative law, economics, and public policy.
15 Policy Integrity’s legal and economic experts have produced extensive scholarship on the best
16 practices for regulatory impact analysis and the proper valuation of regulatory costs and benefits.
17 Most notably, our director, Richard L. Revesz, has published more than eighty articles and books
18 on administrative law, including on the legal and economic principles that inform rational
19 regulatory decisions. *See e.g.*, Richard L. Revesz & Michael A. Livermore, *Retaking Rationality:*
20 *How Cost-Benefit Analysis Can Better Protect the Environment and Our Health* (2008).¹

21 In furtherance of its mission to promote rational decisionmaking, Policy Integrity has
22 filed *amicus curiae* briefs addressing agency analysis of costs and benefits in many recent cases.
23 *See, e.g.*, Br. for Inst. for Policy Integrity as Amicus Curiae, *California v. U.S. Bureau of Land*
24 *Mgmt.*, 277 F. Supp. 3d 1106 (N.D. Cal. 2017) (No. 17-cv-3804) (Laporte, M.J.) (arguing that
25 agency’s failure to consider forgone benefits that would result from a delay in implementation of
26 methane standards was arbitrary); Br. for Inst. for Policy Integrity as Amicus Curiae in Support
27

28 ¹ A full list of publications can be found in Revesz’s online faculty profile, *available at*
<https://its.law.nyu.edu/facultyprofiles/index.cfm?fuseaction=profile.overview&personid=20228>.

1 of Plaintiffs’ Motion for Summary Judgment, *California v. U.S. Dep’t of the Interior*, No. C 17-
2 56948, 2019 WL 2223804 (N.D. Cal. Mar. 29, 2019) (Armstrong, J.) (arguing that repeal of
3 procedural reforms for mineral valuation was unreasonable due to agency’s inaccurate
4 assessment of repeal’s economic impact). In those cases, courts have agreed that the agency
5 analyses—and, in turn, the rules issued in reliance on those analyses—were arbitrary and
6 capricious. *California v. BLM*, 277 F. Supp. 3d at 1123 (holding failure to consider forgone
7 benefits arbitrary); *California v. Interior*, 2019 WL 2223804, at *8-13 (finding repeal arbitrary
8 due in part to agency’s flawed economic impact assessment).

9 Policy Integrity has particular expertise on the regulatory impact analysis that the
10 Department of Health and Human Services (“HHS”) conducted in support of the rule at issue in
11 this case, Protecting Statutory Conscience Rights in Health Care; Delegations of Authority, 84
12 Fed. Reg. 23,170 (May 21, 2019) (“Final Rule”). In 2008, we submitted an expert report on the
13 defective analysis HHS prepared to support a previous effort to expand statutory conscience
14 rights through rulemaking. *See* Inst. for the Study of Regulation, Comments on Ensuring That
15 Department of Health and Human Services Funds Do Not Support Coercive or Discriminatory
16 Policies or Practices in Violation of Federal Law (Sept. 16, 2008).² That 2008 rule was repealed
17 in 2011, but the Final Rule is similar in many respects and has similar fundamental deficiencies
18 in its cost-benefit analysis, as Policy Integrity pointed out in a March 2018 comment letter to
19 HHS. Inst. for Policy Integrity, Comment Letter on Protecting Statutory Conscience Rights in
20 Health Care (Mar. 27, 2018).³ We also presented these critiques to the White House Office of
21 Information and Regulatory Affairs in an April 2019 teleconference.

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

27 _____
28 ² Available at <https://www.regulations.gov/document?D=HHS-OS-2008-0011-4969>. The
Institute for Policy Integrity was formerly called the Institute for the Study of Regulation.

³ Available at <https://www.regulations.gov/document?D=HHS-OCR-2018-0002-72071>.

III. POLICY INTEGRITY'S EXPERTISE WILL BENEFIT THE COURT

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

IV. MEET AND CONFER AND TIMELINESS

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

This motion is timely. Though this Court does not have rules governing the timing of amicus briefs, the Court may look for guidance to the rules of other district courts. In the U.S. District Court for the District of Columbia, the Local Rules require an amicus motion to be filed "in a timely manner such that it does not unduly delay the Court's ability to rule on any pending matter." Rules of the U.S. District Court for the District of Columbia, Local Rule 7(o)(2) at 31 (June 2018), <http://www.dcd.uscourts.gov/sites/dcd/files/LocalRulesJune2018.pdf>. In this case, there is time for the Court to decide Policy Integrity's motion without unduly delaying the decision on the pending matter. Defendants' opposition is due June 26 and Plaintiffs' reply is due July 3.

CONCLUSION

For the forgoing reasons, Policy Integrity respectfully requests that the Court grant this

1 motion and accept for filing the accompanying *amicus curiae* brief.
2

3 Dated: June 21, 2019

Respectfully submitted,

4
5 /s/ Denise A. Grab
6 Denise A. Grab, Cal. State Bar #268097
7 Justin Gundlach, N.Y. State Bar #4915468
8 (*pro hac vice* pending)
9 Jack Lienke, N.Y. State Bar #5066386
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Counsel for Amicus Curiae
Institute for Policy Integrity

CERTIFICATE OF SERVICE

I hereby certify that on June 21, 2019, I electronically filed the NOTICE OF MOTION AND MOTION OF THE INSTITUTE FOR POLICY INTEGRITY AT NEW YORK UNIVERSITY SCHOOL OF LAW TO FILE AN *AMICUS CURIAE* BRIEF IN SUPPORT OF PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION with the Clerk using the CM/ECF system, which I understand to have caused service of the filing to all counsel of record.

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*Counsel for Amicus Curiae
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7 Counsel for *Amicus Curiae* Institute for Policy Integrity

8 **IN THE UNITED STATES DISTRICT COURT**
9 **FOR THE NORTHERN DISTRICT OF CALIFORNIA**

10 CITY AND COUNTY OF SAN FRANCISCO,

11 *Plaintiff,*

12 v.

13 ALEX M. AZAR II, Secretary of U.S.
14 Department of Health and Human Services;
15 ROGER SEVERINO, Director, Office for Civil
16 Rights, Department of Health and Human
17 Services; U.S. DEPARTMENT OF HEALTH
AND HUMAN SERVICES; and DOES 1-25,

18 *Defendants.*

Case No. 3:19-cv-2405-WHA

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

Hearing: July 17, 2019
Time: 8:00 a.m.
Courtroom 12, 19th Floor
Judge: The Honorable William Alsup

19 STATE OF CALIFORNIA, by and through
20 XAVIER BECERRA, Attorney General,

21 *Plaintiff,*

22 v.

23 ALEX M. AZAR, in his OFFICIAL
24 CAPACITY as SECRETARY of the U.S.
DEPARTMENT of HEALTH & HUMAN
25 SERVICES; U.S. DEPARTMENT of
26 HEALTH & HUMAN SERVICES; DOES 1-
100,

27 *Defendants.*
28

Case No. 3:19-cv-2769-WHA

1 COUNTY OF SANTA CLARA, TRUST
2 WOMEN SEATTLE, LOS ANGELES LGBT
3 CENTER, WHITMAN-WALKER CLINIC,
4 INC. d/b/a WHITMAN-WALKER HEALTH,
5 BRADBURY-SULLIVAN LGBT
6 COMMUNITY CENTER, CENTER ON
7 HALSTED, HARTFORD GYN CENTER,
8 MAZZONI CENTER, MEDICAL STUDENTS
9 FOR CHOICE, AGLP: THE ASSOCIATION
10 OF LGBTQ+ PSYCHIATRISTS, AMERICAN
11 ASSOCIATION OF PHYSICIANS FOR
12 HUMAN RIGHTS d/b/a GLMA: HEALTH
13 PROFESSIONALS ADVANCING LGBTQ
14 EQUALITY, COLLEEN MCNICHOLAS,
15 ROBERT BOLAN, WARD CARPENTER,
16 SARAH HENN, and RANDY PUMPHREY,

17 *Plaintiffs,*

18 v.

19 U.S. DEPARTMENT OF HEALTH AND
20 HUMAN SERVICES and ALEX M. AZAR, II,
21 in his official capacity as SECRETARY OF
22 HEALTH AND HUMAN SERVICES,
23

24 *Defendants.*

Case No. 3:19-cv-2916-WHA

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INTEREST OF AMICUS CURIAE 1

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

6 INTEREST OF AMICUS CURIAE

7 Policy Integrity is a nonpartisan, not-for-profit think tank dedicated to improving the quality
8 of government decisionmaking through advocacy and scholarship in the fields of administrative law,
9 economics, and public policy. Our legal and economic experts have produced extensive scholarship
10 on the best practices for regulatory impact analysis and the proper valuation of regulatory costs and
11 benefits. Most notably, our director, Richard L. Revesz, has published more than eighty articles and
12 books on environmental and administrative law, including works on the legal and economic
13 principles that inform rational regulatory decisions. *See, e.g.*, Richard L. Revesz & Michael A.
14 Livermore, *Retaking Rationality: How Cost-Benefit Analysis Can Better Protect the Environment*
15 *and Our Health* (2008).²

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17 *amicus curiae* briefs addressing agency analysis of costs and benefits in many recent cases. *See, e.g.*,
18 Br. for Inst. for Policy Integrity as Amicus Curiae, *California v. U.S. Bureau of Land Mgmt.*, 277 F.
19 Supp. 3d 1106 (N.D. Cal. 2017) (No. 17–cv–03804) (Laporte, M.J.) (arguing that agency’s failure to
20 consider forgone benefits that would result from a delay in implementation of methane standards
21 was arbitrary); Br. for Inst. for Policy Integrity as Amicus Curiae in Support of Plaintiffs’ Motion for
22

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

² A full list of publications can be found in Revesz’s online faculty profile, *available at*
<https://its.law.nyu.edu/facultyprofiles/index.cfm?fuseaction=profile.overview&personid=20228>.

1 Summary Judgment, *California v. U.S. Dep't of the Interior*, No. C 17-56948, 2019 WL 2223804
2 (N.D. Cal. Mar. 29, 2019) (Armstrong, J.) (arguing that repeal of procedural reforms for mineral
3 valuation was unreasonable due to agency's inaccurate assessment of repeal's economic impact). In
4 those cases, courts have agreed that the agency analyses—and, in turn, the rules issued in reliance on
5 those analyses—were arbitrary and capricious. *California v. BLM*, 277 F. Supp. 3d at 1123 (holding
6 failure to consider forgone benefits arbitrary); *California v. Interior*, 2019 WL 2223804, at *8-13
7 (finding repeal arbitrary due in part to agency's flawed economic impact assessment).

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

19 Plaintiffs argue that the Final Rule is arbitrary and capricious in part because “HHS
20 conducted and relied on a flawed cost-benefit analysis.” City and County of San Francisco’s
21 Memorandum of Points and Authorities at 13. Policy Integrity’s expertise in cost-benefit analysis
22 and experience with the Final Rule give it a unique perspective from which to evaluate plaintiffs’
23 claims that the Final Rule is arbitrary and capricious.

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27 ³ Available at <https://www.regulations.gov/document?D=HHS-OS-2008-0011-4969>. The
Institute for Policy Integrity was formerly called the Institute for the Study of Regulation.

28 ⁴ Available at <https://www.regulations.gov/document?D=HHS-OCR-2018-0002-72071>.

SUMMARY OF ARGUMENT

1
2 When an agency relies on a cost-benefit analysis to support its rulemaking, “a serious flaw
3 undermining that analysis can render the rule unreasonable.” *Nat’l Ass’n of Home Builders v. EPA*,
4 682 F.3d 1032, 1040 (D.C. Cir. 2012). HHS has prepared a regulatory impact analysis for the Final
5 Rule in which it concludes that “the benefits of this rule, although not always quantifiable or
6 monetized, justify the burdens.” 84 Fed. Reg. at 23,228. But the analysis underlying that assertion is
7 fundamentally flawed in at least two respects.

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

16 Second, the claimed benefits of the rule are entirely speculative. The Department claims the
17 Final Rule will increase the ranks of healthcare professionals, improve the quality of doctor-patient
18 relationships, reduce individual healthcare professionals’ degree of “moral distress,” and promote
19 the “societal good” of personal freedom for individuals to conduct themselves based on their
20 religious beliefs and moral convictions. 84 Fed. Reg. at 23,246. But these claims are unsupported
21 by—and in some instances contradicted by—evidence in the record.

22 By dismissing reasonably foreseeable costs and touting wholly speculative benefits, HHS
23 “inconsistently and opportunistically frame[s]” the Final Rule’s effects, *Bus. Roundtable v. SEC*, 647
24 F.3d 1144, 1148-49 (D.C. Cir. 2011), and “put[s] a thumb on the scale” in favor of its adoption, *Ctr.*
25 *for Biological Diversity v. Nat’l Highway Traffic Safety Admin.*, 538 F.3d 1172, 1198 (9th Cir.
26 2008). The Department’s reliance on this rigged analysis renders the Final Rule arbitrary and
27 capricious.

ARGUMENT

Final agency actions like the Final Rule are arbitrary and capricious under the Administrative Procedure Act, 5 U.S.C. § 706(2), if the agency fails to “examine the relevant data,” “consider an important aspect of the problem,” or “articulate a satisfactory explanation for its action, including a rational connection between the facts found and the choice made.” *Motor Vehicle Mfrs. Ass’n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) (internal quotation marks omitted). When the justifications for the action include the results of a cost-benefit analysis, “a serious flaw undermining the analysis can render the rule unreasonable.” *Nat’l Ass’n of Home Builders*, 682 F.3d at 1040. This is true even when the agency was not statutorily obligated to conduct the analysis in the first place. *Id.* at 1039-40; *Council of Parent Attorneys and Advocates, Inc. v. DeVos*, 365 F. Supp. 3d 28, 54 n.11 (D.D.C. 2019) (rejecting government’s contention that a regulatory impact analysis “conducted pursuant to Executive Orders” rather than a statutory mandate was “not subject to judicial review”). Finally, if the agency’s action represents a change of position on a particular issue, the agency must provide a “reasoned explanation . . . for disregarding facts and circumstances that underlay or were engendered by the prior policy.” *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515-16 (2009); *see also Organized Vill. of Kake v. U.S. Dep’t of Agric.*, 795 F.3d 956, 968 (9th Cir. 2015) (“[E]ven when reversing a policy after an election, an agency may not simply discard prior factual findings without a reasoned explanation.”).

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

I. HHS DOES NOT ADEQUATELY ASSESS THE FINAL RULE’S SIGNIFICANT INDIRECT COSTS TO PATIENTS AND PROVIDER ORGANIZATIONS

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

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

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

16 More importantly, ignoring indirect costs violates HHS’s duties under the Administrative
17 Procedure Act. “As a general rule, the costs of an agency’s action are a relevant factor that the
18 agency must consider before deciding whether to act,” and “consideration of costs is an essential
19 component of reasoned decisionmaking under the Administrative Procedure Act.” *Mingo Logan*
20 *Coal Co. v. EPA*, 829 F.3d 710, 732–33 (D.C. Cir. 2016) (Kavanaugh, J., dissenting); *see also*
21 *Michigan v. EPA*, 135 S. Ct. 2699, 2707–08 (2015) (“Agencies have long treated cost as a centrally
22 relevant factor when deciding whether to regulate.”).

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

1 consider indirect safety effects of substituting asbestos-free car brakes).

2 HHS’s failure to consider indirect costs to patients would be impermissible in any
3 rulemaking but is particularly arbitrary here, because the Department already recognized the
4 existence of these costs in a prior rulemaking. In 2011, HHS cited indirect costs to justify repealing a
5 2008 conscience rule that purported to implement many of the same statutory provisions as the Final
6 Rule, in very similar ways. *See* 76 Fed. Reg. 9968, 9974 (Feb. 23, 2011) (“2011 Rescission”)
7 (agreeing with commenter concerns that the 2008 rule “could limit access to reproductive health
8 services and information, including contraception, and could impact a wide range of medical
9 services, including care for sexual assault victims, provision of HIV/AIDS treatment, and emergency
10 services”); *see also* 73 Fed. Reg. 78,072, 78,078 (Dec. 19, 2008) (“2008 Rule”). The APA obligates
11 HHS to provide a “reasoned explanation” for disregarding the findings underlying the 2011
12 Rescission, *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515-16 (2009), and the Department
13 has not done so. *See also* *Kake*, 795 F.3d at 968.

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

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

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

25 As Policy Integrity emphasized to HHS in comments on the proposed version of the Final
26 Rule, conscience-related refusals of care can impose a variety of costs—financial, physical, and
27 psychological—on patients. Policy Integrity Comments at 5. At minimum, a patient denied care
28 must incur the cost of seeking out an alternative provider. Furthermore, some patients denied care

1 may be too discouraged to seek out alternative sources of care and decide to forgo treatment
2 altogether, leading to negative health consequences. Or, if the care is denied in an urgent or
3 emergency situation, there may not be adequate time to find an alternative, leading in some cases to
4 catastrophic health consequences.

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

17 LGBT people and individuals living with HIV also contend with denials of a variety of
18 health services, including those unrelated to their sexual orientation, gender identity, and HIV status.
19 *Id.* A rigorously conducted, nationwide survey found in 2010 that nearly eight percent of lesbian,
20 gay, and bisexual respondents and almost twenty-seven percent of transgender respondents reported
21 being refused necessary healthcare because of their sexual orientation and gender identity,
22 respectively. Lambda Legal, *When Health Care Isn't Caring: Lambda Legal's Survey on*
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24

25
26
27 ⁵ Available at <https://perma.cc/6SZU-W5TV>. This report was cited in 43 sets of comments
28 on the Final Rule, according to a search of the docket. See <https://www.regulations.gov/docket?D=HHS-OCR-2018-0002> (last visited on June 12, 2019).

1 *Discrimination Against LGBT People and People Living with HIV* 10 (2010).⁶ Just as they do for
2 women in need of reproductive health services, these conscience-related denials of care can carry
3 substantial costs for affected LGBT and HIV-positive patients. In one example in the record, an
4 HIV-positive patient denied treatment for chest pain ended up “admitted to the hospital” a week
5 later, “with gastrointestinal hemorrhaging and was diagnosed with pneumonia, a staph infection, and
6 AIDS.” Nat’l Women’s Law Ctr. at 2. On a more general level, nearly twenty percent of transgender
7 respondents to a Massachusetts-based survey indicated that prior mistreatment by healthcare
8 providers had led them to postpone or forgo treatment when sick or injured. Sari L. Reisner et al.,
9 *Legal Protections in Public Accommodations Settings: A Critical Public Health Issue for*
10 *Transgender and Gender-Nonconforming People*, 93 *Milbank Q.* 484, 494 (2015).

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

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

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

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

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

20 The Department does cite two studies that it claims found “insufficient evidence to conclude
21 that conscience protections have negative effects on access to care.” 84 Fed. Reg. at 23,251 (citing
22 W. Chavkin et al., *Conscientious Objection and Refusal to Provide Reproductive Healthcare: A*
23 *White Paper Examining Prevalence, Health Consequences, and Policy Responses*, 123 Int’l J.
24 *Gynecol. & Obstet.* S41 (2013); K. Morrell & W. Chavkin, *Conscientious Objection to Abortion and*
25 *Reproductive Healthcare: A Review of Recent Literature and Implications for Adolescents*, 27 *Curr.*
26 *Opin. Obstet. Gynecol.* 333 (2015)). But those studies actually show that conscience-based refusals
27 *are* a material barrier to care and that the only open empirical question is the extent to which such
28 refusals negatively affect patient health. HHS’s quotations from the studies are misleading

1 reflections of their true points—namely, that “it is difficult to disentangle the impact of
2 conscientious objection when *it is one of many barriers* to reproductive healthcare,” Chavkin at S42
3 (emphasis added), and that “[c]onscientious objection is understudied, complicated, and *appears to*
4 *constitute a barrier to care*, especially for certain subgroups.” Morrell & Chavkin at 334 (emphasis
5 added). Thus, HHS’s conclusion that the Final Rule will not negatively affect access to care “runs
6 counter to the evidence before the agency.” *State Farm*, 463 U.S. at 43.

7 **3. Uncertainty Does Not Excuse HHS’s Failure to Estimate the Final Rule’s** 8 **Effects on the Rate and Nature of Conscience-Related Refusals of Care**

9 In addition to suggesting that the Final Rule may have *no* negative effects on patients’ access
10 to care, HHS claims that estimating the magnitude of such effects is simply too difficult. 84 Fed.
11 Reg. at 23,252 (“The Department attempted to quantify the impact of this rule on access to care but
12 determined that there is not enough reliable data, and that the analysis was subject to too many
13 confounding variables, for the Department to arrive at a useful estimate.”). But uncertainty about the
14 precise magnitude of a regulatory effect does not justify assigning that effect no value in a cost-
15 benefit analysis. *Ctr. for Biological Diversity v. Nat’l Highway Traffic Safety Admin.*, 538 F.3d
16 1172, 1190, 1200 (9th Cir. 2008) (finding agency reasoning arbitrary and capricious where agency
17 argued that benefits of carbon dioxide reductions were “too uncertain to support their explicit
18 valuation and inclusion” in a regulatory cost-benefit analysis). Ultimately, while there may be “a
19 range of values” for the costs to patients of the Final Rule, that value “is certainly not zero.” *Id.* at
20 1200. Thus, the costs must be “accounted for in the agency’s analysis.” *Id.*

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

5 Ultimately, even if HHS cannot fully quantify and monetize the expected costs of the rule for
6 patients, the Department should at least engage in a rigorous qualitative analysis, in which it lists the
7 types of procedures that might be denied as a result of the rule and the potential consequences of
8 such denials for 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 can only
10 present discrete alternative scenarios without assessing the relative likelihood of each scenario
11 quantitatively.”); *id.* at 27 (“If you are not able to quantify the effects, you should present any
12 relevant quantitative information along with a description of the unquantified effects . . .”).

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

21 HHS’s criticism of commenters for not providing it with a complete assessment of the Final
22 Rule’s effects on access to care is particularly galling given that the uncertainty surrounding those
23 effects is largely of the Department’s own making. Repeatedly in the preamble to the Final Rule,
24 HHS declines opportunities to provide guidance on the circumstances under which the Final Rule
25 protects refusals of care. For example, in response to comments warning that that the Final Rule
26 could negatively “impact counseling or referrals for LGBT persons,” the Department could easily
27 have clarified that the Final Rule’s protections do not apply to providers who deny care based on
28 objections to a patient’s sexual orientation or gender identity. 84 Fed. Reg. at 23,189. Instead, HHS

1 says only that it “does not pre-judge matters without the benefit of specific facts and
2 circumstances” and that any invocations of conscience rights “will be evaluated on a case-by-case
3 basis.” *Id.* Similarly, in response to concerns that that the Final Rule will promote denials of HIV or
4 infertility treatment, HHS again fails to specify whether and when a refusal to provide such
5 treatment might fall within the scope of protected conduct, noting only that, if it received a
6 complaint from a healthcare worker who felt coerced into providing such treatments, the Department
7 “would examine the facts and circumstances of the complaint to determine whether it falls within the
8 scope of the statute in question and these regulations.” *Id.* at 23,188. If HHS will not explain how its
9 Final Rule changes the legal status quo, it cannot reasonably expect commenters to independently
10 assess the costs of that change.

11 **4. HHS Cannot Excuse Its Failure to Assess Patient Costs by Making a** 12 **Conclusory Assertion that Any Such Costs Are Justified**

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

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

1 mentioned in the regulatory impact analysis for the Final Rule.

2 In the absence of an acknowledgement of these costs, HHS's conclusory assertion that the
3 Final Rule will have a *net* positive effect on healthcare access "adds nothing to the agency's defense
4 of its thesis except perhaps the implication that it was committed to its position regardless of any
5 facts to the contrary." *Chem. Mfrs. Ass'n v. EPA*, 28 F.3d 1259, 1266 (D.C. Cir. 1994). As the
6 Department's own *Guidelines for Regulatory Impact Analysis* warn, "[i]n the absence of
7 information, decision-makers and others may weight nonquantified effects in a manner consistent
8 with their own (unarticulated and perhaps unconscious) beliefs, without sufficiently probing the
9 rationale or the weighting." HHS, *Guidelines for Regulatory Impact Analysis* 47 (2016) [hereinafter
10 *HHS Guidelines*]. To "counterbalance this tendency," HHS's *Guidelines* require "[c]lear
11 presentation of the available evidence," *id.*, which the Department utterly fails to provide in its
12 analysis for the Final Rule.

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

15 HHS's final excuse for inadequately assessing the Final Rule's costs for patients is that any
16 objections to the Final Rule "based on potential (often temporary) lack of access to particular
17 procedures as a result of enforcement of the law are really objections to policy decisions made by the
18 people's representatives in Congress in enacting the Federal conscience and anti-discrimination laws
19 in the first place." 84 Fed. Reg. at 23,251. This argument, too, is unavailing. While the statutory
20 provisions underlying the Final Rule were indeed passed by Congress, HHS has made a
21 discretionary decision to adopt new, unprecedentedly expansive definitions of terms in those
22 provisions and new procedures for enforcing the provisions. That discretionary decision has costs
23 relative to the status quo, which the Administrative Procedure Act obligates the Department to
24 consider. Furthermore, if it *were* true that no patient costs associated with invocations of conscience
25 rights could be attributed to the Final Rule, it would necessarily *also* be true that the Final Rule
26 could claim no credit for patient or provider *benefits* associated with such invocations. HHS, in
27 short, cannot rationally claim that the Final Rule has incremental benefits without acknowledging
28 corresponding incremental costs. *See California v. U.S. Bureau of Land Mgmt.*, 277 F. Supp. 3d

1 1106, 1123 (N.D. Cal. 2017) (agencies cannot consider only “one side of the equation” by
2 calculating benefits and ignoring costs).

3 **B. HHS Completely Ignores Costs to Provider Organizations of Accommodating**
4 **Increased Refusals of Care**

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

12 While the Final Rule authorizes employers to request some advance notice of objections, 84
13 Fed. Reg. at 23,191–92, employers may make such requests only after hiring an employee, and
14 cannot then fire that employee for conscience-based refusals to provide care. Thus, even large, urban
15 hospitals will likely bear significant costs when accommodating employees who refuse to provide or
16 assist with certain forms of care. *See, e.g.*, Hearing Transcript, *Danquah v. Univ. of Med. &*
17 *Dentistry of New Jersey*, Case No. 11-cv-06377, (D.N.J. Dec 16, 2011) (indicating that hospital
18 hired team of nurses to fill staffing gap left by nurses who refused to assist with provision of
19 abortion or related procedures).⁷ For provider organizations with access to fewer resources, such as
20 those in remote locations, the costs of finding replacement staff and adjusting patient and provider
21 schedules to accommodate increased invocation of conscience rights could be greater still. But such
22 costs are mentioned nowhere in HHS’s regulatory impact analysis. HHS’s failure to consider these
23 costs is particularly egregious given that elsewhere in the preamble to the Final Rule the Department
24 expressly contemplates “the use [of] alternate staff” and other staffing adjustments to accommodate

25 _____
26
27 ⁷ HHS cites *Danquah*—but not this particular hearing transcript—in the Final Rule. 84 Fed.
28 Reg. at 3888.

1 objections and refusals on conscience grounds. 84 Fed. Reg. at 23,191–92, 23,202, 23,263.

2 **II. THE FINAL RULE’S PURPORTED BENEFITS ARE SPECULATIVE AND**
 3 **UNSUPPORTED BY EVIDENCE**

4 Courts have explained that, while an agency’s predictive judgments about the likely
 5 economic effects of a rule are entitled to deference,” those judgments “must be based on some logic
 6 and evidence, not sheer speculation.” *Sorenson Commc’ns Inc. v. F.C.C.*, 755 F.3d 702, 708 (D.C.
 7 Cir. 2014) (citations and internal quotation marks omitted). In its regulatory impact analysis, HHS
 8 claims the Final Rule will yield three types of benefits: a net increase in access to healthcare, better
 9 quality of care, and “societal goods that extend beyond health care.” 84 Fed. Reg. at 23,246. HHS
 10 explains further that the Final Rule will deliver these benefits through four mechanisms: first, it will
 11 increase “the availability of qualified health care professionals,” in part by preventing exits from the
 12 field; second, it will improve the quality of doctor-patient relationships; third, it will reduce “moral
 13 distress” among providers; and, fourth, it will promote the “societal good” of “protection of religious
 14 beliefs and moral convictions” by giving providers greater “personal freedom” to act in accordance
 15 with their beliefs. 84 Fed. Reg. at 23,246. But HHS’s analysis of these beneficial effects is grounded
 16 only in “sheer speculation,” *see Sorenson*, 755 F.3d at 708, and in at least one instance is
 17 contradicted by evidence HHS itself added to the record, *see State Farm*, 463 U.S. at 56–57 (action
 18 is arbitrary and capricious if explanation “runs counter to the evidence before the agency”). The
 19 Final Rule is, as a result, arbitrary and capricious. *Nat’l Fuel Gas Supply Corp. v. Fed. Energy Reg’y*
 20 *Comm’n.*, 468 F.3d 831, 839 (D.C. Cir. 2006) (agency action found arbitrary and capricious where
 21 agency “provided no evidence of a real problem” the action would solve); *Arizona Cattle Growers’*
 22 *Ass’n v. U.S. Fish & Wildlife, Bureau of Land Mgmt.*, 273 F.3d 1229, 1244 (9th Cir. 2001) (action
 23 found arbitrary and capricious where based on “speculation ... not supported by the record.”).

24 **A. HHS Offers No Evidence That the Final Rule Will Increase the Number of U.S.**
 25 **Healthcare Professionals**

26 HHS claims that “[n]umerous studies and comments show that the failure to protect
 27 conscience is a barrier to careers in the health care field,” 84 Fed. Reg. at 23,246, but the record
 28 contains only a handful of anecdotes reporting early retirements for reasons of conscience, and *no*
Amicus Curiae Brief of Policy Integrity

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

12 But HHS conducted no follow-up survey of any sort and supplies no quantitative information
13 in its analysis about actual exits from the profession or relocations from one jurisdiction to another in
14 response to the 2011 Rescission. In other words, it makes no effort to confirm whether the post-
15 survey elimination of the expansive protections in the 2008 Rule prompted any survey respondents
16 to follow through on their threat to leave the medical profession.

17 Furthermore, HHS fails to mention that the ranks of the very providers it claims were most
18 likely to leave the profession after the 2011 Rescission seem to have been growing. Not only has the
19 number of obstetricians and gynecologists grown by almost nine percent nationwide from 2011 to
20 2017, ModernMedicine Network, *ACOG Releases New Study on Ob/Gyn Workforce* (July 1, 2017),⁹
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24 ⁸ Notably, though the headline of the 2009 survey was “Online Survey of 2,852 Members of
25 *Faith-Based* Medical Associations,” all respondents were members of a *Christian* medical
26 association. Memorandum from Kellyanne Conway, President & CEO, the polling company™,
27 inc./WomanTrend, to Interested parties 4 (Apr. 8, 2009), available at <https://perma.cc/PC6K-5SML>
(describing survey methodology) (emphases added). The surveys’ results are available at:
<https://perma.cc/WP7R-ARXV> and <https://perma.cc/X2YS-CZFT>.

28 ⁹ Available at <https://perma.cc/65FD-QRES>.

1 but the pro-life group AAPLOG’s ranks have grown by fourteen percent since 2009.¹⁰ This pattern is
 2 at odds with AAPLOG’s 2009 prediction and the organization’s current arguments that its members
 3 would leave the profession without the protections provided by the Final Rule. *See* 84 Fed. Reg. at
 4 23,247. In short, HHS provides no credible evidence to support its claim that people are leaving the
 5 healthcare profession in material numbers for lack of provisions like those in the Final Rule.

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

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

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

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

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

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

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

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

22 Finally, a third study cited by HHS finds, based on a survey of 250 nurses, that the most
23 frequent and intense source of moral distress “related to concern for patients’ feelings and
24 emotions”—again suggesting that the Final Rule might actually increase such distress by causing
25 more refusals of care for certain patients. Fariba Borhani et al., *The Relationship Between Moral*
26 *Distress, Professional Stress, and Intent to Stay in the Nursing Profession*, 7 J. Med. Ethics & Hist.
27 Med. 1, 5 (2014); 84 Fed. Reg. at 23,249 n.330 (citing Borhani et al.). What is more, the study finds
28 no correlation between the moral distress levels reported by respondents and their stated intention to
leave the profession of nursing. Borhani, *supra*, at 4. Thus, it directly contradicts the Department’s
assertion that alleviating moral distress will prevent exits from the medical profession. *See State*

1 *Farm*, 463 U.S. at 56-57 (action is arbitrary and capricious if explanation “runs counter to the
2 evidence before the agency”).

3 In addition to misrepresenting the *causes* of moral distress as described in the academic
4 literature, HHS fails to provide even a minimal amount of evidence or information to support its
5 claim that the Final Rule will reduce the *prevalence* of moral distress. The *HHS Guidelines* explain
6 that when the effects of a rule are less tangible and difficult to quantify—because, for instance, the
7 rule implicates “important human values, such as dignity, equity, and privacy”—HHS should
8 attempt to “count the number of people affected.” *HHS Guidelines* at 48. Similarly, “[w]here some
9 data exist, but are not sufficient to reasonably quantify the effect, HHS should, if possible, report
10 “[i]ntermediate measures, such as the number of individuals affected.” *Id.* at 51; *see also Circular A-*
11 *4* at 27 (“If you are not able to quantify the effects, you should present any relevant quantitative
12 information along with a description of the unquantified effects You should provide a
13 discussion of the strengths and limitations of the qualitative information.”). But HHS has not
14 quantified, in exact or approximate terms, the number of medical practitioners whose moral distress
15 will be alleviated under the Final Rule, nor any of the following antecedent quantities of individuals:
16 (1) those experiencing moral distress for any reason; (2) those experiencing moral distress for the
17 reasons of concern to HHS; or (3) those who would refuse to assist in or conduct medical procedures
18 that prompt their moral distress.

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

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

24 Contrary to the directives in *Circular A-4* and the *HHS Guidelines* mentioned above, HHS
25 has not estimated the number of healthcare professionals who would find that the Final Rule
26 increased their freedom of conscience. Furthermore, HHS uses this departure from analytic norms to
27 avoid acknowledging a vitally important fact: the Final Rule would likely *constrain* the freedom of
28 many individuals whose religious or moral beliefs compel them to offer patients a full range of

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

12 CONCLUSION

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

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

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Dated: June 21, 2019

Respectfully submitted,

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12 **IN THE UNITED STATES DISTRICT COURT**
13 **FOR THE NORTHERN DISTRICT OF CALIFORNIA**

14 CITY AND COUNTY OF SAN FRANCISCO,

15 *Plaintiff,*

16 v.

17 ALEX M. AZAR II, Secretary of U.S.
18 Department of Health and Human Services;
19 ROGER SEVERINO, Director, Office for Civil
20 Rights, Department of Health and Human
21 Services; U.S. DEPARTMENT OF HEALTH
22 AND HUMAN SERVICES; and DOES 1-25,

23 *Defendants.*

Case No. 3:19-cv-2405-WHA

[PROPOSED] ORDER

Judge: The Honorable William Alsup

24 STATE OF CALIFORNIA, by and through
25 XAVIER BECERRA, Attorney General,

26 *Plaintiff,*

27 v.

28 ALEX M. AZAR, in his OFFICIAL
CAPACITY as SECRETARY of the U.S.
DEPARTMENT of HEALTH & HUMAN
SERVICES; U.S. DEPARTMENT of HEALTH
& HUMAN SERVICES; DOES 1-100,

Defendants.

Case No. 3:19-cv-2769-WHA

COUNTY OF SANTA CLARA, TRUST WOMEN SEATTLE, LOS ANGELES LGBT CENTER, WHITMAN-WALKER CLINIC, INC. d/b/a WHITMAN-WALKER HEALTH, BRADBURY-SULLIVAN LGBT COMMUNITY CENTER, CENTER ON HALSTED, HARTFORD GYN CENTER, MAZZONI CENTER, MEDICAL STUDENTS FOR CHOICE, AGLP: THE ASSOCIATION OF LGBTQ+ PSYCHIATRISTS, AMERICAN ASSOCIATION OF PHYSICIANS FOR HUMAN RIGHTS d/b/a GLMA: HEALTH PROFESSIONALS ADVANCING LGBTQ EQUALITY, COLLEEN MCNICHOLAS, ROBERT BOLAN, WARD CARPENTER, SARAH HENN, and RANDY PUMPHREY,

Plaintiffs,

v.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES and ALEX M. AZAR, II, in his official capacity as SECRETARY OF HEALTH AND HUMAN SERVICES,

Defendants.

Case No. 3:19-cv-2916-WHA

This matter having come before the Court by motion of proposed *amicus curiae* Institute for Policy Integrity at New York University School of Law, seeking leave to file a brief *amicus curiae* in the above-captioned matter, and the Court having reviewed the file and pleadings herein, and being otherwise fully advised in the matter, hereby finds good cause to allow *amicus* participation.

IT IS HEREBY ORDERED:

The Motion to File an *Amicus Curiae* Brief in Support of Plaintiffs is GRANTED.

This ____ day of _____, 2019.

The Honorable William Alsup