

1 Denise A. Grab, Cal. State Bar #268097
Justin Gundlach, N.Y. State Bar #4915468 (*pro hac vice*)
2 Jack Lienke, N.Y. State Bar #5066386 (*pro hac vice*)
3 Institute for Policy Integrity
New York University School of Law
4 139 MacDougal Street, 3rd Floor
New York, NY 10012
5 Telephone: (212) 992-8932
6 Email: jack.lienke@nyu.edu
Counsel for *Amicus Curiae* Institute for Policy Integrity

7
8 **IN THE UNITED STATES DISTRICT COURT**
FOR THE NORTHERN DISTRICT OF CALIFORNIA
9 **SAN FRANCISCO DIVISION**

10 CITY AND COUNTY OF SAN FRANCISCO,

11 *Plaintiff,*

12 v.

13 ALEX M. AZAR II et al.,

14 *Defendants.*

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

Related to

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

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

15
16 STATE OF CALIFORNIA, by and through
17 XAVIER BECERRA, Attorney General,

18 *Plaintiff,*

19 v.

20 ALEX M. AZAR II et al.,

21 *Defendants.*

**BRIEF OF THE INSTITUTE FOR POLICY
INTEGRITY AT NEW YORK
UNIVERSITY SCHOOL OF LAW AS
AMICUS CURIAE IN SUPPORT OF
PLAINTIFFS' CROSS-MOTION FOR
SUMMARY JUDGMENT**

Hon. William Alsup

Hearing: October 30, 2019, 8:00 a.m.

22 COUNTY OF SANTA CLARA et al.,

23 *Plaintiffs,*

24 v.

25
26 U.S. DEPARTMENT OF HEALTH AND
HUMAN SERVICES et al.,

27 *Defendants.*

28 Phillip Burton Federal Building & United
States Courthouse
Courtroom 12, 19th Fl.
450 Golden Gate Ave.
San Francisco, CA 94102

TABLE OF CONTENTS

1

2

3 INTEREST OF AMICUS CURIAE 1

4 SUMMARY OF ARGUMENT 2

5 ARGUMENT 3

6 I. HHS DOES NOT ADEQUATELY ASSESS THE FINAL RULE’S SIGNIFICANT

7 INDIRECT COSTS TO PATIENTS AND PROVIDER ORGANIZATIONS 4

8 A. HHS Does Not Adequately Consider Costs to Patients Denied Care as a Result of the

9 Final Rule 5

10 1. Conscience-Based Refusals of Care Impose Costs on Patients 6

11 2. The Final Rule Will Lead to an Increase in Refusals of Care 7

12 3. Uncertainty Does Not Excuse HHS’s Failure to Estimate the Final Rule’s Effects

13 on the Rate and Nature of Conscience-Related Refusals of Care 8

14 4. HHS Cannot Excuse Its Failure to Assess Patient Costs by Making a Conclusory

15 Assertion that Any Such Costs Are Justified 10

16 B. HHS Completely Ignores Costs to Provider Organizations of Accommodating

17 Increased Refusals of Care 11

18 II. THE FINAL RULE’S PURPORTED BENEFITS ARE SPECULATIVE AND

19 UNSUPPORTED BY EVIDENCE 12

20 A. HHS Does Not Adequately Support Its Conclusion That the Final Rule Will Increase

21 the Number of U.S. Healthcare Professionals 13

22 B. HHS Does Not Adequately Support Its Conclusion That the Final Rule Will Reduce

23 the Prevalence of Moral Distress 14

24 CONCLUSION 15

25

26

27

28

TABLE OF AUTHORITIES

1		
2	Cases	Page(s)
3	<i>Am. Petroleum Inst. v. EPA,</i>	
4	862 F.3d 50 (D.C. Cir. 2017).....	14
5	<i>Arizona Cattle Growers’ Ass’n v. U.S. Fish & Wildlife, Bureau of Land Mgmt.,</i>	
6	273 F.3d 1229 (9th Cir. 2001)	13
7	<i>BNSF Ry. Co. v. Surface Transp. Bd.,</i>	
8	526 F.3d 770 (D.C. Cir. 2008).....	12
9	<i>Bus. Roundtable v. SEC,</i>	
10	647 F.3d 1144 (D.C. Cir. 2011).....	3
11	<i>California v. U.S. Bureau of Land Mgmt.,</i>	
12	277 F. Supp. 3d 1106 (N.D. Cal. 2017).....	1
13	<i>California v. U.S. Dep’t of the Interior,</i>	
14	381 F. Supp. 3d 1153 (N.D. Cal. 2019).....	2
15	<i>Chem. Mfrs. Ass’n v. EPA,</i>	
16	28 F.3d 1259 (D.C. Cir. 1994).....	11
17	<i>Competitive Enter. Inst. v. Nat’l Highway Traffic Safety Admin.,</i>	
18	956 F.2d 321 (D.C. Cir. 1992).....	5
19	<i>Corrosion Proof Fittings v. EPA,</i>	
20	947 F.2d 1201 (5th Cir. 1991)	5
21	<i>Council of Parent Attorneys and Advocates, Inc. v. DeVos,</i>	
22	365 F. Supp. 3d 28 (D.D.C. 2019).....	3
23	<i>Ctr. for Biological Diversity v. Nat’l Highway Traffic Safety Admin.,</i>	
24	538 F.3d 1172 (9th Cir. 2008)	3, 9
25	<i>FCC v. Fox Television Stations, Inc.,</i>	
26	556 U.S. 502 (2009).....	3, 8
27	<i>Gen. Chem. Corp. v. United States,</i>	
28	817 F.2d 844 (D.C. Cir. 1987).....	7
	<i>Michigan v. EPA,</i>	
	135 S. Ct. 2699 (2015).....	5
	<i>Mingo Logan Coal Co. v. EPA,</i>	
	829 F.3d 710 (D.C. Cir. 2016).....	5

TABLE OF AUTHORITIES (cont.)

Cases (cont.)	Page(s)
<i>Motor Vehicle Mfrs. Ass’n v. State Farm Mut. Auto. Ins. Co.</i> , 463 U.S. 29 (1983).....	3, 4, 8, 10, 15
<i>Nat’l Ass’n of Home Builders v. EPA</i> , 682 F.3d 1032 (D.C. Cir. 2012).....	2, 3
<i>Nat’l Fuel Gas Supply Corp. v. Fed. Energy Reg’y Comm’n.</i> , 468 F.3d 831 (D.C. Cir. 2006).....	13
<i>Organized Vill. of Kake v. U.S. Dep’t of Agric.</i> , 795 F.3d 956 (9th Cir. 2015)	3, 5
<i>United Techs. Corp. v. Dep’t of Def.</i> , 601 F.3d 557 (D.C. Cir. 2010)	13
Federal Register Notices	
73 Fed. Reg. 78,072 (Dec. 19, 2008)	5
76 Fed. Reg. 9968 (Feb. 23, 2011)	5, 8
84 Fed. Reg. 23,170 (May 21, 2019)	<i>passim</i>
Exec. Order No. 12,866 § 6(a)(3)(C)(ii), 58 Fed. Reg. 51,735 (Oct. 4, 1993)	4
Statutes	
5 U.S.C. § 706(2)	3
Other Authorities	
American Medical Association, Comment Letter on Protecting Statutory Conscience Rights in Health Care (Mar. 27, 2018).....	12
Br. for Inst. for Policy Integrity as Amicus Curiae in Support of Plaintiffs’ Motion for Summary Judgment, <i>California v. U.S. Dep’t of the Interior</i> , 381 F. Supp. 3d 1153 (N.D. Cal. 2019) (No. 17-cv-5948).....	1
Br. for Inst. for Policy Integrity as Amicus Curiae, <i>California v. U.S. Bureau of Land Mgmt.</i> , 277 F. Supp. 3d 1106 (N.D. Cal. 2017) (No. 17-cv-3804).....	1
Christy A. Rentmeester, <i>Moral Damage to Health Care Professionals and Trainees: Legalism and Other Consequences for Patients and Colleagues</i> , 33 J. Med. & Philosophy 27 (2008).....	14
Fariba Borhani et al., <i>The Relationship Between Moral Distress, Professional Stress, and Intent to Stay in the Nursing Profession</i> , 7 J. Med. Ethics & Hist. Med. 1 (2014).....	15

TABLE OF AUTHORITIES (cont.)

Other Authorities (cont.)	Page(s)
Hearing Transcript, <i>Danquah v. Univ. of Med. & Dentistry of New Jersey</i> , Case No. 11-cv-06377 (D.N.J. Dec 16, 2011)	12
Institute for Policy Integrity, Comment Letter on Protecting Statutory Conscience Rights in Health Care (Mar. 27, 2018), available at https://www.regulations.gov/document?D=HHS-OCR-2018-0002-72071	2, 6
Inst. for the Study of Regulation, Comments on Ensuring That Department of Health and Human Services Funds Do Not Support Coercive or Discriminatory Policies or Practices in Violation of Federal Law (Sept. 16, 2008), available at https://www.regulations.gov/document?D=HHS-OS-2008-0011-4969	2
Institute of Medicine, <i>The Health of Lesbian, Gay, Bisexual, and Transgender People: Building a Foundation for Better Understanding</i> (2011), available at https://www.nap.edu/catalog/13128/the-health-of-lesbian-gay-bisexual-and-transgender-people-building/	7
Joan McCarthy & Chris Gastmans, <i>Moral Distress: A Review of the Argument-Based Nursing Ethics Literature</i> , 22 <i>Nursing Ethics</i> 131 (2015)	14
K. Morrell & W. Chavkin, <i>Conscientious Objection to Abortion and Reproductive Healthcare: A Review of Recent Literature and Implications for Adolescents</i> , 27 <i>Curr. Opin. Obstet. Gynecol.</i> 333 (2015)	8
Lambda Legal, <i>When Health Care Isn't Caring: Lambda Legal's Survey on Discrimination Against LGBT People and People Living with HIV</i> (2010), available at https://perma.cc/6SJU-Q9WB	6
Memorandum from Kellyanne Conway, President & CEO, the polling company™, inc./WomanTrend, to Interested parties (Apr. 8, 2009), available at https://perma.cc/65FD-QRES	13
Nat'l Women's Law Ctr., <i>Refusals to Provide Health Care Threaten the Health and Lives of Patients Nationwide</i> (Aug. 30, 2017), available at https://perma.cc/6SZU-W5TV	6, 7
Office of Mgmt. & Budget, <i>Circular A-4 on Regulatory Analysis</i> (2003), available at https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/circulars/A4/a-4.pdf	4, 9
Sari L. Reisner et al., <i>Legal Protections in Public Accommodations Settings: A Critical Public Health Issue for Transgender and Gender-Nonconforming People</i> , 93 <i>Milbank Q.</i> 484 (2015), available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4567851	7
Shabab Ahmed Mirza & Caitlin Rooney, Ctr. for Am. Progress, <i>Discrimination Prevents LGBTQ People from Accessing Health Care</i> (2016), available at https://perma.cc/S3BR-F3WW	7
The polling company™, inc./WomanTrend on behalf of the Christian Medical & Dental Association, <i>Online Survey of 2,852 Members of Faith-Based Medical Associations</i> (Apr. 2009), available at https://perma.cc/WP7R-ARXV	13

TABLE OF AUTHORITIES (cont.)

Other Authorities (cont.)	Page(s)
W. Chavkin et al., <i>Conscientious Objection and Refusal to Provide Reproductive Healthcare: A White Paper Examining Prevalence, Health Consequences, and Policy Responses</i> , 123 Int'l J. Gynecol. & Obstet. S41 (2013)	8

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

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

5 INTEREST OF AMICUS CURIAE

6 Policy Integrity is a nonpartisan, not-for-profit think tank dedicated to improving the quality
7 of government decisionmaking through advocacy and scholarship in the fields of administrative law,
8 economics, and public policy. Our legal and economic experts, led by Richard L. Revesz,² have
9 produced extensive scholarship on the best practices for regulatory impact analysis and the proper
10 valuation of regulatory costs and benefits.

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

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

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

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

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

12 Plaintiffs argue that the Final Rule is arbitrary and capricious in part because “HHS conducted
13 and relied on a flawed cost-benefit analysis.” *San Francisco’s Mem. P. & A. Supp. Mot. Prelim. Inj.*
14 *at 13.* Policy Integrity’s expertise in cost-benefit analysis and experience with the Final Rule give it a
15 unique perspective from which to evaluate this claim.

16 SUMMARY OF ARGUMENT

17 When an agency relies on a cost-benefit analysis to support its rulemaking, “a serious flaw
18 undermining that analysis can render the rule unreasonable.” *Nat’l Ass’n of Home Builders v. EPA*,
19 682 F.3d 1032, 1040 (D.C. Cir. 2012). HHS has prepared a regulatory impact analysis for the Final
20 Rule in which it concludes that “the benefits of this rule, although not always quantifiable or
21 monetized, justify the burdens.” 84 Fed. Reg. at 23,228. But the analysis underlying that assertion is
22 fundamentally flawed in at least two respects.

23 First, although HHS acknowledges that the Final Rule will increase the frequency with which
24 conscience rights are invoked as grounds for refusing to provide healthcare, HHS does not
25 meaningfully assess—qualitatively or quantitatively—the costs of such refusals. Specifically, it fails
26

27
28 ³ The Institute for Policy Integrity was formerly called the Institute for the Study of Regulation.

1 to consider the financial, physical, and psychological harms that increased refusals will impose on
2 women in need of reproductive services; lesbian, gay, bisexual, and transgender (“LGBT”) patients;
3 and patients living with HIV or seeking HIV-preventive services. HHS also ignores staffing costs that
4 provider organizations will incur to accommodate increased refusals of care by their employees.

5 Second, the alleged benefits of the Final Rule are entirely speculative. HHS claims that the rule
6 will both increase the ranks of healthcare professionals and reduce “moral distress” among such
7 professionals. 84 Fed. Reg. at 23,246. But these findings are unsupported by—and in some instances
8 contradicted by—record evidence.

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

14 ARGUMENT

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

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

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

9 HHS’s analysis of the Final Rule’s “economic implications,” 84 Fed. Reg. at 23,228—prepared
10 pursuant to Executive Orders 12,866 and 13,563—fails to account for many of the Final Rule’s likely
11 costs. While this analysis tallies the Final Rule’s direct compliance costs for providers, in the form of
12 familiarization and paperwork-related expenses, *see* 84 Fed. Reg. at 23,240, tbl.6, it fails to assess the
13 new policy’s *indirect* costs, in the form of harms to patients who are refused care on conscience
14 grounds and additional staffing burdens for medical employers who must accommodate such refusals.
15 Indeed, these effects are not even listed in HHS’s summary of unquantified costs. *See* 84 Fed. Reg. at
16 23,227, tbl.1 (listing quantified and non-quantified costs that HHS considered).

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

26 More importantly, ignoring indirect costs violates HHS’s duties under the APA. Agency
27 decisions must be “based on consideration of the relevant factors,” *see State Farm*, 463 U.S. at 42,
28 and “[a]gencies have long treated cost as a centrally relevant factor when deciding whether to

1 regulate,” *Michigan v. EPA*, 135 S. Ct. 2699, 2707 (2015). *See also Mingo Logan Coal Co. v. EPA*,
2 829 F.3d 710, 732 (D.C. Cir. 2016) (Kavanaugh, J., dissenting) (“As a general rule, the costs of an
3 agency’s action are a relevant factor that the agency must consider before deciding whether to act.”).

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

11 HHS’s failure to consider indirect costs to patients would be impermissible in any rulemaking
12 but is particularly arbitrary here, because HHS previously recognized the significance of those costs.
13 In 2011, HHS cited indirect costs to justify repealing a 2008 conscience rule that purported to
14 implement many of the same statutory provisions as the Final Rule, in very similar ways. *See* 76 Fed.
15 Reg. 9968, 9974 (Feb. 23, 2011) (“2011 Rescission”) (agreeing with commenter concerns that 2008
16 rule “could limit access to reproductive health services and information, including contraception, and
17 could impact a wide range of medical services, including care for sexual assault victims, provision of
18 HIV/AIDS treatment, and emergency services”); *see also* 73 Fed. Reg. 78,072, 78,078 (Dec. 19, 2008)
19 (“2008 Rule”). The APA obligates HHS to provide a “reasoned explanation” for disregarding the
20 findings underlying the 2011 Rescission, *Take*, 795 F.3d at 968, and the Department has not done so.

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

23 HHS expects that, as a result of the Final Rule, “more individuals, having been apprised of
24 [conscience] rights, will assert them.” 84 Fed. Reg. at 23,250. Put another way, the Final Rule will
25 lead more healthcare workers to decline to provide services (or information about services) on moral
26 or religious grounds. It follows that patient populations already experiencing costs associated with
27 conscience-related refusals of care—like women in need of reproductive health services; LGBT
28 patients; and patients living with HIV or seeking HIV-preventive services—will see those costs

1 increase as a result of the Final Rule. But in its regulatory impact analysis, HHS refuses to assess these
2 costs appropriately, in either quantitative or qualitative terms.

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

4 As Policy Integrity emphasized in its comments on the proposed version of the Final Rule,
5 conscience-related refusals of care can impose financial, physical, and psychological costs on patients.
6 Policy Integrity Comments at 5. At minimum, a patient denied care must seek out an alternative
7 provider. Furthermore, some patients denied care may be too discouraged to seek out alternatives and
8 decide to forgo treatment altogether, leading to negative health consequences. Or, if care is denied in
9 an urgent or emergency situation, there may not be adequate time to find an alternative, potentially
10 leading to catastrophic consequences.

11 Numerous commenters backed up this fundamental point—that conscience-related refusals of
12 care impose real and significant costs on patients—with evidence of denials of care on conscience
13 grounds and the resulting harms. Record evidence shows that women, for example, already suffer
14 significant physical, psychological, and financial harms from conscience-related denials of
15 reproductive health services. Nat’l Women’s Law Ctr., *Refusals to Provide Health Care Threaten the*
16 *Health and Lives of Patients Nationwide* 1 (Aug. 30, 2017).⁴ LGBT people and individuals living with
17 HIV also contend with denials of health services, including those unrelated to their sexual orientation,
18 gender identity, and HIV status. *Id.* A rigorously conducted, nationwide survey found in 2010 that
19 nearly 8 percent of lesbian, gay, and bisexual respondents and almost 27 percent of transgender
20 respondents reported being refused necessary healthcare because of their sexual orientation and gender
21 identity, respectively. Lambda Legal, *When Health Care Isn’t Caring: Lambda Legal’s Survey on*
22
23
24
25

26
27 ⁴ According to a search of the docket, 43 commenters cited this report. *See*
28 <https://www.regulations.gov/docket?D=HHS-OCR-2018-0002> (last visited Sept. 12, 2019).

1 *Discrimination Against LGBT People and People Living with HIV* 10 (2010).⁵ Just as they do for
2 women in need of reproductive health services, conscience-related denials of care can carry substantial
3 costs for affected LGBT and HIV-positive patients. Nat’l Women’s Law Ctr. at 2. For example, nearly
4 20 percent of transgender respondents to a Massachusetts-based survey indicated that prior
5 mistreatment by healthcare providers had led them to postpone or forgo treatment when sick or injured.
6 Sari L. Reisner et al., *Legal Protections in Public Accommodations Settings: A Critical Public Health*
7 *Issue for Transgender and Gender-Nonconforming People*, 93 *Milbank Q.* 484, 494 (2015).⁶

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. at 23,251. But
10 HHS will not concede that such refusals will increase under the Final Rule. Instead, it argues that
11 commenters claiming “that the rule would result in harm” failed to “establish[] a causal relationship
12 between this rule and how it would affect health care access.” *Id.* at 23,250. This professed uncertainty
13 as to whether the Final Rule will lead to more refusals of care is inconsistent with HHS’s claims about
14 the benefits of the Final Rule, with findings HHS made in the 2011 Rescission, and with studies that
15 HHS relies upon in the current proceeding.

16 As noted earlier, in its description of the Final Rule’s *benefits*, HHS claims that “as a result of
17 this rule, more individuals, having been apprised of [their conscience] rights, will assert them.” *Id.* It
18 is difficult to imagine how a rule could cause more workers to assert a right to deny care without *also*
19 causing an increase in denials of care. HHS cannot have it both ways. If the Final Rule affects
20 providers’ behavior it will also affect patients’ experiences. HHS’s logical inconsistency on this point
21 renders the Final Rule arbitrary and capricious. *See Gen. Chem. Corp. v. United States*, 817 F.2d 844,
22

23
24 ⁵ That survey’s findings were echoed in the Institute of Medicine’s 2011 report *The Health of*
25 *Lesbian, Gay, Bisexual, and Transgender People: Building a Foundation for Better Understanding*
26 (2011), and largely reproduced by a 2016 survey. Shabab Ahmed Mirza & Caitlin Rooney, Ctr. Am.
27 Progress, *Discrimination Prevents LGBTQ People from Accessing Health Care* (2016). Dozens of
commenters cited each of these documents. *See* <https://www.regulations.gov/docket?D=HHS-OCR-2018-0002> (last visited Sept. 12, 2019).

28 ⁶ According to a docket search, 71 commenters cited this article. *See*
<https://www.regulations.gov/docket?D=HHS-OCR-2018-0002> (last visited Sept. 11, 2019).

1 857 (D.C. Cir. 1987) (deeming agency conclusion arbitrary and capricious where supporting analysis
2 was “internally inconsistent”).

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

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

26 **3. Uncertainty Does Not Excuse HHS’s Failure to Estimate the Final Rule’s** 27 **Effects on the Rate and Nature of Conscience-Related Refusals of Care**

28 In addition to suggesting that the Final Rule may have *no* negative effects on patients’ access

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

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

21 Even if HHS could not *fully* quantify and monetize the Final Rule’s expected costs for patients,
22 it should at least have listed procedures, medications, or information that might be denied or withheld
23 due to the rule, described the potential consequences of such denials for patients, and assigned dollar
24 values to *some* of those consequences. *Circular A-4* at 27 (“If you are not able to quantify the effects,
25 you should present any relevant quantitative information along with a description of the unquantified
26 effects”). HHS might, for instance, have monetized the cost of searching for and traveling to an
27 alternative provider but discussed accompanying psychological distress in qualitative terms.

28 Instead, HHS blames commenters for not doing the Department’s work for it. 84 Fed. Reg. at

1 23,250 (arguing that commenters failed “to answer the difficult question of how this rule would affect
2 access to care and health outcomes, and how to quantify those effects”); *id.* at 23,252 (“No comment
3 attempted a detailed description of the actual impact expected from the rule on access to care, health
4 outcomes, and associated concerns.”). But while commenters can supply data to inform an agency’s
5 analysis, and did so here, the agency bears the ultimate burden of supplying “a satisfactory explanation
6 for its action,” including due consideration of “relevant factors” like cost. *State Farm*, 463 U.S. at 42.

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

22 **4. HHS Cannot Excuse Its Failure to Assess Patient Costs by Making a** 23 **Conclusory Assertion that Any Such Costs Are Justified**

24 HHS attempts to excuse its failure to assess the Final Rule’s costs to patients by asserting that
25 “the Department expects any decreases in access to care to be outweighed by significant overall
26 increases in access generated by this rule.” 84 Fed. Reg. at 23,252. In other words, HHS claims that
27 any costs to patients associated with the Final Rule are functionally irrelevant because they are
28 outweighed by benefits. But even if it were true that more refusals of specific types of care under the

1 Final Rule would be outweighed by an increase in access to other types of care—and, as discussed in
2 Section II, HHS has provided no credible evidence of this—a conclusion regarding the Final Rule’s
3 *net* effects does not substitute for a discussion of the relevant factor of cost. HHS must specify who
4 will be harmed by the Final Rule and in what ways they will be harmed, even if it believes those costs
5 are justified by benefits to others. Yet it fails to do so. For example, HHS suggests that conscience
6 protections under the Final Rule might, in some circumstances, extend to ambulance drivers who
7 refuse “emergency transportation of persons with conditions such as an ectopic pregnancy, where the
8 potential procedures performed at the hospital may include abortion.” 84 Fed. Reg. at 23,187. But the
9 Final Rule’s regulatory impact analysis makes no mention of the potentially severe health
10 consequences of such a refusal.

11 In the absence of an acknowledgement of these costs, HHS’s conclusory assertion that the
12 Final Rule will have a *net* positive effect on healthcare access “add[s] nothing to the agency’s defense
13 of its thesis except perhaps the implication that it was committed to its position regardless of any facts
14 to the contrary.” *Chem. Mfrs. Ass’n v. EPA*, 28 F.3d 1259, 1266 (D.C. Cir. 1994).

15 **5. HHS Cannot Excuse Its Failure to Assess Patient Costs by Claiming that the** 16 **Costs Are Attributable to Congressional Decisions**

17 HHS’s final excuse for inadequately assessing the Final Rule’s costs for patients is that
18 objections to the Final Rule “based on potential (often temporary) lack of access to particular
19 procedures as a result of enforcement of the law are really objections to policy decisions made by the
20 people’s representatives in Congress in enacting the Federal conscience and anti-discrimination laws
21 in the first place.” 84 Fed. Reg. at 23,251. This argument, too, is unavailing. While Congress did pass
22 the statutory provisions underlying the Final Rule, HHS has made a discretionary decision to adopt
23 newly expansive definitions of terms in those provisions and new enforcement procedures. That
24 discretionary decision has costs relative to the status quo, which the APA obligates HHS to consider.

25 **B. HHS Completely Ignores Costs to Provider Organizations of Accommodating** 26 **Increased Refusals of Care**

27 In addition to failing to adequately assess costs that more frequent conscience-related refusals
28 of care will impose on patients, HHS completely ignores costs that provider organizations will incur

1 in accommodating such refusals. As the American Medical Association warned in comments,
2 increased invocations of conscience rights by individual healthcare workers “could significantly
3 impact the smooth flow of health care operations for physicians, hospitals, and other health care
4 institutions and could be unworkable in many circumstances.” American Medical Association,
5 Comment Letter on Protecting Statutory Conscience Rights in Health Care 4–5 (Mar. 27, 2018).

6 While the Final Rule authorizes employers to request some advance notice of objections, 84
7 Fed. Reg. at 23,191–92, employers may make such requests only after hiring an employee, and cannot
8 then fire that employee for conscience-based refusals to provide care. Even large, urban hospitals will
9 likely bear significant costs when accommodating employees who refuse to provide or assist with
10 certain forms of care. *See, e.g.,* Hearing Transcript, *Danquah v. Univ. of Med. & Dentistry of New*
11 *Jersey*, No. 11-cv-06377, (D.N.J. Dec 16, 2011) (indicating that hospital hired team of nurses to fill
12 staffing gap left by nurses who refused to assist with provision of abortion or related procedures).⁷ But
13 such costs are not mentioned in HHS’s regulatory impact analysis. This omission is particularly
14 egregious given that, elsewhere, HHS expressly contemplates “the use [of] alternate staff” and other
15 staffing adjustments to accommodate objections. 84 Fed. Reg. at 23,191–92, 23,202, 23,263.

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

18 In its regulatory impact analysis, HHS claims the Final Rule will yield three types of benefits:
19 a net increase in access to healthcare, better quality of care, and “societal goods that extend beyond
20 health care.” 84 Fed. Reg. at 23,246. HHS explains further that the Final Rule will deliver these
21 benefits by, among other things, increasing “the availability of qualified health care professionals” and
22 reducing “moral distress” among providers. 84 Fed. Reg. at 23,246. But HHS cites no credible
23 evidence to support these assertions.

24 While “an agency’s predictive judgments . . . are entitled to particularly deferential review,”
25 that deference is given only “so long as [the predictions] are reasonable.” *BNSF Ry. Co. v. Surface*

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

1 *Transp. Bd.*, 526 F.3d 770, 781 (D.C. Cir. 2008) (Kavanaugh, J.) (internal quotation marks omitted).
2 Here, the Department’s wholly “conclusory [and] unsupported suppositions” of the Final Rule’s
3 benefits are unreasonable and thus “not [entitled to] defer[ence].” *United Techs. Corp. v. Dep’t of Def.*,
4 601 F.3d 557, 562 (D.C. Cir. 2010) (internal quotations marks omitted). And because the Department
5 relies entirely on these speculative and unsupported assumptions to justify the Final Rule, the rule is
6 arbitrary and capricious. *Nat’l Fuel Gas Supply Corp. v. Fed. Energy Reg’y Comm’n*, 468 F.3d 831,
7 839 (D.C. Cir. 2006) (agency action found arbitrary and capricious where agency “provided no
8 evidence of a real problem” the action would solve); *Arizona Cattle Growers’ Ass’n v. U.S. Fish &*
9 *Wildlife, Bureau of Land Mgmt.*, 273 F.3d 1229, 1244 (9th Cir. 2001) (action found arbitrary and
10 capricious where based on “speculation . . . not supported by the record”).

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

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

24
25 ⁸ Although the 2009 survey’s headline was “Online Survey of 2,852 Members of *Faith-*
26 *Based* Medical Associations,” *see* The polling company™, inc./WomanTrend on behalf of the
27 Christian Medical & Dental Association, Online Survey of 2,852 Members of Faith-Based Medical
28 Associations (Apr. 2009), all respondents were members of a *Christian* medical association.
Memorandum from Kellyanne Conway, President & CEO, the polling company™, inc./
WomanTrend, to Interested Parties 4 (Apr. 8, 2009) (describing methodology) (emphasis added).

1 Obstetricians and Gynecologists (“AAPLOG”) to HHS in 2009, that its members “overwhelmingly
2 would leave the medical profession—or relocate to a conscience-friendly jurisdiction—before they
3 would accept coercion to participate or assist in procedures that violate their consciences.” 84 Fed.
4 Reg. at 23,247. But HHS conducted no follow-up survey and supplies no quantitative data in its
5 analysis about actual exits from the profession or relocations in response to the 2011 Rescission. It did
6 not, in short, even try to assess whether the post-survey elimination of the expansive protections in the
7 2008 Rule prompted survey respondents to actually leave the medical profession. In the absence of “a
8 conscientious effort to take into account what is known as to past experience,” the Department’s
9 “theoretical or model-based approaches” to decisionmaking are not entitled to deference. *Am.*
10 *Petroleum Inst. v. EPA*, 862 F.3d 50, 69 (D.C. Cir. 2017), *modified on reh’g*, 883 F.3d 918 (D.C. Cir.
11 2018) (citation and internal quotation marks omitted).

12 **B. HHS Does Not Adequately Support Its Conclusion That the Final Rule Will Reduce**
13 **the Prevalence of Moral Distress**

14 HHS contends that the Final Rule “will reduce the incidence of the harm that being forced to
15 violate one’s conscience inflicts on providers.” 84 Fed. Reg. at 23,249. In making this assertion, HHS
16 claims to rely on “[s]ubstantial academic literature [that] documents the existence among health care
17 providers of ‘moral distress,’” *Id.* But while the literature HHS cites does recognize the existence
18 of moral distress among some medical providers, it rarely if ever specifically links that distress to the
19 type of conduct addressed by the Final Rule (i.e., assisting in the performance of particular procedures
20 to which a provider has a religious or moral objection). One article cited by HHS suggests that moral
21 distress has been generated mainly by “broad systemic changes . . . in how health care institutions are
22 organized, how health care is financed, and how health care resources are managed,” which “reduce[d]
23 the amount of time caregivers are allotted to spend with patients.” Christy A. Rentmeester, *Moral*
24 *Damage to Health Care Professionals and Trainees: Legalism and Other Consequences for Patients*
25 *and Colleagues*, 33 J. Med. & Philosophy 27, 37 (2008). Another article identifies as sources of moral
26 distress unnecessary tests, incompetent or inadequate care, inadequate consent for treatment, poor
27 staffing, and cost cuts, among others. Joan McCarthy & Chris Gastmans, *Moral Distress: A Review of*
28 *the Argument-Based Nursing Ethics Literature*, 22 Nursing Ethics 131, 148–49 (2015); *see also* 84

1 Fed. Reg. at 23,249 n.337 (citing McCarthy & Gastmans). As a result, the Final Rule might *increase*
 2 rather than reduce moral distress among some providers, insofar as it leads to a lack of treatment,
 3 inadequate care, and inadequate consent for treatment (when patients are denied information about
 4 treatment options due to a provider’s religious or moral beliefs). Finally, a third study cited by HHS
 5 finds, based on a survey of 250 nurses, no correlation between reported levels of moral distress and a
 6 stated intention to leave the profession. Fariba Borhani et al., *The Relationship Between Moral*
 7 *Distress, Professional Stress, and Intent to Stay in the Nursing Profession*, 7 J. Med. Ethics & Hist.
 8 Med. 1, 4 (2014); 84 Fed. Reg. at 23,249 n.330 (citing Borhani et al.). This directly contradicts HHS’s
 9 claim that alleviating moral distress will prevent exits from the medical profession. *See State Farm*,
 10 463 U.S. at 56–57 (action is arbitrary and capricious if explanation “runs counter to the evidence”).

11 HHS’s unsupported assertions regarding the Final Rule’s effects on moral distress undermine
 12 the analytical validity of HHS’s regulatory impact analysis and the legal validity of the Final Rule.

13 CONCLUSION

14 This Court should grant Plaintiffs’ Cross-Motion for Summary Judgment.⁹

15
 16 Dated: Sept. 12, 2019

Respectfully submitted,

17 /s/ Jack Lienke

18 Denise A. Grab, Cal. State Bar #268097

Justin Gundlach, N.Y. State Bar #4915468 (*pro hac vice*)

19 Jack Lienke, N.Y. State Bar #5066386 (*pro hac vice*)

Institute for Policy Integrity, NYU School of Law

20 139 MacDougal Street, 3rd Floor

New York, NY 10012

21 Telephone: (212) 992-8932

22 Email: jack.lienke@nyu.edu

23 *Counsel for Amicus Curiae*

24 *Institute for Policy Integrity*

25
 26
 27
 28 ⁹ Policy Integrity gratefully acknowledges James Meresman and Cris Ray, students in NYU
 School of Law’s Regulatory Policy Clinic, for assisting in the preparation of this brief.