UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

STATE OF NEW YORK, *et al.*, Plaintiffs, v. UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, *et al.*, Defendants.	Case No. 1:19-cv-4676 (PAE) (lead) Case No. 19-cv-5433 (PAE) (consolidated) Case No. 19-cv-5435 (PAE) (consolidated)

BRIEF OF THE INSTITUTE FOR POLICY INTEGRITY AS *AMICUS CURIAE* IN SUPPORT OF PLANTIFFS' CROSS-MOTION FOR SUMMARY JUDGMENT

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

INTEREST OF *AMICUS CURIAE*

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

In furtherance of its mission to promote rational decisionmaking, Policy Integrity has filed *amicus curiae* briefs addressing agency analysis of costs and benefits in many recent cases. *See, e.g.*, Br. for Inst. for Policy Integrity as Amicus Curiae, *California v. U.S. Bureau of Land Mgmt.*, 277 F. Supp. 3d 1106 (N.D. Cal. 2017) (No. 17–cv–3804–EDL) (arguing that agency's failure to consider forgone benefits that would result from a delay in implementation of methane standards

[1] This brief does not purport to represent the views of New York University School of Law, if any. Policy Integrity states that no party's counsel authored this brief in whole or in part, and no party or party's counsel contributed money intended to fund the preparation or submission of this 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 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.

was arbitrary); Br. for Inst. for Policy Integrity as Amicus Curiae in Support of Plaintiffs' Motion for Summary Judgment, *California v. U.S. Dep't of the Interior*, 381 F. Supp. 3d 1153 (N.D. Cal. 2019) (No. 17–cv–5948–SBA) (arguing that repeal of procedural reforms for mineral valuation was unreasonable due to agency's inaccurate assessment of repeal's economic impact). In those cases, courts have agreed that the agency analyses—and, in turn, the rules issued in reliance on those analyses—were arbitrary and capricious. *California v. BLM*, 277 F. Supp. 3d at 1123 (holding failure to consider forgone benefits arbitrary); *California v. Interior*, 381 F. Supp. 3d at 1170 (finding repeal arbitrary due in part to agency's flawed economic impact assessment).

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

Plaintiffs argue that the Final Rule is arbitrary and capricious in part because the Department relied on a flawed cost-benefit analysis. Memorandum of Law in Support of State

[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.
[4] *Available at* https://www.regulations.gov/document?D=HHS-OCR-2018-0002-72071.

Plaintiffs' Cross-Motion for Summary Judgment at 36. Policy Integrity's expertise in cost-benefit analysis and experience with the Final Rule give it a unique perspective from which to evaluate this claim.

SUMMARY OF ARGUMENT

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

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

Second, the alleged benefits of the Final Rule are entirely speculative. The Department claims that the rule will increase the ranks of healthcare professionals, improve the quality of doctor-patient relationships, reduce "moral distress" among healthcare professionals, and promote the "societal good" of personal freedom for individuals to conduct themselves based on their religious beliefs and moral convictions. 84 Fed. Reg. at 23,246. But these findings are unsupported

by—and in some instances contradicted by—evidence in the record.

By dismissing reasonably foreseeable costs and touting wholly speculative benefits, HHS "inconsistently and opportunistically frame[s]" the Final Rule's effects, *Bus. Roundtable v. SEC*, 647 F.3d 1144, 1148–49 (D.C. Cir. 2011), and "put[s] a thumb on the scale" in favor of its adoption, *Ctr. for Biological Diversity v. Nat'l Highway Traffic Safety Admin.*, 538 F.3d 1172, 1198 (9th Cir. 2008). The Department's reliance on this one-sided analysis renders the Final Rule arbitrary and 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 that 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 & 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 give a reasoned explanation for disregarding its prior conclusions regarding these harms, and failed to offer credible evidence in support of 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

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

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

More importantly, ignoring indirect costs violates HHS's duties under the Administrative Procedure Act. Agency decisions must be "based on consideration of the relevant factors," *State Farm*, 463 U.S. at 42, and "[a]gencies have long treated cost as a centrally relevant factor when deciding whether to regulate," *Michigan v. EPA*, 135 S. Ct. 2699, 2707 (2015). *See also Mingo Logan Coal Co. v. EPA*, 829 F.3d 710, 732 (D.C. Cir. 2016) (Kavanaugh, J., dissenting) ("As a general rule, the costs of an agency's action are a relevant factor that the agency must consider before deciding whether to act.").

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

[5] *Available at* https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/circulars/A4/a-4.pdf.

for failure to consider indirect safety effects of substituting asbestos-free car brakes).

HHS's failure to consider indirect costs to patients would be impermissible in any rulemaking, but is particularly arbitrary here because the Department previously recognized the significance of these costs. In 2011, HHS cited indirect costs to justify repealing a 2008 conscience rule that purported to implement many of the same statutory provisions as the Final Rule, in very similar ways. *See* 76 Fed. Reg. 9968, 9974 (Feb. 23, 2011) ("2011 Rescission") (agreeing with commenter concerns that the 2008 rule "could limit access to reproductive health services and information, including contraception, and could impact a wide range of medical services, including care for sexual assault victims, provision of HIV/AIDS treatment, and emergency services"); *see also* 73 Fed. Reg. 78,072, 78,078 (Dec. 19, 2008) ("2008 Rule"). The Administrative Procedure Act obligates HHS to provide a "reasoned explanation" for disregarding the findings underlying the 2011 Rescission, *Fox Television*, 556 U.S. at 515–16, and the Department has not done so. *See also Kake*, 795 F.3d at 968.

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

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

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

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

This fundamental point—that conscience-related refusals of care impose real and significant costs on patients—was reinforced by numerous other commenters who submitted evidence to HHS regarding the types of patients who are most often denied care on conscience grounds and the nature of the resulting harms. Record evidence shows that women, for example, already suffer significant physical, psychological, and financial harms from conscience-related denials of reproductive health services. These include refusals by religiously affiliated hospitals to provide sterilization treatment at the time of cesarean delivery—despite the fact that this is the safest and most cost-effective time at which to undergo the procedure—even in cases where a subsequent pregnancy would severely threaten the health or life of the mother; refusals by pharmacies to fill prescriptions for emergency contraception or to transfer prescriptions to pharmacies that will, even for rape survivors; and refusals by insurance plans to cover birth control. Nat'l Women's Law Ctr., *Refusals to Provide Health Care Threaten the Health and Lives of*

Patients Nationwide 1 (Aug. 30, 2017).[6]

LGBT people and individuals living with HIV also contend with denials of a variety of health services, including those unrelated to their sexual orientation, gender identity, and HIV status. *Id.* A rigorously conducted, nationwide survey found in 2010 that nearly 8 percent of lesbian, gay, and bisexual respondents and almost 27 percent of transgender respondents reported being refused necessary healthcare because of their sexual orientation and gender identity, respectively. Lambda Legal, *When Health Care Isn't Caring: Lambda Legal's Survey on Discrimination Against LGBT People and People Living with HIV* 10 (2010).[7] Just as they do for women in need of reproductive health services, these conscience-related denials of care can carry substantial costs for affected LGBT and HIV-positive patients. In one example in the record, an HIV-positive patient denied treatment for chest pain ended up "admitted to the hospital . . . with gastrointestinal hemorrhaging" a week later, and "was diagnosed with pneumonia, a staph infection, and AIDS." Nat'l Women's Law Ctr. at 2. On a more general level, nearly 20 percent of transgender respondents to a Massachusetts-based survey indicated that prior mistreatment by healthcare providers had led them to postpone or forgo treatment when sick or injured. Sari L. Reisner et al., *Legal Protections in Public Accommodations Settings: A Critical Public Health Issue for Transgender and Gender-Nonconforming People*, 93 Milbank Q. 484, 494 (2015).[8]

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

[7] *Available at* https://perma.cc/6SJU-Q9WB. That survey's findings were echoed in a 2011 Institute of Medicine 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 survey of LGBT people conducted in 2016. Shabab Ahmed Mirza & Caitlin Rooney, Ctr. for Am. 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 Final Rule, according to a search of the docket. *See* https://www.regulations.gov/docket?D=HHS-OCR-2018-0002 (last visited Sept. 12, 2019).

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

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

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

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

HHS's unwillingness to concede that the Final Rule will result in increased refusals of care is particularly unreasonable in light of its findings to the contrary in the 2011 Rescission. In that proceeding, HHS agreed with commenters that the 2008 Rule "could limit access to reproductive health services and information, including contraception, and could impact a wide range of medical

services, including care for sexual assault victims, provision of HIV/AIDS treatment, and emergency services." 76 Fed. Reg. at 9974. Because the Final Rule "generally reinstates the structure of the 2008 Rule," 84 Fed. Reg. at 23,179, one would expect it to pose the same threat to access to care for sexual assault victims and those living with HIV. If HHS disagrees, it must provide a "reasoned explanation" for reaching a different conclusion than it did in the 2011 Rescission—for example, by citing evidence suggesting that, contrary to the Department's previous findings, an expansive conscience rule will *not* reduce access to care for these populations. *Fox*, 556 U.S. at 515–16.

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

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

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

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

benefits of a faster decision."). An agency does not prove that it is impossible to ascertain the answer to a question by refusing to ask it.

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

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

HHS's criticism of commenters for not providing it with a complete assessment of the Final Rule's effects on access to care is particularly galling given that the uncertainty surrounding those effects is largely of the Department's own making. Repeatedly in the preamble to the Final Rule, HHS declines opportunities to provide guidance on the circumstances under which the Final Rule

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

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

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

But even if it were true that any increase in refusals of some types of care under the Final Rule would be outweighed by an increase in access to other types of care—and, as discussed in Section II, HHS has provided no credible evidence that this is the case—a conclusion regarding

the Final Rule's *net* effects does not substitute for a discussion of the relevant factor of cost. The Department remains obligated to specify who will be harmed by the Final Rule and in what ways they will be harmed, even if it believes those costs are justified by benefits to others. For example, elsewhere in the preamble to the Final Rule, HHS suggests that conscience protections under the Final Rule might, in some circumstances, extend to ambulance drivers who refuse "emergency transportation of persons with conditions such as an ectopic pregnancy, where the potential procedures performed at the hospital may include abortion." 84 Fed. Reg. at 23,187. The health consequences of such a refusal could be severe, yet they are not mentioned in the regulatory impact analysis for the Final Rule.

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

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

HHS's final excuse for inadequately assessing the Final Rule's costs for patients is that any

[9] *Available at* https://aspe.hhs.gov/system/files/pdf/242926/HHS_RIAGuidance.pdf.

objections to the Final Rule "based on potential (often temporary) lack of access to particular procedures as a result of enforcement of the law are really objections to policy decisions made by the people's representatives in Congress in enacting the Federal conscience and anti-discrimination laws in the first place." 84 Fed. Reg. at 23,251. This argument, too, is unavailing. While the statutory provisions underlying the Final Rule were indeed passed by Congress, HHS has made a discretionary decision to adopt new, unprecedentedly expansive definitions of terms in those provisions and new procedures for enforcing the provisions. That discretionary decision has costs relative to the status quo, which the Administrative Procedure Act obligates the Department to consider. Furthermore, if it *were* true that no patient costs associated with invocations of conscience rights could be attributed to the Final Rule, it would necessarily also be true that the Final Rule could claim no credit for patient or provider *benefits* associated with such invocations. HHS, in short, cannot rationally claim that the Final Rule has incremental benefits without acknowledging corresponding incremental costs. *See California v. U.S. Bureau of Land Mgmt.*, 277 F. Supp. 3d 1106, 1123 (N.D. Cal. 2017) (agencies cannot consider only "one side of the equation" by calculating benefits and ignoring costs).

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

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

4–5 (Mar. 27, 2018).

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

II. THE FINAL RULE'S PURPORTED BENEFITS ARE SPECULATIVE AND UNSUPPORTED BY EVIDENCE

In its regulatory impact analysis, HHS claims the Final Rule will yield three types of benefits: a net increase in access to healthcare, better quality of care, and "societal goods that extend beyond health care." 84 Fed. Reg. at 23,246. HHS explains further that the Final Rule will deliver these benefits through four mechanisms: first, it will increase "the availability of qualified health care professionals," in part by preventing exits from the field; second, it will improve the

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

quality of doctor-patient relationships; third, it will reduce "moral distress" among providers; and, fourth, it will promote the "societal good" of "protection of religious beliefs and moral convictions" by giving providers greater "personal freedom" to act in accordance with their beliefs. 84 Fed. Reg. at 23,246. But HHS cites no credible evidence to support any of these assertions.

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

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

HHS claims that "[n]umerous studies and comments show that the failure to protect conscience is a barrier to careers in the health care field," 84 Fed. Reg. at 23,246, but the record contains only a handful of anecdotes reporting early retirements for reasons of conscience, and *no* data evidencing a noticeable rate of professional exit. Instead, HHS refers repeatedly to the results of an online survey of self-selecting members of five Christian medical associations conducted on behalf of the Christian Medical and Dental Association in 2009, just after HHS proposed to repeal

the 2008 Rule.[11] *See* 84 Fed. Reg. at 23,175–253 nn.15, 38, 309, 316–18, 322, 340, 347, 349. HHS highlights repeatedly that 91 percent of respondents said that they "would rather stop practicing medicine altogether than be forced to violate [their] conscience." *See id.* at 23,191 nn.46 & 48, 23,246–47. At one point, it pairs this point with a reference to the claim, submitted by the American Association of Pro-Life Obstetricians and Gynecologists ("AAPLOG") to HHS in 2009, that its members "overwhelmingly would leave the medical profession—or relocate to a conscience-friendly jurisdiction—before they would accept coercion to participate or assist in procedures that violate their consciences." 84 Fed. Reg. at 23,247.

But HHS conducted no follow-up survey of any sort and supplies no quantitative information in its analysis about actual exits from the profession or relocations from one jurisdiction to another in response to the 2011 Rescission. In other words, it makes no effort to confirm whether the post-survey elimination of the expansive protections in the 2008 Rule prompted any survey respondents to follow through on their threat to leave the medical profession. In the absence of "a conscientious effort to take into account what is known as to past experience," the Department's "theoretical or model-based approaches" to decisionmaking are not entitled to deference. *Am. Petroleum Inst. v. EPA*, 862 F.3d 50, 69 (D.C. Cir. 2017), *modified on reh'g*, 883 F.3d 918 (D.C. Cir. 2018) (citation and internal quotation marks omitted).

Furthermore, HHS fails to mention that the ranks of the very providers it claims were most likely to leave the profession after the 2011 Rescission seem to have been growing. Not only has the number of obstetricians and gynecologists grown by almost 9 percent nationwide from 2011

[11] Notably, though the headline of the 2009 survey was "Online Survey of 2,852 Members of *Faith-Based* Medical Associations," 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), *available at* https://perma.cc/PC6K-5SML (describing survey methodology) (emphases added). The survey's results are available at https://perma.cc/WP7R-ARXV.

to 2017, ModernMedicine Network, *ACOG Releases New Study on Ob/Gyn Workforce* (July 1, 2017),[12] but the pro-life group AAPLOG's ranks have also grown by 14 percent since 2009.[13] This pattern is at odds with AAPLOG's 2009 prediction and the organization's current arguments that its members would leave the profession without the protections provided by the Final Rule. *See* 84 Fed. Reg. at 23,247; *see also Am. Petroleum Inst.*, 862 F.3d at 69 ("[W]hat we seek is some indication of a reasonable concurrence between model and reality.").

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

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

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

[12] Available at https://perma.cc/65FD-QRES.

[13] *Compare* American Association of Pro-Life Obstetricians and Gynecologists, *About Us*, http://aaplog.org/about-us [https://perma.cc/BBV7-T2YP] (accessed May 18, 2019) (reporting 2,500 members and associates), *with* Letter from Lawrence J. Joseph, on behalf of the American 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).

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

HHS contends that the Final Rule "will reduce the incidence of the harm that being forced to violate one's conscience inflicts on providers." 84 Fed. Reg. at 23,249. In making this assertion, the Department claims to rely on "[s]ubstantial academic literature [that] documents the existence among health care providers of 'moral distress,' . . . ." *Id*. But while the literature HHS cites does recognize the existence of moral distress among some medical providers, it rarely if ever specifically links that distress to the type of conduct addressed by the Final Rule (i.e., performing or assisting in the performance of particular procedures to which a provider has a religious or moral objection). One article cited by HHS suggests that moral distress has been generated by "broad systemic changes . . . in how health care institutions are organized, how health care is financed, and how health care resources are managed," which "reduce[d] the amount of time caregivers are allotted to spend with patients." Christy A. Rentmeester, *Moral Damage to Health Care Professionals and Trainees: Legalism and Other Consequences for Patients and Colleagues*, 33 J. Med. & Philosophy 27, 37 (2008). Another article lists the following sources of distress:

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

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

Finally, a third study cited by HHS finds, based on a survey of 250 nurses, that the most frequent and intense source of moral distress "related to concern for patients' feelings and emotions"—again suggesting that the Final Rule might actually increase such distress by causing more refusals of care for certain patients. Fariba Borhani et al., *The Relationship Between Moral Distress, Professional Stress, and Intent to Stay in the Nursing Profession*, 7 J. Med. Ethics & Hist. Med. 1, 5 (2014); 84 Fed. Reg. at 23,249 n.330 (citing Borhani et al.). What is more, the study finds 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 Farm*, 463 U.S. at 56–57 (action is arbitrary and capricious if explanation "runs counter to the evidence before the agency").

In addition to misrepresenting the *causes* of moral distress as described in the academic literature, HHS fails to provide even a minimal amount of evidence or information to support its claim that the Final Rule will reduce the *prevalence* of moral distress. The *HHS Guidelines* explain that when the effects of a rule are less tangible and difficult to quantify—because, for instance, the rule implicates "important human values, such as dignity, equity, and privacy"—HHS should attempt to "count the number of people affected." *HHS Guidelines* at 48. Similarly, "[w]here some data exist, but are not sufficient to reasonably quantify the effect," HHS should, if possible, report "[i]ntermediate measures, such as the number of individuals affected." *Id.* at 51; *see also Circular A-4* at 27 ("If you are not able to quantify the effects, you should present any relevant quantitative information along with a description of the unquantified effects . . . . You should provide a discussion of the strengths and limitations of the qualitative information."). But HHS has not quantified, in exact or approximate terms, the number of medical practitioners whose moral

distress will be alleviated under the Final Rule, nor any of the following antecedent quantities of individuals: (1) those experiencing moral distress for any reason; (2) those experiencing moral distress for the reasons of concern to HHS; or (3) those who would refuse to assist in or conduct medical procedures that prompt their moral distress.

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

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

Contrary to the directives in Circular *A-4* and the *HHS Guidelines* mentioned above, HHS has not estimated the number of healthcare professionals who would find that the Final Rule increased their freedom of conscience. Furthermore, HHS uses this departure from analytic norms to avoid acknowledging a vitally important fact: the Final Rule would likely *constrain* the freedom of many individuals whose religious or moral beliefs compel them to offer patients a full range of treatment options. *See* The Public Rights/Private Conscience Project Comment Letter on Protecting Statutory Conscience Rights in Health Care 1 (Mar. 27, 2018)[14] (explaining that where a provider organization bars employees from providing some services on religious grounds, "medical professionals whose religious or moral beliefs require them to provide patients with the full range of reproductive health services may be prohibited by their employer from acting on this belief"); *see also id.* at 2–6 (describing diverse views of religious communities on morality of reproductive healthcare services, including abortion). HHS asserts that "[t]he rule will promote protection of religious beliefs and moral convictions," but it has made no apparent effort to determine the relative numbers of people who would experience the Final Rule as supporting or

[14] *Available at* https://www.regulations.gov/document?D=HHS-OCR-2018-0002-70101.

interfering with their religious beliefs and moral convictions. As a result, the assertion is entirely conclusory and thus arbitrary and capricious.

CONCLUSION

This Court should grant Plaintiffs' Cross-Motion for Summary Judgment.[15]

Dated: September 12, 2019

Respectfully submitted,

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[15] Policy Integrity gratefully acknowledges James Meresman and Cris Ray, students in New York University School of Law's Regulatory Policy Clinic, for assisting in the preparation of this brief.