Nos. 20-15398, 20-15399, 20-16045, and 20-35044

IN THE UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

CITY AND COUNTY OF SAN FRANCISCO, et al.,

Plaintiffs-Appellees,

v.

ALEX M. AZAR II, et al.,

Defendants-Appellants.

On Appeal from the United States District Courts for the Northern District of California and the Eastern District of Washington

BRIEF OF AMICUS CURIAE INSTITUTE FOR POLICY INTEGRITY AT NEW YORK UNIVERSITY SCHOOL OF LAW IN SUPPORT OF PLAINTIFFS-APPELLEES

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The Institute for Policy Integrity at New York University School of Law ("Policy Integrity") submits this brief as *amicus curiae* in support of Plaintiffs-Appellees' challenge to 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").[1]

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, Policy Integrity has filed *amicus* briefs in

[1] All parties have consented to this filing.

[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 (last visited Oct. 10, 2020).

numerous recent cases addressing economic analyses performed by administrative agencies. *See, e.g.*, Br. of Inst. for Pol'y Integrity as Amicus Curiae, *New York v. U.S. Dep't of Homeland Sec.*, 969 F.3d 42 (2d Cir. 2020) (critiquing cost-benefit analysis underlying Department of Homeland Security's public charge rule for disregarding key health and welfare harms). In many such cases, courts have agreed that the administrative agency's analysis—and thus the rule relying on that analysis—was arbitrary and capricious for mischaracterizing or ignoring the costs of a regulatory rollback. *See, e.g.*, *California v. U.S. Dep't of the Interior*, 381 F. Supp. 3d 1153, 1170 (N.D. Cal. 2019) (finding Bureau of Land Management's repeal of mineral-valuation rule arbitrary due in part to agency's flawed regulatory impact assessment).

Policy Integrity has particular expertise on the regulatory impact analysis that HHS conducted in support of the Final Rule. In 2008, Policy Integrity submitted an expert report on the defective analysis HHS prepared to support a previous effort to expand statutory conscience rights through rulemaking. 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").[3]

Appellants challenge the district court orders granting summary judgment for Appellees and vacating the Final Rule. In support of their motions for summary judgment, Appellees argued, as they do before this Court, that the Final Rule was arbitrary and capricious because HHS failed to "reasonably evaluate the benefits and burdens of the [Final] Rule." Brief for S.F. 2. Policy Integrity's expertise in cost-benefit analysis provides a unique perspective on that claim.

SUMMARY OF ARGUMENT

An agency's reliance on a "flawed … cost benefit analysis" can render its action arbitrary and capricious. *California v. FCC*, 39 F.3d 919, 930 (9th Cir. 1994). 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, it fails to consider the

[3] *Available at* https://www.regulations.gov/document?D=HHS-OCR-2018-0002-72071 (last visited Oct. 10, 2020).

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. HHS 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—record evidence.

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 Biol. Diversity v. Nat'l Hw'y Traffic Saf. Admin.*, 538 F.3d 1172, 1198 (9th Cir. 2008). HHS'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 ("APA"), 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 justification includes a cost-benefit analysis, "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), even if the agency was not statutorily obligated to conduct the analysis, *id.* at 1039–40. Finally, if an action represents a change in policy, the agency must provide a "reasoned explanation . . . for disregarding facts and circumstances that underlay . . . 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 fails to consider relevant information regarding the harms that more frequent conscience-related denials of healthcare would impose on patients and providers, fails to give a reasoned explanation for disregarding its prior conclusions regarding these harms, and fails 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 APA 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, 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 medical employers who must accommodate such refusals. Indeed, these effects are not even listed in HHS's summary of unquantified costs. *See id*. at 23,227 tbl.1.

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 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*].[4]

More importantly, ignoring indirect costs violates HHS's duties under the APA. Agency decisions must be "based on consideration of the relevant factors," *see 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.").

Relevant costs "include[] more than the expense of complying with regulations" and encompass "any disadvantage." *Michigan*, 135 S. Ct. at 2707. Accordingly, courts have repeatedly struck down rules that disregard potentially significant indirect costs. *See, e.g.*, *Compet. Enter. Inst. v. Nat'l Hw'y Traffic Saf. 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 for failure to consider

[4] *Available at* https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/circulars/A4/a-4.pdf (last visited Oct 11, 2020).

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 HHS previously recognized the significance of those 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") (finding 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 (Dec. 19, 2008) ("2008 Rule"). But in the Final Rule, HHS "fail[s] to supply a reasoned explanation for its policy change from the previous Rule." E.R. 30. Per the reasoning that the Eastern District of Washington "adopt[ed]," *id.*, HHS ignores its "prior factual finding . . . in favor of a new, contradictory one . . . without acknowledging or explaining the inconsistency in its positions," which alone "is sufficient to render [the Final Rule] arbitrary and capricious." *New York v. HHS*, 414 F. Supp. 3d 475, 547, 551 (S.D.N.Y. 2019) (quoting *Encino Motorcars, LLC v. Navarro*, 136 S. Ct. 2117, 2126 (2016)).

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 already experiencing 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 under the Final Rule. But HHS refuses to assess these costs appropriately, in quantitative or qualitative terms.

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

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

Numerous commenters bolstered Policy Integrity's argument with evidence of denials of care on conscience grounds and 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).[5]

LGBT people and individuals living with HIV also contend with denials 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*

[5] *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 Oct. 11, 2020).

People and People Living with HIV 10 (2010).[6] Such denials 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).[7]

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.

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[6] *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 Oct. 11, 2020).

[7] *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 Oct. 11, 2020).

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."). But HHS will not concede that such refusals will increase under the Final Rule. Instead, it argues 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 is inconsistent with HHS's claims about the Final Rule's benefits, findings HHS made in the 2011 Rescission, and studies that HHS relies upon in the current proceeding.

As noted earlier, in its description of the Final Rule's benefits, HHS 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. If the Final Rule affects providers' behavior it will also affect patients' experience. HHS'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 contrary findings in the 2011 Rescission. There, 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, it presumably also threatens 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.

HHS 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.[8] 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

[8] 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).

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 size of such effects is simply too difficult. 84 Fed. Reg. at 23,252. 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*, 538 F.3d at 1190 (finding rule arbitrary and capricious where agency argued certain benefits were "too uncertain to support their explicit valuation and inclusion" in a regulatory cost-benefit analysis). There may be "a range of values" for the Final Rule's costs to patients, but 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 . . . ."); *id.* ("[T]he Department lacks the predicate for estimating the impact on health outcomes of any change in the availability of services."). But HHS could *generate* 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."). An agency does not prove that it is impossible to ascertain the answer to a question by refusing to ask it.

Even if HHS could not fully quantify and monetize the Final Rule's expected costs for patients, it should at least have listed procedures, medications, or information that might be denied or withheld due to the rule, described the potential consequences of such denials, and assigned dollar values to *some* of these consequences. *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 . . . ."). HHS might, for instance, have monetized the cost of searching for and traveling to an alternative provider but discussed related psychological distress qualitatively.

Instead, HHS blames commenters for not doing 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 data to inform an agency's analysis, and 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 HHS's own making. HHS repeatedly declines to provide guidance within the Final Rule on circumstances under which the rule protects refusals of care. For example, in response to comments warning that the Final Rule could negatively "impact counseling or referrals for LGBT persons," HHS could 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 invocations of conscience rights "will be evaluated on a case-by-case basis." *Id.* Similarly, in response to concerns about denials of HIV or infertility treatment, HHS will not say whether such denial would be protected

conduct, noting only that, if it received a complaint on the subject, it "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 its Final Rule changes the legal status quo, it cannot expect commenters to 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 this were true—and, as discussed in Section II, HHS has provided no credible evidence of this—a conclusion regarding the Final Rule's *net* effects does not substitute for a discussion of the relevant factor of cost. HHS must 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. Yet the Department fails to do so. For example, 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. But the Final Rule's regulatory impact analysis makes no mention of the potentially severe health consequences of such a refusal.

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." *Chem. 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.

[9] *Available at* https://aspe.hhs.gov/system/files/pdf/242926/HHS_RIAGuidance.pdf (last visited Oct. 11, 2020).

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—a claim it renews in its opening brief—is that "[t]he Rule's definitions . . . necessarily impose no costs beyond the [conscience] statutes themselves." Brief for Defendants-Appellants 18; *see also* 84 Fed. Reg. at 23,251 (arguing that objections to the Final Rule "are really objections to policy decisions made by . . . Congress in enacting the Federal conscience and anti-discrimination laws in the first place"). This argument, too, is unavailing. While Congress did pass the statutory provisions underlying the Final Rule, HHS has made a discretionary decision to adopt newly expansive definitions of terms in those provisions, as well as new enforcement procedures. That discretionary decision has costs relative to the status quo, which the APA obligates HHS to consider. Furthermore, if it *were* true that no costs to patients 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 costs that provider organizations will incur in accommodating such refusals. As the American Medical Association warned in comments, increased invocations of conscience rights by 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 of care. 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-06377, (D.N.J. Dec. 16, 2011) (indicating that hospital hired additional nurses due to numerous refusals 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 not mentioned in HHS's regulatory impact analysis. This omission is particularly egregious given that, elsewhere, HHS expressly contemplates "the use [of] alternate staff" and other staffing adjustments to accommodate objections. 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 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

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

evidence to support 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 entirely on these speculative and unsupported assumptions 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 vacated 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") 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 and supplies no quantitative data about actual exits from the profession or relocations in response to the 2011 Rescission. It makes no attempt, in other words, to assess whether the post-survey elimination of the expansive protections in the 2008 Rule prompted any survey

[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.

respondents to follow through on their threats 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).

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

HHS argues that the Final Rule will improve patient care by inducing 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 the commenter had confined either the scope or geographic footprint of its services as a result of the 2011 Rescission, that the "status quo risk[ed] 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]

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, HHS 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.

One article cited by HHS suggests that moral distress has been generated mainly 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 identifies as sources of moral distress unnecessary tests, incompetent care, inadequate consent for treatment, poor staffing,

[12] *Available at* https://www.regulations.gov/document?D=HHS-OCR-2018-0002-68575 (last visited Oct. 11, 2020).

and cost cuts, among others. 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). As a result, the Final Rule might *increase* rather than reduce moral distress among some providers, insofar as it leads to a lack of treatment, inadequate care, and inadequate consent for treatment (when patients are denied information about 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 claim 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").

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; *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.

By making unsupported assertions regarding the Final Rule's effects on moral distress, the Department undermines the validity of its regulatory impact analysis and, in turn, the legality of the Final Rule.

CONCLUSION

This Court should affirm the district court orders.

Dated: October 20, 2020

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE WITH RULE 32(a)(7)

Counsel hereby certifies that, in accordance with Federal Rule of Appellate Procedure 32(a)(7), the foregoing brief contains 6,414 words, as counted by counsel's word processing system, and this complies with the applicable word limit established by the Court.

This brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type-style requirements of Fed. R. App. P. 32(a)(6) because this document has been prepared in a proportionally spaced typeface using Microsoft Word, version 16.39, in 14-point Times New Roman font.

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CERTIFICATE OF SERVICE

I hereby certify that on this 20th day of October, 2020, a true and correct copy of the foregoing brief was filed with the Clerk of the United States Court of Appeals for the Ninth Circuit via the Court's CM/ECF system. Counsel for all parties are registered CM/ECF users and will be served by the appellate CM/ECF system.

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