No. 19-35386

IN THE UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

STATE OF OREGON et al.,

Plaintiffs-Appellees,

v.

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

Defendants-Appellants.

AMERICAN MEDICAL ASSOCIATION, et al.,

Plaintiffs-Appellees,

v.

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

Defendants-Appellants.

On Appeal from the District of Oregon
The Honorable Michael J. McShane
Nos. 19-cv-317, 19-cv-318

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

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Date: July 5, 2019

/s/ Richard L. Revesz
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INTERESTS OF AMICUS CURIAE

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 (Appellees) and affirmance. Policy Integrity is 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).[3] Our legal director, Jason A. Schwartz, has similarly produced expert scholarship on regulatory decision-making, including the book chapter, "Approaches to Cost-Benefit Analysis," in *Handbook of Regulatory Impact Assessment* (Claire A. Dunlop & Claudio M. Radaelli eds., 2016).

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[3] 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.

Harnessing this expertise, Policy Integrity has filed many *amicus curiae* briefs assessing agencies' economic analyses of regulatory actions. *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–03804) (arguing that agency's failure to consider forgone benefits from a delay in methane standards was arbitrary); Br. for Inst. for Policy Integrity as Amicus Curiae, *California v. U.S. Dep't of the Interior*, No. C 17-56948, 2019 WL 2223804 (N.D. Cal. Mar. 29, 2019) (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. Bureau Land Mgmt.*, 277 F. Supp. 3d at 1123 (holding failure to consider forgone benefits arbitrary); *California v. Interior*, 2019 WL 2223804, at *8-13 (holding that the repeal of the mineral valuation reform rule was arbitrary and capricious).

Like the agencies in those cases, the Department of Health and Human Services (HHS) has failed to adequately account for the substantial costs of the rule challenged here, "Compliance with Statutory Program Integrity Requirements," 84 Fed. Reg. 7714 (Mar. 4, 2019) ("Final Rule"). This amicus brief explains HHS's "arbitrary approach to cost-benefit analysis in detail," as Policy Integrity did in the district court. *See* Pls.-Appellees' Answering Br., *National Family Planning &*

Reproductive Health Assoc. v. Azar, No. 19-35394, at 37, ECF No. 46 ("Family Planning Br.").

Policy Integrity has particular expertise on the regulatory impact analysis that HHS conducted in support of the Final Rule. Policy Integrity both submitted comments on the proposed rule, Policy Integrity Comment Ltr. (Aug. 1, 2018), and formally met with the Office of Information and Regulatory Affairs to present critiques of the regulatory impact analysis. Appellees argue here, and the district courts found below, that the Final Rule is arbitrary and capricious, in part because HHS relies on a flawed analysis of regulatory impacts. *See, e.g.*, Family Planning Br. at 37; Medical Ass'ns' Answering Br., *AMA v. Azar*, No. 19-35386, at 44-50, ECF No. 73 ("Medical Ass'ns' Br."). The U.S. District Court for the Northern District of California in particular found that the agency's analysis of the costs of the Final Rule were inadequate and relied upon the arguments advanced in our amicus brief to make that finding. *California v. Azar*, No. 19-cv-01184, 2019 WL 1877392, at *32-34, *37-41 (N.D. Cal. Apr. 26, 2019) (citing Policy Integrity's amicus brief and agreeing that inadequate economic analysis rendered the Final Rule arbitrary). 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.

Policy Integrity consulted with the parties per Fed. R. App. P. 29(a)(2), and all parties have consented to the filing of this amicus brief. Policy Integrity has also

consulted with other potential amici, per Circuit Advisory Comm. Note on Rule 29-1, to ensure that this brief presents distinct arguments that are not duplicated in other briefs.

SUMMARY OF ARGUMENT

Appellees explain that the district courts' preliminary injunction of the Final Rule should be upheld for multiple reasons, including because HHS's gross misrepresentation of the Final Rule's impacts is arbitrary and capricious. *See, e.g.*, Family Planning Br. at 37; Medical Ass'ns' Br. at 44-50; Pls.-Appellees' Answering Brief Pet. Reh'g. En Banc, *Essential Access Health v. Azar*, No. 19-15979, at 65-67, ECF No. 31. This amicus brief expands on this point to explain how guidelines for regulatory impact analysis advise HHS to conduct its analysis of a rule's impacts, and to show how HHS ignores that guidance and conducts a fundamentally flawed and arbitrary cost-benefit analysis in three specific respects.

First, the Final Rule disregards several important categories of significant costs highlighted by commenters. Courts have made clear that agencies must reasonably account for all important regulatory costs, including any significant direct or indirect health costs. Yet HHS unreasonably concludes that the Final Rule will impose no costs on public health or patient wellbeing, despite ample evidence in the record to the contrary, and despite clear guidelines on the need to quantitatively assess such health costs to the fullest extent practicable.

Second, the Final Rule significantly underestimates the direct costs of compliance, contrary to both common sense and evidence in the record indicating these costs will be larger by an order of magnitude. HHS cites no market data, literature, economic models, grantee interviews, or any other source or methodology to support its gross underestimates. HHS's resulting estimates are arbitrary and capricious.

Third, HHS fails to provide any evidence to support many of the claimed expected benefits of the Final Rule, including a predicted net reduction in unwanted pregnancies and "enhanced compliance" with Title X's prohibition on the use of funds for abortion services. Those speculative benefits do not justify the Final Rule. By ignoring best practices and plucking from thin air its estimates of costs and benefits, HHS relies on a flawed justification of the Final Rule, rendering its decisionmaking 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. ("State Farm"), 463 U.S. 29, 43 (1983) (internal quotation marks omitted).

HHS has several forms of detailed guidance it could have followed to assist it in assessing the rule's effects, but it ignores all of that guidance in the Final Rule. Executive Order 12,866—the main executive order that has governed regulatory decisionmaking since 1993 and that continues to apply today, *see* 84 Fed. Reg. at 7775 (following Exec. Order 12,866)[4]—directs agencies to "assess both the costs and the benefits of the intended regulation and . . . adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify its costs." Exec. Order 12,866 § 1(b)(6), 58 Fed. Reg. 51,735 (Sept. 30, 1993). HHS's *Guidelines* instruct the agency to analyze a rule's costs and benefits consistent with Executive Order 12,866. U.S. Dep't of Health and Human Servs., *Guidelines for Regulatory Impact Analysis* at 1 ("*Guidelines*") (2016).[5] And the Office of Management and Budget's *Circular A-4 on Regulatory Analysis* sets out further best practices for conducting cost-benefit analysis. Office of Mgmt. & Budget, Circular A-4 at 1 (2003).

[4] *See* Office of Mgmt. & Budget, Memorandum: Implementing Executive Order 13,771, Titled "Reducing Regulation and Controlling Regulatory Costs" pt. II (Apr. 5, 2017) ("EO 12866 remains the primary governing EO regarding regulatory planning and review.").

[5] Website urls are provided in the Table of Authorities.

As required under both HHS's *Guidelines* and Executive Order 12,866, HHS prepared an analysis of the Final Rule's "Economic Impacts." 84 Fed. Reg. at 7777. But in that analysis, HHS does not heed any of the advice in those guidance documents and instead relies on justifications for the Final Rule that are "serious[ly] flawed" and "unreasonable." *National Ass'n of Home Builders v. EPA*, 682 F.3d 1032, 1040 (D.C. Cir. 2012). In assessing the likely impacts of the Final Rule, HHS fails to consider the harms that the Final Rule would impose on patients, fails to provide a reasonable estimation of compliance costs, and fails to provide any evidence to support many of the claimed expected benefits of the rule. As a result, the Final Rule is arbitrary and capricious under the Administrative Procedure Act and the district courts' preliminary injunctions should be upheld.

I. HHS Arbitrarily Fails to Assess the Rule's Harms to Patients, Ignoring Best Practices for Regulatory Impact Analysis

HHS's analysis of the Final Rule's economic impacts is fundamentally flawed. Executive Order 12,866 instructs agencies to consider "any adverse effects" a rule might have on "the efficient functioning of the economy, private markets . . . *health*, safety, and the natural environment." Exec. Order 12,866 § 6(a)(3)(C)(ii) (emphasis added). HHS's *Guidelines* also make clear that HHS must consider not just "compliance costs" but instead must evaluate "the net effect on society." *Guidelines* at 24.

Despite the guidance instructing HHS to assess all important costs, HHS's regulatory impact analysis focuses instead almost exclusively on the direct costs of compliance and ignores multiple other costs of the rule. Ignoring these categories of costs violates HHS's duties under the Administrative Procedure Act. As the Supreme Court has noted, rational rulemaking "requires paying attention to the advantages *and* the disadvantages of agency decisions," and the "cost" that agencies should consider includes not just compliance costs but also "harms that regulation might do to human health." *Michigan v. EPA*, 135 S. Ct. 2699, 2707 (2015).[6] Regulatory costs are an "important aspect of the problem," and ignoring them renders the rule arbitrary and capricious. *See State Farm*, 463 U.S. at 43; *accord Air All. Hous. v. EPA*, 906 F.3d 1049, 1067 (D.C. Cir. 2018) (holding that suspension was arbitrary in part for failing to adequately address the rule's forgone benefits); *California v. U.S. Bureau of Land Mgmt.*, 277 F. Supp. 3d 1106, 1122 (N.D. Cal. 2017) (holding that failure to consider forgone benefits was arbitrary).

A. The Final Rule Will Harm Patients and Increase Costs for Providers

The Final Rule will cause significant costs, in the form of harms to the health of those patients who lose access to services, the costs of increased

[6] *See also Mingo Logan Coal Co. v. EPA*, 829 F.3d 710, 732–33 (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," and "consideration of costs is an essential component of reasoned decisionmaking under the Administrative Procedure Act.").

unwanted pregnancies and births, and the transaction costs of finding replacement care. Title X grantees provide a wide range of services beyond the provision of contraceptives, including "conducting screening for cervical cancer, diabetes, high blood pressure, and sexually transmitted infections," and, as pointed out by a public health expert in comments, these Title X-provided services are often low-income women's "only interaction with the health care system at all." Brindis, Claire, Comment Ltr. 3 (July 31, 2018) ("Brindis Comment Ltr."). Similarly, many Title X recipients operate in rural areas where their patients have scarce access to substitute healthcare providers. *See, e.g.*, Washington Answering Br., *Washington v. Azar*, No. 19-35394, at 11-13, ECF No. 43; Planned Parenthood Comment Ltr. 15-16, 70 (July 31, 2018).

As a result, if providers close their doors or raise their fees because of the Final Rule, some patients will be left without a meaningful alternative, incurring substantial health costs. *See* Answering Br. of Pls.-Appellees Oregon, et al. at 40-41, *Oregon v. Azar*, No. 19-35386, ECF No. 76 ("State Br.") (summarizing additional evidence). Clinic closures will cause undesirable health outcomes, such as the spike in HIV that occurred when Planned Parenthood was forced to close a rural clinic in Indiana. Brindis Comment Ltr. 6-7. And some patients will lose access to care that was previously affordable through Title X support.

B. HHS Fails to Provide a Reasoned Explanation for Ignoring the Final Rule's Substantial Harms

HHS's *Guidelines* for conducting regulatory impact analyses emphasize that "reductions in government payments" to healthcare providers may affect patient access and treatments, "in turn affecting health outcomes," and that these changes "should be addressed in the benefit-cost analysis." *Guidelines* at 23. Yet despite having received evidence of the likely harm that will be caused by the reductions in government payments contemplated by the Final Rule, HHS tallies only the direct compliance costs for providers. *See* 84 Fed. Reg. at 7777, tbl.1, 7777-82 (spending six pages on costs like training and documenting compliance); *but see infra* Section II (explaining why HHS's compliance cost estimates are also arbitrary). HHS then spends only a few paragraphs responding to commenters' extensive documentation of the significant probable effects on patient health which will be caused by provider closures, 84 Fed. Reg. at 7775, before assuming without any quantitative analysis that the "net impact" to patients "will be zero," *id.* at 7782. Indeed, the Final Rule's summary of expected costs indicates that HHS concludes that there are *no* costs beyond the quantified compliance costs. 84 Fed. Reg. at 7777, tbl. 1 (listing "Non-quantified Costs: None").

There is no evidence that, in reaching its conclusion, HHS consulted any data on the health outcomes of Title X patients, conducted any interviews with Title X grantees or patients, ran any models, seriously considered data from public

comments, or otherwise attempted to quantify any of the likely impacts to patients, such as lost access to care, increased unwanted pregnancies, and transaction costs. HHS instead provides a few conclusory justifications for dismissing the harms of the Final Rule, but none of them hold up to scrutiny.

1. HHS's Assertion that the Final Rule Will Cause No Harm Because New Providers Will Enter the Program Is Unsupported by Evidence and Is Not Entitled to Deference

Rather than account for the Final Rule's health costs, HHS dismisses all of the costs that this loss of service will cause by asserting—with no analysis or evidentiary support—that patients will not be harmed because an equal number of new providers will enter the program now thanks to the Final Rule's conscience protections. 84 Fed. Reg. at 7723, 7782. But that assumes that providers were not entering the program because of conscience concerns, and as Appellees have explained, there is no reason for providers to have such concerns in the first place. *See* State Br. at 41-43. Moreover, contrary to Appellant's claim, HHS's assumption that new providers would enter the market was not a "prediction" that is entitled to deference. *See* Appellants' Opening Br. at 41, *California v. Azar*, No. 19-15974 & 19-15979, ECF. No. 16 ("Appellants' Br.").

While "an agency's predictive judgments . . . are entitled to particularly deferential review," that deference is only given "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). Further, in assessing whether a regulation is supported by the reasoned explanation required under the APA, courts "do not defer to the agency's conclusory or unsupported suppositions." *United Techs. Corp. v. Dep't of Def.*, 601 F.3d 557, 562 (D.C. Cir. 2010) (quotations marks omitted). When a predictive judgment is unreasonable, no special deference is granted.

Here, HHS's claim that the Final Rule will increase, rather than decrease, the number of providers in the Title X program is supported by citation to a *single* online survey, released by the Christian Medical Association in 2009. 84 Fed. Reg. at 7781, n.139. While HHS characterizes the results of the survey as showing that "82% of medical professionals" would limit the scope of their practice if conscience protection rules were not in place, *id.*, the survey in fact was directed at "*faith-based* healthcare professionals," with the vast majority of responses coming from members of the Christian and Catholic Medical Associations.[7] HHS does not acknowledge how limited this sample is. Nor does HHS explain how that single sample of responses from a particular religious subset would be representative of the total affected population of providers. Further, the agency fails to explain how

[7] The online survey was "completed by 2,298 members of the Christian Medical Association, 400 members of the Catholic Medical Association, 69 members of the Fellowship of Christian Physicians Assistants, 206 members of the Christian Pharmacists Fellowship International, and 8 members of Nurses Christian Fellowship." *National Poll Shows Majority Support Healthcare Conscience Rights, Conscience Law* (May 3, 2011).

these survey respondents are not already sufficiently protected by existing statutes that prohibit the government from compelling providers to perform services against which they hold religious or moral convictions. *See* State Br. at 43.

Appellants argue that "an agency's predictive judgments 'are entitled to particularly deferential review.'" *See* Appellants' Opening Br. at 41 (quoting *Trout Unlimited v. Lohn*, 559 F.3d 946, 959 (9th Cir. 2009)). But in the case that Appellants rely on, *Trout Unlimited*, the agency's decision had been made "in a thoughtful, comprehensive manner" that relied on "substantial—though not dispositive—scientific data." 559 F.3d at 959*; see also Lands Council v. McNair*, 537 F.3d 981, 995 (9th Cir. 2008) (acknowledging that the "relatively sparse" record "approaches the limits of our deference [but] nevertheless conclud[ing] that there is sufficient evidence to defer," where the agency cited to four different academic studies and conducted its own survey).

HHS's reliance on the single Christian and Catholic Medical Associations sample stands in stark contrast to the analysis at issue in *Trout Unlimited*. In order for agency predictions to receive deference, the agency must "explain . . . the reasons it considers the underlying evidence to be reliable." *Lands Council*, 537 F.3d at 994. Here, HHS concedes that the Final Rule "may" force some Title X recipients to drop out of the program. 84 Fed. Reg. at 7782 ("Various entities may change their decision to apply to be a grantee."). Yet HHS brushes aside the

significance of that fact, relying solely on an online survey conducted ten years ago. In failing to acknowledge or discuss whether that single sample of responses from a particular religious group is representative of the total affected population of providers the agency has engaged in classically arbitrary and capricious conduct. *See Am. Petroleum Inst. v. EPA*, 862 F.3d 50, 69 (D.C. Cir. 2017), *decision modified on reh'g*, 883 F.3d 918 (D.C. Cir. 2018) (the agency "is free to rely on theoretical or model-based approaches, as long as that reliance is reasonable in context" and there is "some indication of a reasonable concurrence between model and reality").

Even putting aside the agency's deceptive presentation of the Christian Medical Association survey, HHS makes no attempt to explain how the 2009 survey of individual (Christian) medical professionals is related to the anticipated effects of the many other changes to the Title X program now at issue, including the rule's "Separation Requirement," a requirement that forces clinics providing abortion services to maintain separate facilities and finances for their Title X programs. 84 Fed. Reg. at 7763-67.

Further, even if the number of new providers entering the program were somehow equal to the providers who will be forced to leave the program under the Final Rule, the providers that HHS assumes will enter the program are unlikely to serve as perfect substitutes for the exiting providers. The Final Rule specifically

intends to award Title X funding to providers who offer only a limited range of family planning methods, including only natural planning and abstinence counseling (as opposed to traditional contraception). *Id.* at 7741. These hypothetical new grantees are significantly different from the providers who offer a full range of services. The only rational conclusion is that some number of patients will lose access to needed services.

HHS's assumption that new providers will perfectly substitute for current providers displaced by the Final Rule also overlooks the significant transaction costs patients will incur when searching for replacement healthcare providers. HHS predicts that with new providers entering the program, "any redistribution of the location of facilities will mean that some seeking services will have shorter travel times and others seeking services will have longer travel times to reach a facility." *Id.* at 7782. But, again, this analysis assumes perfect and immediate replacement of exiting grantees with entering grantees, and ignores any significant costs incurred by patients during inevitable transition gaps and delays. It also ignores the transaction costs incurred by patients in seeking out these new services as well as the emotional costs of having lost a familiar healthcare provider. For those current Title X-funded facilities that do not close and instead choose to comply with the Separation Requirement, the Final Rule's compliance requirements may also make it more difficult for patients to access care at these service sites: for example, if

sites change their phone numbers, email addresses, websites, and entrances in order to comply, *id.* at 7789, patients may have difficulty finding and accessing care even at service sites previously familiar to them.

HHS's *Guidelines* urge the agency not to make the unreasonable assumption that new providers will perfectly substitute for existing providers displaced by the rule, with no transaction costs or health impacts to patients. The *Guidelines* explain that if compliance costs cause "substituting behaviors" by providers or consumers, "analysts should consider the net effect on society." *Guidelines* at 24. In particular, if compliance costs cause "changes in available services," consumers may face "additional" costs, including "non-pecuniary" costs such as "time losses associated with needing to find new doctors or traveling farther for treatment[]." *Id.* at 25. Indeed, the *Guidelines* detail precisely how to quantify the costs of time losses and travel. *Id.* at 26-28, 30-32. More generally, the *Guidelines* require that "[e]vidence must be used" to assess policy response outcomes. *Id.* at 7. HHS's ignores this guidance to come to its arbitrary conclusions. Because HHS's assumption of perfect substitution of providers with no health costs or transaction costs relies on a single survey of a narrow population subset and contradicts economic logic, the assumption is not entitled to deference, and HHS's failure to consider the Final Rule's likely negative health impacts is arbitrary.

2. HHS's Assumption that Patients Are More Likely to Visit Clinics that Respect Their Beliefs Does Not Justify the Decision to Ignore the Harms of the Final Rule

The agency also claims that it can disregard the substantial record evidence showing harm to patient health and transaction costs because clients who would not have otherwise visited Title X-funded clinics will now do so thanks to the fact that there are clinics "that respect their views and beliefs." 84 Fed. Reg. at 7743. Yet the agency provides no evidence or quantitative analysis to estimate how many people currently decline to seek Title X care because of their personal beliefs; patients with religious or moral objections to certain services already receive protection as Title X counseling is nondirective and given only in response to patient requests. Nor does the agency provide any quantitative assessment of whether this group outweighs the sizable number that will lose access to the services they currently receive under Title X. Quantifying effects serves as an important tool to help agencies "appropriately balance" a regulation's competing costs and risk reductions, *see Guidelines* at 47, yet HHS disregards that advice in order to reach its arbitrary conclusion.

Moreover, HHS's assertion that clinic closures will not result in an increase in unwanted pregnancies "runs counter to the evidence before the agency." *State Farm*, 463 U.S. at 439. In response to the Final Rule's proposed version, experts submitted comments highlighting that the public funding of family planning

services has averted millions of unintended pregnancies each year, resulting in significant avoided costs related to child health care and maternity. *See, e.g.*, Brindis Comment Ltr. 12. HHS's assertion that "[c]ommenters offer no compelling evidence that this rule will increase unintended pregnancies or decrease access to contraception," 84 Fed. Reg. at 7785, is at odds with record evidence to the contrary, including the fact that Texas's cuts to family-planning funding resulted in a substantial decrease in use of effective birth control and increase in births. Brindis Comment Ltr. 12. Even if HHS could not fully quantify the health costs resulting from the Final Rule, the agency minimally could have attempted to quantify "counts" of "the number of organizations . . . [or] individuals affected," or otherwise used all the data provided by commenters as "indicators of potential costs or benefits." *Guidelines* at 48. Instead, and contrary to the requirements of the Administrative Procedure Act, HHS ignored commenters' data while failing to provide any reasoned explanation on why this evidence is not "compelling." *See McDonnell Douglas Corp. v. U.S. Dep't of the Air Force*, 375 F.3d 1182, 1187 (D.C. Cir. 2004) (holding that "conclusory or unsupported suppositions" fail to satisfy the requirements of reasoned decisionmaking).

3. HHS Cannot Ignore the Final Rule's Harms Just Because They Are Uncertain or Difficult to Quantify

HHS attempts to justify its choice to ignore the costs of an increase in unintended pregnancies and births by arguing that "the Department is not

aware . . . of actual data that could demonstrate a causal connection between the [Final Rule] and an increase in unintended pregnancies, births, or costs associated with either, much less data that could reliably calculate the magnitude of that hypothetical impact." 84 Fed. Reg. at 7775. HHS concludes that these costs "are not likely or calculable impacts," *id*., and then makes a further leap to conclude that the costs are "None." *Id.* at 7777, Table 1.

But even assuming HHS is right that the data needed to quantify this cost is unavailable, HHS cannot rationally ignore the cost just because it is unquantified. "The mere fact that the magnitude of [an effect] is *uncertain* is no justification for *disregarding* the effect entirely." *Public Citizen v. Fed. Motor Carrier Safety Admin.*, 374 F.3d 1209, 1219 (D.C. Cir. 2004) (emphasis in original). Stated differently, HHS has no license to ignore the effects of its decisions just because they are "difficult, if not impossible, to quantify reliably." *Am. Trucking Ass'ns., Inc. v. EPA*, 175 F.3d 1027, 1052 (D.C. Cir. 1999), *rev'd on other grounds sub nom. Whitman v. Am. Trucking Ass'ns*, 531 U.S. 457 (2001).

It is crucial to consider unquantified costs, because those effects may be massive and may render the rule unjustified.[8] For that reason, Executive Order

[8] The mere fact that a cost or benefit cannot currently be quantified says little about its magnitude; in fact, some of the most substantial categories of monetized benefits that appear in current economic analyses were once considered unquantifiable. *See* Richard L. Revesz, *Quantifying Regulatory Benefits*, 102 CAL.

12,866 makes clear that it is "essential to consider" the "qualitative measures of costs and benefits that are difficult to quantify." Exec. Order No. 12,866 § 1(a). Circular A-4 counsels agencies to quantify all benefits "to the extent feasible." *Circular A-4* at 45. HHS's *Guidelines* require the agency to "quantify[] impacts to the greatest extent possible." *Guidelines* at 43. In fact, the *Guidelines* contain an entire chapter on the importance of, and approaches for, meaningfully considering nonquantified effects. *See id.* at 47-51; *id.* at 47 ("Ignoring potentially important nonquantified effects may lead to poor decisions."). *Compare id.* at 51 (providing that "[a]t minimum" agencies "should list significant nonquantified effects in a table and discuss them qualitatively"), *with* 84 Fed. Reg. at 7777, Table 1 (listing "Non-quantified Costs: None").

Here, the Final Rule will cause more "unintended pregnancies, riskier pregnancies, more abortions, more sexually transmitted infections, and worse health outcomes." State Br. at 41 (citing record support). HHS has no excuse for ignoring these unquantified harms. Indeed, HHS's lack of consideration of difficult-to-quantify health costs is even more egregious when compared to the agency's willingness to enumerate a long list of Final Rule's alleged benefits, each of which are unquantified, and many of which lack any evidentiary support at all,

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L. REV. 1423, 1436 (2014) (explaining, for example, how the value of statistical life had "initially evaded quantification").

even of an anecdotal nature. *See infra* Section III. It is arbitrary for HHS to "put a thumb on the scale" in this way. *Ctr. for Biological Diversity v. Nat'l Highway Traffic Safety Admin.*, 538 F.3d 1172, 1198 (9th Cir. 2008).

II. HHS Arbitrarily Ignores Both Its Own Guidelines and Record Evidence in Grossly Underestimating Compliance Costs

Because the costs of complying with regulations often can be directly estimated from market data, assessing compliance costs is typically a straightforward part of agencies' regulatory impact analyses. *See* Schwartz, *supra*, at 38 ("Many costs and some benefits will already be expressed in monetary terms, like prices of compliance equipment."); *see also Circular A-4* at 21 ("Economists ordinarily consider market prices as the most accurate measure of the marginal value of goods and services to society.").

HHS's own guidelines on conducting cost-benefit analysis clearly direct how to evaluate capital and operating compliance costs:

> 1. Use market data to estimate the price of purchasing and installing equipment required by the regulation. . . . 2. Use market data to value the annual costs of labor, utilities, and other resources required for production, service provision, and the operation and maintenance of capital equipment.

HHS, *Guidelines for Regulatory Impact Analysis: A Primer* at 8 (2016). The *Guidelines* elaborate that such market data "may be obtained through interviews, literature reviews, review of online merchandise catalogues, or other sources." *Guidelines* at 32.

Yet in calculating the Final Rule's direct compliance costs, there is no evidence that HHS followed its *Guidelines* or conducted any interviews of grantees, consulted any literature or market price data, ran any cost models, or even seriously considered public comments. For example, under the Separation Requirement, healthcare clinics that currently provide both Title X services and abortion services—including abortion referrals—must physically alter their facilities to create separate "treatment, consultation, examination and waiting rooms" and "office entrances and exits," 84 Fed. Reg. at 7789. In the proposed rule, HHS estimated—without any reference to any evidence, methodology, or assumptions to support the numbers—that it would cost "an average of between $10,000 and $30,000, with a central estimate of $20,000" in one-time expenses for facilities to comply with the Separation Requirement. 83 Fed. Reg. 25,502, 25,525 (June 1, 2018). Those estimates were seemingly derived from thin air, in stark contrast to HHS's own best practices for estimating costs.

In response to that proposal, multiple Title X grantees (the regulated entities subject to the Rule's compliance costs) submitted detailed comments that indicated their own capital costs of renovation and construction would be much higher than HHS estimated, based on third-party reports and grantees' historical experiences. *See, e.g.*, Planned Parenthood Comment Ltr. 32 (estimating capital costs of $625,000 per affected service site); Nat'l. Family Planning & Reproductive Health

Ass'n. Comment Ltr. 37 (July 31, 2018) (estimating cost per site of at least $300,000).

HHS's failure to adequately assess compliance costs is more than simply a decision to make a "different judgment than plaintiffs." *See* Appellants' Br. at 39. While HHS is not required to respond to every comment, it must respond to "comments which, if true, raise points relevant to the agency's decision and which, if adopted, would require a change in an agency's proposed rule." *Nat'l Shooting Sports Found. v. Jones*, 716 F.3d 200, 215 (D.C. Cir. 2013) (quotation marks omitted). Yet in the Final Rule, HHS's only response to those comments was a trivial increase $10,000 in its central estimate of capital costs, from $20,000 to $30,000 per facility. 84 Fed. Reg. at 7718, 7782. That trivially increased estimate is still more than ten to twenty times below the capital cost estimates submitted by grantees themselves, and HHS still does not identify any data source, assumptions, methodology, or literature that supports its estimates.

Not only was HHS's estimate of one-time capital costs drastically off from grantees' own estimates by hundreds of thousands of dollars per site, but public comments also pointed out that HHS completely ignored ongoing costs for the additional staff and contracts for goods and services to operate the separate facilities. *See, e.g.*, Planned Parenthood Comment Ltr. 32-33. The district court noted Appellee Essential Access Health's estimates that its own compliance with

the Separation Rule will cost "$325,000 in the first year and $212,500 every year thereafter." *California v. Azar*, 2019 WL 1877392 at *11. Despite public comments, the Final Rule does not estimate any ongoing costs of the Separation Requirement, which grantees report will cost them millions more on top of the capital expenses.

In other rules, HHS has been able to follow its best practices for calculating compliance costs. For example, when HHS issued new rules affecting Head Start grantees, its regulatory impact analysis relied on "internal datasets" based on grantees' budgetary data and comprehensive surveys of grantees. *See* 81 Fed. Reg. 61,294, 61,375 (Sept. 6, 2016). By contrast, there is no indication that HHS talked to any Title X grantees about their likely costs before proposing or finalizing the Final Rule.

Instead, HHS insists here, without any evidence of its own, that grantees' estimates were simply too "high," and HHS vaguely anticipates, again without any evidence, that lower cost methods of compliance will materialize. 84 Fed. Reg. at 7781. Ultimately, HHS seeks to fault the commenters for "not provid[ing] sufficient data to estimate these effects." *Id.* But even if the commenters' precise cost estimates, based on their own financial history and third-party reports, were somehow insufficient, it is the responsibility of the agency, not of commenters, to consider the "important aspect[s] of the problem" and "examine the relevant data."

State Farm, 463 U.S. at 43. Specifically, under HHS's *Guidelines*, it was the agency's responsibility to "use market data . . . obtained through interviews, literature reviews, review of online merchandise catalogues, or other sources" to accurately assess costs. *Guidelines* at 32. Here, HHS has instead ignored the best evidence before it (i.e., public comments) and offered no other evidence or reasonable theories of how affected clinics could install new waiting rooms, exam rooms, entrances, websites, and personnel, all for just $30,000. In the absence of data to back up its estimates, HHS has provided no explanation for disregarding commenters' own compliance estimates. "[L]imited data do not justify unlimited inferences," particularly when the data available does not support the agency's determination. *Am. Petroleum Inst.*, 862 F.3d at 70.

The Final Rule's analysis of direct compliance costs underestimates capital expenses and completely ignores tens or hundreds of millions more in ongoing costs. These serious omissions show that HHS arbitrarily failed to examine relevant data, consider important aspects of the problem, and to otherwise engage in the kind of rational analysis required by the Administrative Procedure Act.

III. HHS Makes Conclusory and Unsupported Claims About the Final Rule's Benefits

HHS lists a number of expected "benefits" of the Final Rule, including an alleged increase in the number of providers seeking to participate in Title X, enhanced patient service and care, and increased compliance with Title X's

prohibition on the use of funds for abortion services. *See* 84 Fed. Reg. at 7777. For each of these expected benefits, the agency makes no attempt to provide evidence supporting a conclusion that the benefit is likely to come about, nor to estimate the magnitude of these alleged effects. This omission is contrary to both best practices and settled caselaw.

Circular A-4 counsels agencies to quantify all benefits "to the extent feasible." *Circular A-4* at 45. For those benefits that the agency is unable to quantify, the agency must provide information on why it was unable to quantify the effects of the regulation. *Id.* at 27. HHS guidance on cost-benefit analysis further explains that quantification of a rule's effects helps to guard against bias and the tendency of "decision-makers . . . [to] weigh[] nonquantified effects in a manner consistent with their own . . . beliefs." *Guidelines* at 47. Therefore, "[c]lear presentation of the available evidence" is needed to support unbiased and transparent reasoning. *Id.*

Instead of following HHS *Guidelines*, the agency claims that the Final Rule will result in increased compliance with rules guarding against the misuse of Title X funds while providing *no* evidence of the misapplication of funds under the present regulatory scheme. 84 Fed. Reg. at 7764. As noted in Circular A-4, a regulation's impact can only be measured against an established baseline. *See Circular A-4* at 15. Without this baseline—i.e., without *any* analysis or evidence of

current misuse of funds—the agency cannot convincingly assert that the Final Rule will "enhance" compliance. *See* 84 Fed. Reg. at 7777. In making claims about enhanced compliance without assessing baseline compliance, HHS arbitrarily ignores an "important aspect of the problem." *State Farm*, 463 U.S. at 43.

Similarly, as explained above, *supra* Section I.B.1, HHS provides no evidence for its assertion that the Final Rule will result in benefits because an "expanded number" of providers will enter the Title X program. *See* 84 Fed. Reg. at 7777. HHS provides no evidence to support the assertion that new grantees will enter the program now that they are permitted to offer only a limited range of contraception services. *See id.* at 7741. And HHS provides no evidence to support its claim that a larger number of providers will enter the program as exit. *See id.* at 7782.

In assessing whether a regulation is supported by the reasoned explanation required under the APA, courts "do not defer to the agency's conclusory or unsupported suppositions," *United Techs. Corp.*, 601 F.3d at 562 (quotation marks omitted). Here, each of the benefits identified by HHS lack evidentiary support and are contrary to both the record and common sense. *State Farm*, 463 U.S. at 43 (An agency may not "offe[r] an explanation for its decision that runs counter to the evidence before [it]."). That the Final Rule's entire beneficial impact is comprised of "unsupported suppositions" renders the Rule arbitrary and capricious. *United*

Techs. Corp., 601 F.3d at 562; *see also Nat'l Ass'n of Home Builders*, 682 F.3d at 1040 ("[W]hen an agency decides to rely on a cost-benefit analysis as part of its rulemaking, a serious flaw undermining that analysis can render the rule unreasonable.").

CONCLUSION

For the reasons discussed above, the district courts' preliminary injunctions should be affirmed.

Dated: July 5, 2019

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

Pursuant to Fed. R. App. P. 32(a)(7)(C), I certify that:

This brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B) because this brief contains 6,456 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii). 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 brief has been prepared in a proportionately spaced typeface using Microsoft Word 2013 Times New Roman 14-point font.

Date: July 5, 2019

/s/ Richard L. Revesz
Richard L. Revesz

CERTIFICATE OF SERVICE

I hereby certify that on July 5, 2019, I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Ninth Circuit by using the appellate CM/ECF system.

Participants in the case who are registered CM/ECF users will be served by the appellate CM/ECF system.

Date: July 5, 2019

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