No. 19-1614

IN THE UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

MAYOR AND CITY COUNCIL OF BALTIMORE,

Plaintiff-Appellee,

v.

ALEX M. AZAR II, in his official capacity as the Secretary of Health and Human Services, et al.

Defendants-Appellants.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

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

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Date: August 5, 2019 */s/ Bethany Davis Noll*
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[1] Under Federal Rule of Appellate Procedure 29(a)(4)(E), the Institute for 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 or submission of this brief.

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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 Plaintiff-Appellee, the Mayor and City Council of Baltimore ("Baltimore"). 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, *Air Alliance Houston v. EPA*, 906 F.3d 1049 (D.C. Cir. 2018) (arguing that agency had failed to adequately address the forgone benefits in delay of safety rule); Br. for Inst. for Policy Integrity as Amicus Curiae, *California v. U.S. Dep't of the Interior*, 381 F. Supp. 3d 1153 (N.D. Cal. 2019) (arguing that repeal of procedural reforms for mineral valuation was unreasonable due to agency's inaccurate assessment of repeal's economic impact); 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) (arguing that agency's failure to consider forgone benefits from a delay in methane standards was arbitrary). 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. *Air Alliance Houston v. EPA*, 906 F.3d at 1067 (holding that the agency had failed to explain how the rule's forgone benefits were "only 'speculative'"); *California v. U.S. Dep't of the Interior*, 381 F. Supp. 3d at 1178 (holding that the repeal of the mineral valuation reform rule was arbitrary and capricious); *California v. U.S. Bureau of Land Mgmt.*, 277 F. Supp. 3d at 1123 (holding that the failure to consider forgone benefits was arbitrary).

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"). 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),[4] and formally met with the Office of Information and Regulatory Affairs to present critiques of the regulatory impact analysis. In addition, Policy Integrity filed briefs in support of plaintiffs' motions for a preliminary injunction in the U.S. District Courts for the Northern District of California, District of Oregon, Eastern District of Washington, and District of Maine.[5] The district court in the Northern District of California relied on the arguments advanced in Policy Integrity's amicus brief to find that the agency's analysis of the costs of the Final Rule was inadequate. *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), stay granted, 927 F.3d 1068 (9th Cir. 2019). Policy Integrity's expertise in cost-benefit analysis and experience with the Final Rule give it a unique perspective from which to evaluate the claims in this case.

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

[5] *See* Policy Integrity, Amicus Briefs on Harmful Changes to Title X Women's Health Services, https://policyintegrity.org/projects/update/amicus-brief-on-harmful-changes-to-title-x-womens-health-services.

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.

SUMMARY OF ARGUMENT

Baltimore has argued that the injunction should be upheld because the Final Rule raises unreasonable barriers to care in violation of two federal statutes. *See* Brief for Appellee ("Appellee Br.") at 1, 66. In addition, Baltimore has argued that the Final Rule will force providers to either close or to compromise their standard of care, thus harming patients, *id.* at 12, as well as that the Court's consideration of its claims must be viewed in light of the highly irregular and unreasonably hasty way in which the Final Rule was adopted, *see id.* at 6-7.

This amicus brief expands on these points to explain how HHS provided substandard analysis in the Final Rule, ignoring guidelines for regulatory impact analysis and failing to offer a sufficient explanation for the harms that the Final Rule imposes on both patients and providers. In fact, 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.

Further, 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. The speculative benefits do not justify the barriers to care that the Final Rule raises. In ignoring best practices and plucking from thin air its estimates of costs and benefits, HHS has produced a Final Rule that is riddled with errors and flaws and unreasonably harms patient care.

ARGUMENT

In its haste to issue the Final Rule, HHS provides a fatally flawed analysis that contravenes even its own internal guidance. HHS has several forms of detailed guidance that it should have followed to assist it in assessing the rule's effects, but it ignores all of that guidance in the Final Rule to arbitrarily harm patients. 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)[6]—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). Moreover, for "significant" rulemakings, like the Final Rule, 84 Fed. Reg. at 7775-76, agencies are expected to conduct a careful and searching analysis. Exec. Order 12,866 §

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[6] *See also* 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.").

6(a)(3)(B)-(C). HHS's *Guidelines for Regulatory Impact Analysis* 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 (2016) ("*Guidelines*").[7] And *Circular A-4 on Regulatory Analysis*, guidance issued by the Office of Management and Budget, sets out further best practices for conducting cost-benefit analysis. Office of Mgmt. & Budget, Circular A-4 at 1 (2003).

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 the *Guidelines*' calls for a careful, complete, and transparent analysis grounded in data and rational assumptions, and instead relies on a "fast-tracked" and "fundamentally flawed rulemaking process that favored speed at all costs." Appellee Br. at 6-7. The agency's flawed analysis resulted in a rule that harms patients in exchange for completely speculative benefits.

I. The Final Rule Ignores Best Practices for Regulatory Impact Analysis and Harms Patients

Executive Order 12,866 instructs agencies to consider "any adverse effects" a rule might have on "the efficient functioning of the economy, private markets . . .

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

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 use the "best reasonably obtainable evidence" to assess compliance costs. *See Guidelines* at A-1; *accord* Exec. Order 12,866 § 1(b)(7). And 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 instead vastly underestimates the costs of compliance and ignores multiple other costs of the rule.

A. The Final Rule Harms Patients by Increasing Costs for Providers and Forcing Some to Close, All Without a Rational Explanation

As HHS's *Guidelines* for conducting regulatory impact analyses emphasize, compliance costs shift resources from other productive tasks, *Guidelines* at 23, 24, and "reductions in government payments" to healthcare providers may affect patient access and treatments, "in turn affecting health outcomes." *Guidelines* at 23. Studies confirm the *Guidelines*' conclusions and show that when clinics are forced to restrict services, patients suffer. JA 32, 101.[8] The Final Rule will both impose steep compliance costs and severely affect patient access to care and treatment.

[8] "JA" refers to the Joint Appendix, ECF No. 17.

1. The Final Rule Imposes Steep Compliance Costs

The Final Rule's actual compliance costs are significant but have been drastically underestimated by HHS. For example, under the Final Rule's 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. Yet in the Final Rule, HHS completely ignores the ongoing costs for the additional staff and contracts for goods and services to operate those separate facilities. *See, e.g.*, Planned Parenthood Comment Ltr. 32-33. In addition, HHS has vastly underestimated the costs of building those separate facilities. Multiple Title X grantees submitted detailed comments based on third-party reports and grantees' historical experiences that indicated the capital costs of renovation and construction would be much higher than HHS estimated. *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 results from more than simply a disagreement with Baltimore or other grantees "on their view of the merits." *See* Appellants' Opening Br. at 40, *Mayor of Baltimore v. Azar*, No. 19-1614, ECF.

No. 18 ("Appellants' Br."). While HHS is not required to respond to every public 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 grantees' comments about costs was a trivial increase of $10,000 in the agency's 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 does not identify any data source, assumptions, methodology, or literature to support its estimates.

HHS's own guidelines on conducting cost-benefit analysis direct the agency to use "market data to estimate the price of purchasing and installing equipment required by the regulation," and to also 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 the Final

Rule's estimates were seemingly derived from thin air, in stark contrast to those best practices.

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 consulted with any Title X grantees about their likely costs before proposing or finalizing the Final Rule. In short, HHS failed to follow the steps laid out in its own *Guidelines* for conducting a rational economic analysis. Instead, it ignored data, made unreasonable assumptions, and skipped steps in its rush to finalize the Rule, and in so doing dramatically underestimated direct compliance costs and completely ignored millions in ongoing expenses. As providers are forced to either close or alter their services in response to the Final Rule's actual steep costs, patients will suffer.

2. The Final Rule Harms Patients

As demonstrated by overwhelming evidence, the Final Rule will also force providers to either give patients advice that will undermine their health, *see* JA 219-221, or to leave the Title X program. For example, Planned Parenthood, a prominent provider of Title X-funded programs in Baltimore City, *see* JA 225, 235, 257, has stated that it would withdraw from the Title X program due to the Final Rule.

Planned Parenthood Comment Ltr. at 15; *see also* JA 57 (describing the impact of a potential loss of Planned Parenthood clinics in Baltimore City); Appellee Br. at 66.

As attested by a physician who supervises multiple family planning clinics and programs in Baltimore City, under both the scenario where providers are forced to give substandard care or the alternative where providers are forced to close, "patients will suffer." JA 220. Title X grantees provide a wide range of services beyond the provision of reproductive health care, 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." JA 177. In Baltimore City, Title X-provided services are the "final safety net for healthcare for one third of women" in the city. Appellee Br. at 40; JA 211, 226; *see also* Planned Parenthood Comment Ltr. 15-16, 70.

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* JA 220, 238-239. Clinic closures can cause severe health problems, potentially leaving residents of Baltimore with multiple "undiagnosed and untreated" cases of sexually transmitted diseases. JA 227. Indeed, when Planned Parenthood was forced to close a clinic in rural Indiana, a devastating spike in HIV occurred there. Brindis, Claire, Comment Ltr. 6-7 (July 31, 2018); *see also* JA 182-

183. Moreover, some low-income patients will lose access to care that was previously affordable through Title X support. *See* JA 229. These costs all impose barriers to care.

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

Despite receiving extensive evidence of the harms that the Final Rule would cause, HHS tallies only limited direct compliance costs for providers and ignores all other costs as well as the impact of those compliance costs on healthcare. *See* 84 Fed. Reg. at 7777, tbl.1, 7777-82 (spending six pages on costs like training and documenting compliance). HHS 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

Instead of following the instructions from its own *Guidelines* to analyze step-by-step how increased compliance costs and "reductions in government payments" may affect patient access and treatments, *Guidelines* at 23, HHS dismisses all of the Final Rule's likely health costs 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. Contrary to Appellant's claim, HHS's assumption that new providers will enter the market is not a "predictive judgement" that is entitled to deference. *See* Appellants' Br. at 40.

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.) (quotation marks omitted). When a predictive judgment is unreasonable, no special deference is granted.

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."). HHS nonetheless claims that the Final Rule will increase, rather than decrease, the number of providers in the Title X program. But that claim is supported by citation to a *single* online survey, released by the Christian Medical Association in 2009, which addresses only whether some practitioners would limit the scope of their practice if a conscience protection rule were not in place. *See* Appellants' Br. at 40 (citing 84 Fed. Reg. at 7781, n.139). That survey has only limited, if any, relevance. The fact that some providers might limit their practice under a hypothetical scenario (under a different rule) is not evidence that providers would expand their practice into Title X under the Final Rule.

Moreover, 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 a small number of "*faith-based* healthcare professionals," with the vast majority of responses coming from members of the Christian and Catholic Medical Associations.[9] But HHS has not explained "the reasons it considers the underlying evidence to be reliable." *Lands Council v. McNair*, 537 F.3d 981, 994 (9th Cir.

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[9] 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).

2008). 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. Moreover, the agency fails to explain how 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.

Appellants claim that its "expert determination" is entitled to deference. But what HHS calls its "expert determination," is based on only one unrepresentative sample and thus is no more than speculation. *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"). Moreover, Appellants cite *Ohio Valley Environmental Coalition v. Aracoma Coal*, 556 F.3d 177, 199-201 (4th Cir. 2009), to argue that its expert judgment should receive deference. Appellants' Br. at 40. But in that case the agency not only "used detailed measurements . . . to draw conclusions" but also "include[d] substantial analysis and explanation" on the agency's findings. *Ohio Valley Envtl. Coal.*, 556 F.3d at 199-201; *see also Lands Council*, 537 F.3d at 995 (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 *Ohio Valley Environmental Coalition*.

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 number of 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 ignores this guidance to reach unreasonable conclusions in the Final Rule. 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.

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. This claim is suspect because 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 hypothetical group of clients outweighs the sizable number of existing patients 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 flawed conclusion.

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.[10] For that reason, Executive Order 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*

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

at 45. HHS's *Guidelines* likewise 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 patients to lose access to health care, leading to unintended and riskier pregnancies and more sexually transmitted infections. JA 238-239. HHS has no excuse for ignoring these unquantified harms. 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 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).

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, even of an anecdotal nature. See *infra*, Section II. In sum, there were significant errors in HHS's consideration of the harms that will be caused by the Final Rule, helping demonstrate the irregular and unreasonable nature of the rulemaking process that the agency engaged in here.

II. HHS's Claims About the Final Rule's Benefits Are Conclusory and Unsupported

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 its own *Guidelines*, HHS 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 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 provides fundamentally flawed analysis.

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 than exit it. *See id.* at 7782.

In sum, each of the benefits identified by HHS are contrary to both the record and common sense. *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) (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 speculation serves only to demonstrate how flawed, irregular, and unreasonable the rulemaking process was here. *See National Ass'n of Home Builders v. EPA*, 682 F.3d 1032, 1040 (D.C. Cir. 2012) ("[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 above reasons, the preliminary injunction should be affirmed.

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Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

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

This brief complies with the type-volume limitation of Fed. R. App. P. 29(a)(5), because this brief contains 5638 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(f). 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: August 5, 2019

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CERTIFICATE OF SERVICE

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

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Date: August 5, 2019

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