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IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

STATE OF CALIFORNIA, by and through XAVIER BECERRA, Attorney General; *Plaintiff,* v. ALEX AZAR, in his OFFICIAL CAPACITY as SECRETARY of the U.S. DEPARTMENT of HEALTH & HUMAN SERVICES; U.S. DEPARTMENT of HEALTH & HUMAN SERVICES, *Defendants*.	Case No. 3:19-cv-01184-EMC NOTICE OF MOTION AND UNOPPOSED MOTION OF INSTITUTE FOR POLICY INTEGRITY AT NEW YORK UNIVERSITY SCHOOL OF LAW TO FILE AN AMICUS CURIAE BRIEF IN SUPPORT OF PLAINTIFFS Judge: The Honorable Edward M. Chen
ESSENTIAL ACCESS HEALTH, INC.; MELISSA MARSHALL, M.D. *Plaintiffs,* v. ALEX AZAR, in his OFFICIAL CAPACITY as SECRETARY of the U.S. DEPARTMENT of HEALTH & HUMAN SERVICES; U.S. DEPARTMENT of HEALTH & HUMAN SERVICES; and DOES 1-25 *Defendants*.	Case No. 3:19-cv-01195-EMC

TO ALL PARTIES AND THEIR ATTORNEYS OF RECORD:

PLEASE TAKE NOTICE THAT the Institute for Policy Integrity ("Policy Integrity") hereby moves the Court for leave to file the accompanying *amicus curiae* brief in the above-captioned case in support of Plaintiffs' Motion for a Preliminary Injunction, calendared for hearing before this Court on April 18, 2019 at 12:30pm. Policy Integrity has conferred with the parties concerning the filing of this motion. Counsel for Plaintiffs and Defendants have indicated that they both consent to this motion.

I. LEGAL STANDARD

The question of whether to grant permission to file an amicus brief lies solely within the discretion of the Court. *Hoptowit v. Ray*, 682 F.2d 1237, 1260 (9th Cir. 1982). In general, courts have "exercised great liberality" when determining whether to allow amicus participation. *Woodfin Suite Hotels, LLC v. City of Emeryville*, No. C-06-1254, 2007 WL 81911, at *3 (N.D. Cal. Jan. 9, 2007) (Armstrong, J.); *accord Ou-Young v. Roberts*, No. C-13-4442 EMC, 2013 WL 6732118, at *3 (N.D. Cal. Dec. 20, 2013) (Chen, J.). "[A]n individual seeking to appear as amicus must merely make a showing that his participation is useful or otherwise desirable to the court." *Woodfin Suite Hotels*, 2007 WL 81911, at *3. As such, district courts welcome amicus briefs where "the amicus has unique information or perspective that can help the court beyond the help that the lawyers for the parties are able to provide." *NGV Gaming, Ltd. v. Upstream Point Molate, LLC*, 355 F. Supp. 2d 1061, 1067 (N.D. Cal. 2005) (Conti, J.) (internal quotation marks omitted). And courts welcome briefs "from non-parties concerning legal issues that have potential ramifications beyond the parties directly involved." *Sonoma Falls Developers, LLC v. Nevada Gold & Casinos, Inc.*, 272 F. Supp. 2d 919, 925 (N.D. Cal. 2003) (Walker, J.). Moreover, amicus briefs should normally be allowed when the amicus has an interest in the case. *See In re Heath*, 331 B.R. 424, 430 (9th Cir. B.A.P. 2005). Policy Integrity's motion satisfies all of these factors.

II. INTEREST OF *AMICUS CURIAE*

Policy Integrity has a strong interest in this case. 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. Policy Integrity's

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. Our director, Richard L. Revesz, has published more than eighty articles and books on environmental and administrative law, including on the legal and economic principles for rational regulatory decisions. *See e.g.*, Richard Revesz & Michael Livermore, *Retaking Rationality: How Cost-Benefit Analysis Can Better Protect the Environment and Our Health* (2008).[1] 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 the *Handbook of Regulatory Impact Assessment* (Claire A. Dunlop & Claudio M. Radaelli eds., 2016).

In furtherance of its mission to promote rational decisionmaking, Policy Integrity has filed many *amicus curiae* briefs advising courts on 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) (arguing that failure to consider costs, in the form of forgone benefits, is arbitrary); *see California*, 277 F. Supp. 3d at 1123 (ruling that failure to consider the forgone benefits was arbitrary).

Policy Integrity has particular expertise on the regulatory impact analysis that the Department of Health and Human Services ("HHS") conducted in support of its rulemaking on the obligations of Title X grantees. We both submitted comments on the proposed rule, Policy Integrity Comment Ltr. (Aug. 1, 2018)[2], and formally met with the Office of Information and Regulatory Affairs to present critiques of the regulatory impact analysis. Policy Integrity seeks to provide this court with context on the legal and economic standards for best practices in regulatory impact analysis, which will show that HHS's analysis of the Final Rule's costs and benefits arbitrarily violated those standards. Policy Integrity therefore seeks leave to appear as amicus and file the accompanying memorandum in support of the motions for preliminary injunction.

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[1] A full list of publications is available on Professor Revesz's online faculty profile, https://its.law.nyu.edu/facultyprofiles/index.cfm?fuseaction=profile.overview&personid=20228.
[2] https://www.regulations.gov/document?D=HHS-OS-2018-0008-192646.

The Administrative Procedure Act requires an agency to "examine the relevant data and articulate a satisfactory explanation for its action." *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983). Courts reverse where an examination of that explanation makes clear that the agency failed to consider "an important aspect of the problem." *Id.* One important factor that agencies must address when explaining a decision is the cost that the decision imposes on society. Executive Order 12,866, which has governed regulatory decisionmaking since 1993 and continues to apply today,[3] instructs agencies to consider a regulation's costs, including "any adverse effects . . . on health [and] safety." Exec. Order No. 12,866 § 6(a)(3)(C)(ii), 58 Fed. Reg. 51,735 (Oct. 4, 1993). And courts have consistently required agencies to take the costs of their actions into account. *See Michigan v. EPA*, 135 S. Ct. 2699, 2707 (2015) (explaining that under 42 U.S.C. § 7412, "[n]o regulation is 'appropriate' if it does significantly more harm than good").

In this case, as explained in the proposed amicus brief, HHS has not adequately assessed the health and economic impacts of its final rule, Compliance with Statutory Program Integrity Requirements, 84 Fed. Reg. 7714 (Mar. 4, 2019) ("Final Rule"). In particular, HHS has failed to assess the Final Rule's substantial health costs, grossly underestimated and ignored direct compliance costs, and made conclusory statements about the Rule's alleged benefits without evidentiary support. Policy Integrity's general interest in this case is to ensure that agencies comply with their obligation to accurately assess the economic and health impacts of regulatory decisions.

III. POLICY INTEGRITY'S EXPERTISE WILL BENEFIT THE COURT

Policy Integrity's proposed *amicus* brief is also useful to the court. Policy Integrity has experience with the Final Rule at issue in this case, having submitted comments to HSS in its proposal phase. Policy Integrity Comment, *supra*. Policy Integrity has harnessed that experience, as well as its expertise in cost-benefit analysis, to explain why HHS's treatment of the Final Rule's economic

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[3] *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."), https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/memoranda/2017/M-17-21-OMB.pdf.

impacts was arbitrary and capricious. While Plaintiffs have made arguments about HHS's failure to provide a reasoned explanation for the Final Rule, Policy Integrity's focus on the agency's economic analysis is unique.

IV. MEET AND CONFER AND TIMELINESS

Policy Integrity has conferred with the parties concerning the filing of this motion. Plaintiffs and Defendants both consent to this motion.

This motion is timely. Though this Court does not have rules governing the timing of *amicus* briefs, the Court may look for guidance to the rules of other district courts. In the U.S. District Court for the District of Columbia, the Local Rules require an amicus motion to be filed "in a timely manner such that it does not unduly delay the Court's ability to rule on any pending matter." Rules of the U.S. District Court for the District of Columbia, Local Rule 7(o)(2) at 31 (June 2018), http://www.dcd.uscourts.gov/sites/dcd/files/LocalRulesJune2018.pdf. In this case, there is time for the Court to decide Policy Integrity's motion without unduly delaying the decision on the pending matter. Defendants' opposition is due April 8 and Plaintiffs' reply is due April 11.

CONCLUSION

For the forgoing reasons, Policy Integrity respectfully requests that the Court grant this motion and accept for filing the accompanying *amicus curiae* brief.

Dated: New York, NY
April 5, 2019

Respectfully submitted,

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IN THE UNITED STATES DISTRICT COURT
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STATE OF CALIFORNIA, by and through XAVIER BECERRA, Attorney General; *Plaintiff,* v. ALEX AZAR, in his OFFICIAL CAPACITY as SECRETARY of the U.S. DEPARTMENT of HEALTH & HUMAN SERVICES; U.S. DEPARTMENT of HEALTH & HUMAN SERVICES, *Defendants*.	Case No. 3:19-cv-01184-EMC BRIEF OF THE INSTITUTE FOR POLICY INTEGRITY AT NEW YORK UNIVERSITY SCHOOL OF LAW AS AMICUS CURIAE IN SUPPORT OF PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION Hearing: April 18, 2019 Time: 12:30 p.m. Courtroom: Courtroom 5, 17th Floor Judge: The Honorable Edward M. Chen
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The Institute for Policy Integrity at New York University School of Law ("Policy Integrity")[1] submits this brief as *amicus curiae* in support of Plaintiffs' motions for preliminary injunction of Defendants' final rule, Compliance with Statutory Program Integrity Requirements, 84 Fed. Reg. 7714 (Mar. 4, 2019) ("Final Rule").

INTEREST OF AMICUS CURIAE

Policy Integrity is a nonpartisan, not-for-profit think tank dedicated to improving the quality of government decisionmaking through advocacy and scholarship in the fields of administrative law, economics, and public policy. Policy Integrity's 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. Our director, Richard L. Revesz, has published more than eighty articles and books on environmental and administrative law, including on the legal and economic principles for rational regulatory decisions. *See e.g.*, Richard Revesz & Michael Livermore, *Retaking Rationality: How Cost-Benefit Analysis Can Better Protect the Environment and Our Health* (2008).[2] 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 the *Handbook of Regulatory Impact Assessment* (Claire A. Dunlop & Claudio M. Radaelli eds., 2016).

Policy Integrity has filed many *amicus curiae* briefs advising courts on 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) (arguing that failure to consider forgone benefits is arbitrary); *see California*, 277 F. Supp. 3d at 1123 (ruling that failure to consider the forgone benefits was arbitrary).

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

[2] A full list of publications is available on Professor Revesz's online faculty profile, https://its.law.nyu.edu/facultyprofiles/index.cfm?fuseaction=profile.overview&personid=20228

Policy Integrity has particular expertise on the regulatory impact analysis that the Department of Health and Human Services (HHS) conducted in support of its rulemaking on the obligations of Title X grantees. We both submitted comments on the proposed rule, Policy Integrity Comment Ltr. (Aug. 1, 2018)[3], and formally met with the Office of Information and Regulatory Affairs to present critiques of the regulatory impact analysis. Policy Integrity seeks to provide this court with context on the legal and economic standards for best practices in regulatory impact analysis, which will show that HHS's analysis of the Final Rule's costs and benefits arbitrarily violated those standards. Policy Integrity therefore seeks leave to appear as amicus and file the following memorandum in support of the motions for preliminary injunction.

SUMMARY OF ARGUMENT

Plaintiffs' motions for preliminary injunction argue that the Final Rule is arbitrary and capricious because HHS failed to assess the Rule's substantial health costs, grossly underestimated and ignored compliance costs, and made conclusory statements about the Rule's alleged benefits without evidentiary support. *E.g.*, Cal. Mot. Prelim. Inj. 15-19 (19-1184, ECF No. 26) ("Cal. Mot."); Pls.' Mot. Prelim. Inj. 15-19 (19-1195, ECF No. 25) ("Essential Health Mot."). This memorandum provides this Court with context on the legal standards for reviewing regulatory impact analyses and the economic standards for conducting regulatory impact analyses—including HHS's own guidelines on best practices for assessing costs and benefits. The Final Rule's regulatory impact analysis thoroughly flunks those standards, and HHS's justification for the Final Rule is therefore arbitrary.

HHS's justification for the Final Rule enumerates a few highly speculative benefits while simultaneously disregarding several important categories of significant costs highlighted by commenters. Both the conclusory pronouncement of benefits and the outright dismissal of probable costs lack the reasoned explanation required under the Administrative Procedure Act and violate clear instructions from both the Office of Management and Budget's *Circular A-4 on Regulatory*

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[3] *Available at* https://www.regulations.gov/document?D=HHS-OS-2018-0008-192646.

Analysis and HHS's *Guidelines for Regulatory Impact Analysis*.

Courts have made clear that agencies must reasonably consider 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.

Similarly, 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.

Finally, HHS fails to provide any evidence to support many of its 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.

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, 5 U.S.C. § 706(2) (2012), if an agency failed 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). "Important aspects" of the Final Rule include its costs and benefits because, as the Supreme Court has made clear, "reasonable regulation ordinarily requires paying attention to the advantages *and* the disadvantages of agency decisions." *Michigan v. EPA*, 135 S. Ct. 2699, 2707 (2015) (emphasis in original). In weighing regulatory actions, agencies cannot "put a thumb on the scale" by undervaluing key effects and overvaluing others. *Ctr. for Biological Diversity v. Nat'l Highway Traffic Safety Admin.*, 538 F.3d 1172, 1198 (9th Cir. 2008); *see also California v. BLM*,

277 F. Supp. 3d 1106, 1123 (N.D. Cal. 2017) (agencies impermissibly considered only "one side of the equation" by calculating benefits and ignoring costs).

Regulatory impact analyses can reveal to courts whether an agency ignored an "important aspect" of the rule's costs or benefits, failed to examine "relevant data" from the record on the rule's costs or benefits, or otherwise irrationally based its regulatory choices on arbitrary analysis. *See Nat'l Ass'n of Home Builders v. EPA*, 682 F.3d 1032, 1040 (D.C. Cir. 2012); *id.* at 1036 ("When 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.").

Agencies conduct regulatory impact analyses under Executive Order 12,866. 58 Fed. Reg. 51,735 (Oct. 4, 1993). Pursuant to Executive Order 12,866, the Office of Management and Budget classified the Final Rule as a "significant regulatory action," requiring a thorough regulatory impact analysis. *See* 84 Fed. Reg. at 7775-76. Indeed, any regulation that, like the Final Rule, "materially alters the . . . obligations" of federal grantees is a "significant" action. Exec. Order No. 12,866 § 3(f)(3); *see also* Policy Integrity Comment Ltr. 2. Executive Order 12,866 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). The Office of Management and Budget under President George W. Bush issued *Circular A-4 on Regulatory Analysis*, to "standardiz[e] the way benefits and costs of Federal regulatory actions are measured." Office of Mgmt. & Budget, *Circular A-4* at 1 (2003) [hereinafter *Circular A-4*]. HHS has also published its own internal guidelines for best practices. HHS, *Guidelines for Regulatory Impact Analysis* (2016) [hereinafter HHS, *Guidelines*][4]. Both *Circular A-4* and HHS's *Guidelines* detail the best economic practices for gathering data, making reasonable assumptions, assessing costs and benefits, and comparing overall regulatory impacts.

In particular, *Circular A-4* and HHS's *Guidelines* explain that direct and indirect health costs must be accounted for and quantified to the fullest extent practicable; that estimates of direct

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

compliance costs should be based on surveys, literature reviews, and other reliable sources and reasonable assumptions; and that benefits should be quantified to the fullest extent practicable and based on reasonable estimates. As detailed in the next three sections, the Final Rule's impact analysis violates all these standards for best practices and ignores both "important aspects of the problem" and "relevant data," *State Farm*, 463 U.S. at 43, and consequently HHS has arbitrarily and capriciously violated the requirements of the Administrative Procedure Act.

I. HHS's Failure to Assess the Rule's Significant Health Costs Violated Best Practices for Regulatory Impact Analysis and Was Arbitrary and Capricious

Courts have made clear that agencies must reasonably consider the important costs of their rules, including any significant direct or indirect health costs. In *Michigan v. EPA*, the Supreme Court ruled that "'cost' includes more than the expense of complying with regulations" and that "any disadvantage could be termed a cost." 135 S. Ct. 2699, 2707 (2015). In fact, the Supreme Court highlighted that it would generally be irrational not to consider the "harms that regulation might do to human health." *Id.* Other courts have similarly long required agencies to assess all important regulatory costs to health, safety, and welfare, whether the costs are direct or indirect. *E.g.*, *Competitive Enter. Inst. v. Nat'l Highway Traffic Safety Admin.*, 956 F.2d 321, 326-27 (D.C. Cir. 1992) (remanding a fuel-efficiency rule due to the agency's failure to acknowledge indirect safety costs); *Corrosion Proof Fittings v. EPA*, 947 F.2d 1201, 1225 (5th Cir. 1991) (striking down a rule banning asbestos for failure to consider the indirect safety effects of substitute, asbestos-free car brakes being less effective).

Proper consideration of direct and indirect effects is a crucial part of any regulatory impact analysis. *See* Revesz & Livermore, *Retaking Rationality*, *supra*, at 57-58. Executive Order 12,866 requires 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). Longstanding guidance on regulatory impact analysis from the Office of Management and Budget similarly instructs 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." *Circular A-4* at 26. Furthermore, agencies must try to the extent "feasible" to "quantify and monetize

ancillary benefits and countervailing risks," and "[t]he same standards of information and analysis quality that apply to direct benefits and costs should be applied" to indirect effects as well. *Id.*; *see also* HHS, *Guidelines* at 43 (requiring HHS to "quantify[ ] impacts to the greatest extent possible").

Despite these requirements to assess all important costs, HHS's regulatory impact analysis focuses instead almost exclusively on the direct costs of compliance, like the paperwork costs of additional documentation and learning the rule. 84 Fed. Reg. 7714, 7777-82 (spending six pages on costs like training and documenting compliance). In contrast, the Final Rule spends a mere two paragraphs responding to commenters' extensive documentation of the significant probable impacts to the health of patients, *Id.* at 7775, before later assuming without any quantitative analysis that the "net impact" to patients "will be zero," *Id.* at 7782. In reaching this conclusion, there is no evidence that 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 the data from public comments, or otherwise attempted in any meaningful way to quantify any of the likely impacts to patients, such as lost access to care, increased pregnancies, and transaction costs. The likely impacts to patients are discussed in the following subsections.

A. The Final Rule Will Inevitably and Detrimentally Affect Patients' Health

To understand the categories and magnitude of health costs that HHS failed to properly consider, it is useful to understand grantees' and providers' potential responses to the Final Rule. The Final Rule's Separation Requirement forces clinics that provide abortion services to maintain separate facilities and finances for their Title X programs, a requirement that would undoubtedly increase their expenses. Additionally, many Title X recipients, including Plaintiffs, assert that compliance with the Final Rule's Gag Requirement would be inconsistent with ethical and professional principles, and indicate that many providers will respond by dropping out of the program rather than violate these standards.

Therefore, affected entities may choose to respond to the Final Rule in a handful of ways:

(1) Comply with the rule and incur the additional costs of the Separation Requirement;

(2) Forgo Title X funding;

(3) Cease to provide abortion services or abortion counseling; or

(4) Close due to the requirements of the Final Rule.

In the first two of these scenarios, it is likely that family planning and reproductive health services become costlier for patients. Their care providers must raise costs to either meet the Separation Requirement (e.g., to establish new facilities and hire new staff) or to replace lost federal funding. In the third response scenario, women lose access to legal, safe, and affordable abortion services and to information about their options. In the final scenario, patients must go elsewhere to receive the reproductive healthcare and family planning services that they have come to rely on. In all scenarios, the end result is that some patients will lose access to some critical healthcare services, and that loss of access will result in a number of very real health, financial, physical, and psychological consequences for patients and their families.

These likely scenarios implicate at least three categories of costs that were either dismissed without reasoned explanation or ignored entirely by the agency. These costs are: (i) the health costs arising from lack of access to healthcare providers; (ii) the likely increase in unwanted pregnancies and births; and (iii) the transaction costs imposed on patients searching for new providers. Each of these costs is ignored in the Final Rule, which instead asserts that there are *no* costs beyond quantified compliance costs. 84 Fed. Reg. at 7777, Table 1 (listing "Non-quantified Costs: None").

B. Patients Will Experience Significant Costs from Lost Access to Healthcare

Numerous commenters supplied HHS with arguments and evidence that the changes in the Title X program brought about by the Final Rule would adversely affect patient health. 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 diseases," 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 Comment Ltr. 3 (July 31, 2018). If these providers close their doors or raise their costs as a result of the Final Rule, some patients will be left without a meaningful alternative, incurring substantial health costs. Many Title X recipients operate in rural areas where their patients have scarce access to substitute healthcare providers. Cal. Mot. 20; Essential Health Mot. 19; Planned Parenthood Comment Ltr. 15-16, 70 (July 31, 2018). These closures will result in 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. These negative health effects weigh against the Final Rule, and the agency must acknowledge and account for them. HHS's own 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." HHS, *Guidelines* at 23. HHS arbitrarily and capriciously failed to do so in the Final Rule.

C. Patients Will Experience Significant Costs from Increased Unintended Pregnancies and Births

Although HHS acknowledges that it expects some Title X grantees to exit the program in response to the Final Rule, the agency argues that lost grantees will be replaced by new grantees entering the program, with no net costs to the patient population. However, the agency provides no evidence to support its claim that an equal number providers will enter the program as exit, 84 Fed. Reg. at 7782, or the assumption that new providers will be able to cover the same large patient population that existing providers previously served. Further, the Final Rule specifically intends to open up 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. Therefore, these hypothetical new grantees are unlikely to serve as perfect substitutes for those providers that currently provide a full range of services but may be forced to exit the program in response to the Final Rule. The only rational conclusion is that some number of patients will lose access to contraceptive services they have come to rely on. HHS, however, argues that enabling Title X funding to support clinics that provide only natural planning methods will, in fact, "decrease unintended pregnancies, not increase them, because clients are more likely to visit clinics that respect their views and beliefs." *Id.* at 7743. The agency provides no evidence or quantitative analysis to estimate how many women currently decline to seek Title X care because of their personal beliefs. Nor does the agency provide any quantitative assessment of whether this body of women 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* HHS, *Guidelines* at 47, yet HHS disregards its own

Guidelines in order to reach its arbitrary conclusion.

HHS's assertion that clinic closures will not result in an increase in unwanted pregnancies runs counter to the substantial weight of record evidence. In response to the Final Rule's proposed version, experts submitted comments highlighting that 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. 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 from clinic closures, the agency minimally should 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." HHS, *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).

D. Patients Will Experience Significant Transaction Costs

HHS acknowledges that it expects some healthcare facilities to cease providing Title X services as a result of the Final Rule, but nevertheless predicts that "the net impact on those seeking services from current grantees will be zero," as new grantees will apply for participation in the program, replacing those that have exited, and "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." 84 Fed. Reg. at 7782. 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 that new grantees are, according to the very intention of the Final Rule itself, likely to provide a more limited range of services than

existing grantees. Further, the analysis ignores the costs incurred by patients in seeking out these new services as well as the emotional costs of having lost a familiar healthcare provider. *See* HHS, *Guidelines* at 26-28, 30-32 (detailing how to quantify the costs of time and travel). Finally, 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, 84 Fed. Reg. at 7789, patients may have difficulty finding and accessing care even at service sites previously familiar to them.

E. HHS Cannot Ignore Costs Even If 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." *Id.* at 7775. Therefore, the Department concluded that these costs "are not likely or calculable impacts." *Id*. In other words, just because indirect health costs are hard to quantify, HHS assumes that the costs are "not likely" or are "None." *Id.* at 7777, Table 1 (listing "Non-quantified Costs: None").

However, HHS cannot rationally ignore costs even if they are 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 Assocs., 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). Executive Order 12,866 also 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). HHS's own guidelines on regulatory analysis contain an entire chapter on the importance of, and approaches for, meaningfully considering nonquantified effects. *See* HHS, *Guidelines* at 47-51; *id.* at 47 ("Ignoring potentially important nonquantified effects may lead to poor decisions."); *compare* HHS, *Guidelines* 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").

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 III.

II. HHS Arbitrarily Ignored Both Its Own Guidelines and Record Evidence and Grossly Underestimated 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*, in *Handbook of Regulatory Impact Assessment* 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 *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." HHS, *Guidelines* at 32.

Yet in calculating the Rule's direct compliance costs, there is no evidence that HHS followed its own 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. Those estimates were seemingly derived from thin air, in stark contrast to HHS's own best practices for estimating costs. For example, when HHS has issued rules affecting Head Start grantees, its regulatory impact analyses rely on "internal datasets" based on grantees' budgetary data and comprehensive surveys of grantees. *See* 81 Fed. Reg. 61,293, 61,375. By contrast, there is no indication that HHS talked to any Title X grantees about their likely costs before finalizing this Rule. That omission is particularly troubling because, under the longstanding Executive Order on regulatory impact analysis, proposed rules that "materially alter the . . . obligations of recipients" of federal grants are deemed to be "significant regulatory action[s]," Exec. Order 12,866 § 3(f)(3), and agencies must detail "the potential costs and benefits" of such actions, *id.* § 6(a)(3)(B)(ii).

Multiple Title X grantees (the regulated entities subject to the Rule's compliance costs) submitted detailed comments in response to the proposed rule that, indicated their own capital costs of renovation and construction would be much higher, 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). 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. Plaintiff Essential Health estimates that its own compliance with the Separation Rule will cost "$325,000 for the first year, and $212,500 for every year after." Essential Health Mot. 32.

In the Final Rule, HHS reports that "[a]fter receiving public comments," 84 Fed. Reg. at 7718, it increased its central estimate of capital costs from $20,000 to $30,000 per facility, *id.* at 7782. Yet even that trivially increased estimate is still more than 10 to 20 times below the estimates

submitted by grantees themselves. HHS still does not identify any data source, assumptions, methodology, or literature that supports its estimates. And HHS still has not estimated any of the ongoing costs of the Separation Requirement, which grantees report will cost them millions more on top of the capital expenses. HHS instead insists, without any evidence, that grantees' estimates were simply too "high," and HHS vaguely anticipates, again without any evidence, that lower cost methods of compliance will materialize. *Id.* at 7781. Ultimately, HHS seeks to fault the commenters for "not provid[ing] sufficient data to estimate these effects." *Id.* But it is the responsibility of the agency, not of commenters, to consider the "important aspect[s] of the problem" and "examine relevant data." *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983). Specifically, under its own guidelines for analysis, it was HHS's responsibility to "use market data . . . obtained through interviews, literature reviews, review of online merchandise catalogues, or other sources" to accurately assess costs. HHS, *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.

The Final Rule's analysis of direct compliance costs underestimates capital expenses by an order of magnitude 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. The Final Rule's Enumerated Benefits Are Conclusory and Unsupported by Evidence

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 following the erosion of the nondirective mandate, 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 its likelihood, 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." HHS, *Guidelines* at 47. Therefore, "[c]lear presentation of the available evidence" is needed to support unbiased and transparent reasoning. *Id*.

While HHS claims that the Final Rule will result in "increased compliance" with rules guarding against the misuse of Title X funds, the agency presents *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, HHS provides no evidence for its assertion that the Final Rule will result in "an expanded number" of providers entering the Title X program. *See* 84 Fed. Reg. at 7777. While HHS acknowledges that it expects some Title X grantees to exit the program in response to the Final Rule, the agency argues that they will be replaced by new grantees entering the program now that they are permitted to offer only a limited range of contraception services. *See id.* at 7741. However, the agency provides no evidence to support its claim that a larger number of providers will enter the program as exit. *See id.* at 7782. Moreover, these hypothetical new grantees are unlikely to serve as perfect substitutes for those providers that currently provide a full range of services but must exit the program as their ethical and professional response to the Final Rule. As a result, some number of patients will lose access to contraceptive services they have come to rely on. HHS nevertheless argues that enabling Title X funding to support clinics that provide only natural planning methods will, in fact, "*decrease* unintended pregnancies… because clients are more likely to visit clinics that respect their views and beliefs." *Id.* at 7743 (emphasis added). The agency provides no evidence or analysis to estimate how many women currently do not seek Title X care because of their personal beliefs, nor does the agency

provide any rational argument that this body of women outweighs the sizable number that will lose access to the services they current receive under the Title X program.

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) (quoting *McDonnell Douglas Corp*, 375 F.3d at 1187). Here, each of the benefits identified by HHS lack evidentiary support and are contrary to both the record and common sense. That the Final Rule's entire beneficial impact is comprised of "unsupported suppositions" renders the Rule arbitrary and capricious. *Id.*; *see also 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]").

CONCLUSION

This Court should grant plaintiffs' motions for preliminary injunction.

Dated: New York, NY
April 5, 2019

Respectfully submitted,

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IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

STATE OF CALIFORNIA, by and through XAVIER BECERRA, Attorney General; *Plaintiff,* v. ALEX AZAR, in his OFFICIAL CAPACITY as SECRETARY of the U.S. DEPARTMENT of HEALTH & HUMAN SERVICES; U.S. DEPARTMENT of HEALTH & HUMAN SERVICES, *Defendants*.	Case No. 3:19-cv-01184-EMC [PROPOSED] ORDER Judge: The Honorable Edward M. Chen
ESSENTIAL ACCESS HEALTH, INC.; MELISSA MARSHALL, M.D. *Plaintiffs,* v. ALEX AZAR, in his OFFICIAL CAPACITY as SECRETARY of the U.S. DEPARTMENT of HEALTH & HUMAN SERVICES; U.S. DEPARTMENT of HEALTH & HUMAN SERVICES; and DOES 1-25 *Defendants*.	Case No. 3:19-cv-01195-EMC

This matter having come before the Court by motion of proposed *amicus curiae* Institute for Policy Integrity at New York University School of Law, seeking leave to file a brief *amicus curiae* in the above-captioned matter, and the Court having reviewed the file and pleadings herein, and being otherwise fully advised in the matter, hereby finds good cause to allow *amicus* participation.

IT IS HEREBY ORDERED:

The Motion to File an *Amicus Curiae* Brief in Support of Plaintiffs is GRANTED.

This ____ day of _____, 2019.

_____
The Honorable Edward M. Chen