

Exhibit A

Taylor Washburn, WSBA #51524
LANE POWELL PC

JUDGE STANLEY A. BASTIAN

1420 Fifth Avenue, Suite 4200
Seattle, WA 98101-2375
washburnt@lanepowell.com; T: (206) 223-7000

Madison Condon, New York State Bar # 5653480 (*pro hac vice pending*)
Jason Schwartz, Virginia State Bar # 73398 (*pro hac vice pending*)
Institute for Policy Integrity, New York University Law School
139 MacDougal Street, 3rd Floor, New York, NY 10012
madison.condon@nyu.edu; T: (212) 998-6239

**UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF WASHINGTON
AT YAKIMA**

STATE OF WASHINGTON,

Plaintiff,

v.

ALEX M. AZAR II, et al.,

Defendants.

No. 1:19-cv-03040-SAB

NATIONAL FAMILY PLANNING &
REPRODUCTIVE HEALTH
ASSOCIATION, et al.,

Plaintiffs,

v.

ALEX M. AZAR II, et al.,

Defendants.

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

Noted for April 25, 2019
With Oral Argument at 10:00 a.m.

TABLE OF CONTENTS

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23

I. INTEREST OF AMICUS CURIAE1

II. SUMMARY OF ARGUMENT3

III. ARGUMENT4

 A. HHS’s Failure to Assess the Rule’s Significant Health Costs Violated Best Practices for Regulatory Impact Analysis and Was Arbitrary and Capricious...7

 B. The New Rule Will Inevitably and Detrimentally Affect Patients’ Health9

 1. Patients Will Experience Significant Costs From Lost Access To Healthcare10

 2. Patients Will Experience Significant Costs From Increased Unintended Pregnancies and Births11

 3. Patients Will Experience Significant Transaction Costs13

 4. HHS Cannot Ignore Costs Even If They Are Uncertain or Difficult to Quantify14

 C. HHS Arbitrarily Ignored Both Its Own Guidelines and Record Evidence and Grossly Underestimated Compliance Costs16

 D. The New Rule’s Enumerated Benefits Are Conclusory and Unsupported by Evidence19

IV. CONCLUSION22

TABLE OF AUTHORITIES

Cases

Am. Trucking Associations, Inc. v. EPA, 175 F.3d 1027 (D.C. Cir. 1999) 15

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)..... 2

California v. BLM, 277 F. Supp. 3d 1106 (N.D. Cal. 2017) 2, 5

Competitive Enter. Inst. v. Nat’l Highway Traffic Safety Admin., 956 F.2d 321 (D.C. Cir. 1992)..... 7

Corrosion Proof Fittings v. EPA, 947 F.2d 1201 (5th Cir. 1991) 7

Ctr. for Biological Diversity v. Nat’l Highway Traffic Safety Admin., 538 F.3d 1172 (9th Cir. 2008) 5

McDonnell Douglas Corp. v. U.S. Dep’t of the Air Force, 375 F.3d 1182 (D.C. Cir. 2004)..... 13, 21

Michigan v. EPA, 135 S. Ct. 2699 (2015) 5, 7

Motor Vehicle Mfrs. Ass’n v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29 (1983) passim

Nat’l Ass’n of Home Builders v. EPA, 682 F.3d 1032 (D.C. Cir. 2012) 5

Public Citizen v. Fed. Motor Carrier Safety Admin., 374 F.3d 1209 (D.C. Cir. 2004)..... 15

United Techs. Corp. v. Dep’t of Def., 601 F.3d 557 (D.C. Cir. 2010) 21

Whitman v. Am. Trucking Ass’ns, 531 U.S. 457 (2001) 15

Statutes

5 U.S.C. § 706(2) 4

Regulations

58 Fed. Reg. 51,735 (Oct. 4, 1993)..... passim

1 81 Fed. Reg. 61,293 (Sep. 6, 2016) 17

2 83 Fed. Reg. 25,502 (June 1, 2018)..... 17

3 84 Fed. Reg. 7714 (Mar. 4, 2019).....passim

4 **Comments**

5 Brindis Comment Ltr. (July 31, 2018)..... 11, 13

6 Essential Access Health Comment Ltr. (Aug 1, 2019)..... 17, 18

7 Nat’l Family Planning & Reproductive Health Ass’n. Comment Ltr. (July 31,
8 2018)..... 18

9 Policy Integrity Comment Ltr. (Aug. 1, 2018) 2, 5

10 Planned Parenthood Comment Ltr. (July 31, 2018) 11, 18

11 **Other Authorities**

12 Dep’t of Health and Human Services,
13 *Guidelines for Regulatory Impact Analysis* (2016).....passim

14 Dep’t of Health and Human Services,
15 *Guidelines for Regulatory Impact Analysis: A Primer* (2016)..... 16

16 Office of Mgmt. & Budget, *Circular A-4* (2003)passim

17 Revesz, Richard & Michael Livermore, *Retaking Rationality: How Cost-Benefit*
18 *Analysis Can Better Protect the Environment and Our Health* (2008) 1, 7

19 Schwartz, Jason “Approaches to Cost-Benefit Analysis” in the *Handbook of*
20 *Regulatory Impact Assessment* (Claire A. Dunlop & Claudio M. Radaelli eds.,
21 2016)..... 1, 2, 16

22

23

1 The Institute for Policy Integrity at New York University School of Law
2 (“Policy Integrity”)¹ submits this brief as *amicus curiae* in support of Plaintiffs’
3 motions for preliminary injunction of Defendants’ final rule, Compliance with
4 Statutory Program Integrity Requirements, 84 Fed. Reg. 7714 (Mar. 4, 2019) (“New
5 Rule”).

6 I. INTEREST OF AMICUS CURIAE

7 Policy Integrity is a nonpartisan, not-for-profit think tank dedicated to
8 improving the quality of government decisionmaking through advocacy and
9 scholarship in the fields of administrative law, economics, and public policy. Policy
10 Integrity’s legal and economic experts have produced extensive scholarship on the
11 best practices for regulatory impact analysis and the proper valuation of regulatory
12 costs and benefits. Our director, Richard L. Revesz, has published more than eighty
13 articles and books on environmental and administrative law, including on the legal
14 and economic principles for rational regulatory decisions. *See e.g.*, Richard Revesz
15 & Michael Livermore, *Retaking Rationality: How Cost-Benefit Analysis Can Better*
16 *Protect the Environment and Our Health* (2008).² Our legal director, Jason A.
17 Schwartz, has similarly produced expert scholarship on regulatory decision-making,

18
19 ¹ This brief does not purport to represent the views of New York University School
20 of Law, if any. Policy Integrity states that no party’s counsel authored this brief in
21 whole or in part, and no party or party’s counsel contributed money intended to
22 fund the preparation or submission of this brief. No person—other than the *amicus*
23 *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 faculty profile,
[https://its.law.nyu.edu/facultyprofiles/index.cfm?fuseaction=profile.overview&per
sonid=20228](https://its.law.nyu.edu/facultyprofiles/index.cfm?fuseaction=profile.overview&personid=20228).

1 including the book chapter, “Approaches to Cost-Benefit Analysis” in the *Handbook*
2 *of Regulatory Impact Assessment* (Claire A. Dunlop & Claudio M. Radaelli eds.,
3 2016).

4 Policy Integrity has filed many *amicus curiae* briefs advising courts on
5 agencies’ economic analyses of regulatory actions. *See e.g.*, Br. for Inst. for Policy
6 Integrity as Amicus Curiae, *California v. U.S. Bureau of Land Mgmt.*, 277 F. Supp.
7 3d 1106 (N.D. Cal. 2017) (arguing that failure to consider forgone benefits is
8 arbitrary); *see California*, 277 F. Supp. 3d at 1123 (ruling that failure to consider the
9 forgone benefits was arbitrary).

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

21
22
23 ³ Available at <https://www.regulations.gov/document?D=HHS-OS-2018-0008-19264>.

II. SUMMARY OF ARGUMENT

1
2 Plaintiffs' motions for preliminary injunction argue that the New Rule is
3 arbitrary and capricious because HHS failed to assess the Rule's substantial health
4 costs, grossly underestimated and ignored compliance costs, and made conclusory
5 statements about the Rule's alleged benefits without evidentiary support. *E.g.*, Wash.
6 Mot. Prelim. Inj. 11-12; 27-29; 34-38 ECF No. 9 ("Wash. Mot."); Nat'l Fam. Plan.
7 & Reprod. Health Ass'n. Pls.' Mot. Prelim. Inj. 18-27, ECF No. 18 ("NRPRHA
8 Mot."). This memorandum provides this Court with context on the legal standards
9 for reviewing regulatory impact analyses and the economic standards for conducting
10 regulatory impact analyses—including HHS's own guidelines on best practices for
11 assessing costs and benefits. The New Rule's regulatory impact analysis thoroughly
12 flunks those standards, and HHS's justification for the New Rule is therefore
13 arbitrary.

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

21 Courts have made clear that agencies must reasonably consider all important
22 regulatory costs, including any significant direct or indirect health costs. Yet HHS
23 unreasonably concludes that the New Rule will impose no costs on public health or

1 patient wellbeing, despite ample evidence in the record to the contrary, and despite
2 clear guidelines on the need to quantitatively assess such health costs to the fullest
3 extent practicable.

4 Similarly, the New Rule significantly underestimates the direct costs of
5 compliance, contrary to both common sense and evidence in the record indicating
6 these costs will be larger by an order of magnitude. HHS cites no market data,
7 literature, economic models, grantee interviews, or any other source or methodology
8 to support its gross underestimates.

9 Finally, HHS fails to provide any evidence to support many of its claimed
10 expected benefits of the New Rule, including a predicted net reduction in unwanted
11 pregnancies and “enhanced compliance” with Title X’s prohibition on the use of
12 funds for abortion services.

13 By ignoring best practices and plucking from thin air its estimates of costs and
14 benefits, HHS relies on a flawed justification of the New Rule, rendering its
15 decisionmaking arbitrary and capricious.

16 **III. ARGUMENT**

17 Final agency actions, like the New Rule, are arbitrary and capricious under
18 the Administrative Procedure Act, 5 U.S.C. § 706(2) (2012), if an agency failed to
19 “examine the relevant data,” “consider an important aspect of the problem,” or
20 “articulate a satisfactory explanation for its action, including a rational connection
21 between the facts found and the choice made.” *Motor Vehicle Mfrs. Ass’n v. State*
22 *Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) (internal quotation marks omitted).
23 “Important aspects” of the New Rule include its costs and benefits because, as the

1 Supreme Court has made clear, “reasonable regulation ordinarily requires paying
2 attention to the advantages and the disadvantages of agency decisions.” *Michigan v.*
3 *EPA*, 135 S. Ct. 2699, 2707 (2015) (emphasis in original). In weighing regulatory
4 actions, agencies cannot “put a thumb on the scale” by undervaluing key effects and
5 overvaluing others. *Ctr. for Biological Diversity v. Nat’l Highway Traffic Safety*
6 *Admin.*, 538 F.3d 1172, 1198 (9th Cir. 2008); *see also California v. BLM*, 277 F.
7 Supp. 3d 1106, 1123 (N.D. Cal. 2017) (agencies impermissibly considered only “one
8 side of the equation” by calculating benefits and ignoring costs).

9 Regulatory impact analyses can reveal to courts whether an agency ignored
10 an “important aspect” of the rule’s costs or benefits, failed to examine “relevant
11 data” from the record on the rule’s costs or benefits, or otherwise irrationally based
12 its regulatory choices on arbitrary analysis. *See Nat’l Ass’n of Home Builders v. EPA*,
13 682 F.3d 1032, 1040 (D.C. Cir. 2012); *id.* at 1036 (“When an agency decides to rely
14 on a cost-benefit analysis as part of its rulemaking, a serious flaw undermining that
15 analysis can render the rule unreasonable.”).

16 Agencies conduct regulatory impact analyses under Executive Order 12,866.
17 58 Fed. Reg. 51,735 (Oct. 4, 1993). Pursuant to Executive Order 12,866, the Office
18 of Management and Budget classified the New Rule as a “significant regulatory
19 action,” requiring a thorough regulatory impact analysis. *See* 84 Fed. Reg. at 7775-
20 76. Indeed, any regulation that, like the New Rule, “materially alters the . . .
21 obligations” of federal grantees is a “significant” action. Exec. Order No. 12,866 §
22 3(f)(3); *see also* Policy Integrity Comment Ltr. 2. Executive Order 12,866 directs
23 agencies to “assess both the costs and the benefits of the intended regulation and . .

1 . adopt a regulation only upon a reasoned determination that the benefits of the
2 intended regulation justify its costs.” Exec. Order 12,866 § 1(b)(6). The Office of
3 Management and Budget under President George W. Bush issued *Circular A-4 on*
4 *Regulatory Analysis*, to “standardiz[e] the way benefits and costs of Federal
5 regulatory actions are measured.” Office of Mgmt. & Budget, *Circular A-4* at 1
6 (2003) [hereinafter *Circular A-4*]. HHS has also published its own internal
7 guidelines for best practices. HHS, *Guidelines for Regulatory Impact Analysis*
8 (2016) [hereinafter HHS, *Guidelines*]⁴. Both *Circular A-4* and HHS’s *Guidelines*
9 detail the best economic practices for gathering data, making reasonable
10 assumptions, assessing costs and benefits, and comparing overall regulatory
11 impacts.

12 In particular, *Circular A-4* and HHS’s *Guidelines* explain that direct and
13 indirect health costs must be accounted for and quantified to the fullest extent
14 practicable; that estimates of direct compliance costs should be based on surveys,
15 literature reviews, and other reliable sources and reasonable assumptions; and that
16 benefits should be quantified to the fullest extent practicable and based on reasonable
17 estimates. As detailed in the next three sections, the New Rule’s impact analysis
18 violates all of these standards for best practices and ignores both “important aspects
19 of the problem” and “relevant data,” *State Farm*, 463 U.S. at 43, and consequently
20 HHS has arbitrarily and capriciously violated the requirements of the Administrative
21 Procedure Act.

22 _____
23 ⁴ Available at
https://aspe.hhs.gov/system/files/pdf/242926/HHS_RIAGuidance.pdf.

1 **A. HHS’s Failure to Assess the Rule’s Significant Health Costs Violated Best**
2 **Practices for Regulatory Impact Analysis and Was Arbitrary and**
3 **Capricious**

4 Courts have made clear that agencies must reasonably consider the important
5 costs of their rules, including any significant direct or indirect health costs. In
6 *Michigan v. EPA*, the Supreme Court ruled that “‘cost’ includes more than the
7 expense of complying with regulations” and that “any disadvantage could be termed
8 a cost.” 135 S. Ct. 2699, 2707 (2015). In fact, the Supreme Court highlighted that it
9 would generally be irrational not to consider the “harms that regulation might do to
10 human health.” *Id.* Other courts have similarly long required agencies to assess all
11 important regulatory costs to health, safety, and welfare, whether the costs are direct
12 or indirect. *E.g.*, *Competitive Enter. Inst. v. Nat’l Highway Traffic Safety Admin.*,
13 956 F.2d 321, 326-27 (D.C. Cir. 1992) (remanding a fuel-efficiency rule due to the
14 agency’s failure to acknowledge indirect safety costs); *Corrosion Proof Fittings v.*
15 *EPA*, 947 F.2d 1201, 1225 (5th Cir. 1991) (striking down a rule banning asbestos
16 for failure to consider the indirect safety effects of substitute, asbestos-free car
17 brakes being less effective).

18 Proper consideration of direct and indirect effects is a crucial part of any
19 regulatory impact analysis. *See Revesz & Livermore, Retaking Rationality, supra*,
20 at 57-58. Executive Order 12,866 requires agencies to consider not just “direct cost
21 . . . to businesses and others in complying with the regulation,” but also “any adverse
22 effects” the rule might have on “the efficient functioning of the economy, private
23 markets . . . health, safety, and the natural environment.” Exec. Order No. 12,866 §

1 6(a)(3)(C)(ii). Longstanding guidance on regulatory impact analysis from the Office
2 of Management and Budget similarly instructs agencies to “look beyond the direct
3 benefits and direct costs of [their] rulemaking and consider any important ancillary
4 [i.e., indirect] benefits and countervailing risks.” *Circular A-4* at 26. Furthermore,
5 agencies must try to the extent “feasible” to “quantify and monetize ancillary
6 benefits and countervailing risks,” and “[t]he same standards of information and
7 analysis quality that apply to direct benefits and costs should be applied” to indirect
8 effects as well. *Id.*; *see also* HHS, *Guidelines* at 43 (requiring HHS to “quantify []
9 impacts to the greatest extent possible”).

10 Despite these requirements to assess all important costs, HHS’s regulatory
11 impact analysis focuses instead almost exclusively on the direct costs of compliance,
12 like the paperwork costs of additional documentation and learning the rule. 84 Fed.
13 Reg. 7714, 7777-82 (spending six pages on costs like training and documenting
14 compliance). In contrast, the New Rule spends a mere two paragraphs responding to
15 commenters’ extensive documentation of the significant probable impacts to the
16 health of patients, *Id.* at 7775, before later assuming without any quantitative
17 analysis that the “net impact” to patients “will be zero,” *Id.* at 7782. In reaching this
18 conclusion, there is no evidence that HHS consulted any data on the health outcomes
19 of Title X patients, conducted any interviews with Title X grantees or patients, ran
20 any models, seriously considered the data from public comments, or otherwise
21 attempted in any meaningful way to quantify any of the likely impacts to patients,
22 such as lost access to care, increased pregnancies, and transaction costs. The likely
23 impacts to patients are discussed in the following subsections.

1 **B. The New Rule Will Inevitably and Detrimentally Affect Patients' Health**

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

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

- 13 (1) Comply with the rule and incur the additional costs of the Separation
14 Requirement;
15 (2) Forgo Title X funding;
16 (3) Cease to provide abortion services or abortion counseling; and/or
17 (4) Close due to the requirements of the New Rule.

18 In the first two of these scenarios, it is likely that family planning and
19 reproductive health services become costlier for patients. Their care providers must
20 raise costs to either meet the Separation Requirement (e.g., to establish new facilities
21 and hire new staff) or to replace lost federal funding. In the third response scenario,
22 women lose access to legal, safe, and affordable abortion services and to information
23 about their options. In the final scenario, patients must go elsewhere to receive the

1 reproductive healthcare and family planning services that they have come to rely on.
2 In all scenarios, the end result is that some patients will lose access to some critical
3 healthcare services, and that loss of access will result in a number of very real health,
4 financial, physical, and psychological consequences for patients and their families.

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

13 **1. Patients Will Experience Significant Costs From Lost Access To** 14 **Healthcare**

15 Numerous commenters supplied HHS with arguments and evidence that the
16 changes in the Title X program brought about by the New Rule would adversely
17 affect patient health. Title X grantees provide a wide range of services beyond the
18 provision of contraceptives, including “conducting screening for cervical cancer,
19 diabetes, high blood pressure, and sexually transmitted diseases,” and, as pointed out
20 by a public health expert in comments, these Title X-provided services are often low-
21 income women’s “only interaction with the health care system at all.” Brindis
22 Comment Ltr. 3 (July 31, 2018). If these providers close their doors or raise their
23 costs as a result of the New Rule, some patients will be left without a meaningful

1 alternative, incurring substantial health costs. Many Title X recipients operate in
2 rural areas where their patients have scarce access to substitute healthcare providers.
3 Wash. Mot. 14, 23; NRPRHA Mot. 31; Planned Parenthood Comment Ltr. 15-16,
4 70 (July 31, 2018). These closures will result in undesirable health outcomes, such
5 as the spike in HIV that occurred when Planned Parenthood was forced to close a
6 rural clinic in Indiana. Brindis Comment Ltr. 6-7. These negative health effects
7 weigh against the New Rule, and the agency must acknowledge and account for
8 them. HHS’s own guidelines for conducting regulatory impact analyses emphasize
9 that “reductions in government payments” to healthcare providers may affect patient
10 access and treatments, “in turn affecting health outcomes,” and that these changes
11 “should be addressed in the benefit-cost analysis.” HHS, *Guidelines* at 23. HHS
12 arbitrarily and capriciously failed to do so in the New Rule.

13 **2. Patients Will Experience Significant Costs From Increased** 14 **Unintended Pregnancies and Births**

15 Although HHS acknowledges that it expects some Title X grantees to exit the
16 program in response to the New Rule, the agency argues that lost grantees will be
17 replaced by new grantees entering the program, with no net costs to the patient
18 population. However, the agency provides no evidence to support its claim that an
19 equal number providers will enter the program as exit, 84 Fed. Reg. at 7782, or its
20 assumption that new providers will be able to cover the same large patient population
21 that existing providers previously served. Further, the New Rule specifically intends
22 to open up Title X funding to providers who offer only a limited range of family
23 planning methods, including only natural planning and abstinence counseling (as

1 opposed to traditional contraception). *Id.* at 7741. Therefore, these hypothetical new
2 grantees are unlikely to serve as perfect substitutes for those providers that currently
3 provide a full range of services but may be forced to exit the program in response to
4 the New Rule. The only rational conclusion is that some number of patients will lose
5 access to contraceptive services they have come to rely on. HHS, however, argues
6 that enabling Title X funding to support clinics that provide only natural planning
7 methods will, in fact, “decrease unintended pregnancies, not increase them, because
8 clients are more likely to visit clinics that respect their views and beliefs.” *Id.* at
9 7743. The agency provides no evidence or quantitative analysis to estimate how
10 many women, if any, currently decline to seek Title X care because of their personal
11 beliefs. Nor does the agency provide any quantitative assessment of whether this
12 body of women outweighs the sizable number that will lose access to the services
13 they currently receive under Title X. Quantifying effects serves as an important tool
14 to help agencies “appropriately balance” a regulation’s competing costs and risk
15 reductions, *see* HHS, *Guidelines* at 47, yet HHS disregards its own *Guidelines* in
16 order to reach its arbitrary conclusion.

17 HHS’s assertion that clinic closures will not result in an increase in unwanted
18 pregnancies runs counter to the substantial weight of record evidence. In response
19 to the New Rule’s proposed version, experts submitted comments highlighting that
20 public funding of family planning services has averted millions of unintended
21 pregnancies each year, resulting in significant avoided costs related to child health
22 care and maternity. Brindis Comment Ltr. 12. HHS’s assertion that “[c]ommenters
23 offer no compelling evidence that this rule will increase unintended pregnancies,”

1 84 Fed. Reg. at 7785, is at odds with record evidence to the contrary, including the
2 fact that Texas’s cuts to family-planning funding resulted in a substantial decrease
3 in use of effective birth control and increase in births. Brindis Comment Ltr. 12.
4 Even if HHS could not fully quantify the health costs from clinic closures, the agency
5 minimally should have attempted to quantify “counts” of “the number of
6 organizations . . . [or] individuals affected,” or otherwise used all the data provided
7 by commenters as “indicators of potential costs or benefits.” HHS, *Guidelines* at 48.
8 Instead, and contrary to the requirements of the Administrative Procedure Act, HHS
9 ignored commenters’ data while failing to provide any reasoned explanation on why
10 this evidence is not “compelling.” See *McDonnell Douglas Corp. v. U.S. Dep’t of*
11 *the Air Force*, 375 F.3d 1182, 1187 (D.C. Cir. 2004) (holding that “conclusory or
12 unsupported suppositions” fail to satisfy the requirements of reasoned
13 decisionmaking).

14 **3. Patients Will Experience Significant Transaction Costs**

15 HHS acknowledges that it expects some healthcare facilities to cease
16 providing Title X services as a result of the New Rule, but nevertheless predicts that
17 “the net impact on those seeking services from current grantees will be zero,” as new
18 grantees will apply for participation in the program, replacing those that have exited,
19 and “any redistribution of the location of facilities will mean that some seeking
20 services will have shorter travel times and others seeking services will have longer
21 travel times to reach a facility.” 84 Fed. Reg. at 7782. This analysis assumes perfect
22 and immediate replacement of exiting grantees with entering grantees, and ignores
23 any significant costs incurred by patients during inevitable transition gaps and

1 delays. It also ignores that new grantees are, according to the very intention of the
2 New Rule itself, likely to provide a more limited range of services than existing
3 grantees. Further, the analysis ignores the costs incurred by patients in seeking out
4 these new services as well as the emotional costs of having lost a familiar healthcare
5 provider. *See HHS, Guidelines* at 26-28, 30-32 (detailing how to quantify the costs
6 of time and travel). Finally, for those current Title X-funded facilities that do not
7 close and instead choose to comply with the Separation Requirement, the New
8 Rule’s compliance requirements may also make it more difficult for patients to
9 access care at these service sites: for example, if sites change their phone numbers,
10 email addresses, websites, and entrances in order to comply, 84 Fed. Reg. at 7789,
11 patients may have difficulty finding and accessing care even at service sites
12 previously familiar to them.

13 **4. HHS Cannot Ignore Costs Even If They Are Uncertain or Difficult to** 14 **Quantify**

15 HHS attempts to justify its choice to ignore the costs of an increase in
16 unintended pregnancies and births by arguing that “the Department is not aware ...
17 of actual data that could demonstrate a causal connection between the [New Rule]
18 and an increase in unintended pregnancies, births, or costs associated with either,
19 much less data that could reliably calculate the magnitude of that hypothetical
20 impact.” *Id.* at 7775. Therefore, the Department concluded that these costs “are not
21 likely or calculable impacts.” *Id.* In other words, just because indirect health costs
22 are hard to quantify, HHS assumes that the costs are “not likely” or are “None.” *Id.*
23 at 7777, Table 1 (listing “Non-quantified Costs: None”).

1 However, HHS cannot rationally ignore costs even if they are unquantified.
2 “The mere fact that the magnitude of [an effect] is uncertain is no justification for
3 disregarding the effect entirely.” *Public Citizen v. Fed. Motor Carrier Safety Admin.*,
4 374 F.3d 1209, 1219 (D.C. Cir. 2004) (emphasis in original). Stated differently, HHS
5 has no license to ignore the effects of its decisions just because they are “difficult, if
6 not impossible, to quantify reliably.” *Am. Trucking Assocs., Inc. v. EPA*, 175 F.3d
7 1027, 1052 (D.C. Cir. 1999), *rev’d on other grounds sub nom. Whitman v. Am.*
8 *Trucking Ass’ns*, 531 U.S. 457 (2001). Executive Order 12,866 also makes clear that
9 it is “essential to consider” the “qualitative measures of costs and benefits that are
10 difficult to quantify.” Exec. Order No. 12,866 § 1(a). HHS’s own guidelines on
11 regulatory analysis contain an entire chapter on the importance of, and approaches
12 for, meaningfully considering nonquantified effects. *See HHS, Guidelines* at 47-51;
13 *id.* at 47 (“Ignoring potentially important nonquantified effects may lead to poor
14 decisions.”); *compare HHS, Guidelines* at 51 (providing that “[a]t minimum”
15 agencies “should list significant nonquantified effects in a table and discuss them
16 qualitatively”), *with* 84 Fed. Reg. at 7777, Table 1 (listing “Non-quantified Costs:
17 None”).

18 Indeed, HHS’s lack of consideration of difficult-to-quantify health costs is
19 even more egregious when compared to the agency’s willingness to enumerate a
20 long list of New Rule’s alleged benefits, each of which are unquantified, and many
21 of which lack any evidentiary support at all, even of an anecdotal nature. *See infra*
22 Section III.

1 **C. HHS Arbitrarily Ignored Both Its Own Guidelines and Record Evidence**
2 **and Grossly Underestimated Compliance Costs**

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

10 HHS's *Guidelines* on conducting cost-benefit analysis clearly direct how to
11 evaluate capital and operating compliance costs: “1. Use market data to estimate the
12 price of purchasing and installing equipment required by the regulation. . . . 2. Use
13 market data to value the annual costs of labor, utilities, and other resources required
14 for production, service provision, and the operation and maintenance of capital
15 equipment.” HHS, *Guidelines for Regulatory Impact Analysis: A Primer* at 8 (2016).
16 The *Guidelines* elaborate that such market data “may be obtained through
17 interviews, literature reviews, review of online merchandise catalogues, or other
18 sources.” HHS, *Guidelines* at 32.

19 Yet in calculating the Rule's direct compliance costs, there is no evidence that
20 HHS followed its own guidelines or conducted any interviews of grantees, consulted
21 any literature or market price data, ran any cost models, or even seriously considered
22 public comments. For example, under the Separation Requirement, healthcare
23 clinics that currently provide both Title X services and abortion services—including

1 abortion referrals—must physically alter their facilities to create separate “treatment,
2 consultation, examination and waiting rooms” and “office entrances and exits,” 84
3 Fed. Reg. at 7789. In the proposed rule, HHS estimated—without any reference to
4 any evidence, methodology, or assumptions to support the numbers—that it would
5 cost “an average of between \$10,000 and \$30,000, with a central estimate of
6 \$20,000” in one-time expenses for facilities to comply with the Separation
7 Requirement. 83 Fed. Reg. 25,502, 25,525. Those estimates were seemingly derived
8 from thin air, in stark contrast to HHS’s own best practices for estimating costs. For
9 example, when HHS has issued rules affecting Head Start grantees, its regulatory
10 impact analyses rely on “internal datasets” based on grantees’ budgetary data and
11 comprehensive surveys of grantees. *See* 81 Fed. Reg. 61,293, 61,375. By contrast,
12 there is no indication that HHS talked to any Title X grantees about their likely costs
13 before finalizing this Rule. That omission is particularly troubling because, under
14 the longstanding Executive Order on regulatory impact analysis, proposed rules that
15 “materially alter the . . . obligations of recipients” of federal grants are deemed to be
16 “significant regulatory action[s],” Exec. Order 12,866 § 3(f)(3), and agencies must
17 detail “the potential costs and benefits” of such actions, *id.* § 6(a)(3)(B)(ii).

18 Multiple Title X grantees (the regulated entities subject to the Rule’s
19 compliance costs) submitted detailed comments in response to the proposed rule that
20 indicated their own capital costs of renovation and construction would be much
21 higher, based on third-party reports and grantees’ historical experiences. *See, e.g.,*
22 Planned Parenthood Comment Ltr. 32 (estimating capital costs of \$625,000 per
23 affected service site); Essential Access Health Comment Ltr. 13 (Aug. 1, 2018)

1 (arguing that HHS’s compliance cost estimates are “unrealistically low, and could
2 feasibly amount to hundreds of thousands of dollars). Not only was HHS’s estimate
3 of one-time capital costs drastically off from grantees’ own estimates by hundreds
4 of thousands of dollars per site, but public comments also pointed out that HHS
5 completely ignored ongoing costs for the additional staff and contracts for goods and
6 services to operate the separate facilities. *See, e.g.*, Planned Parenthood Comment
7 Ltr. 32-33. In its own comments to HHS, Plaintiff NFPRHA estimated that its own
8 compliance with the Separation Rule would cost at least \$300,000 per site. Nat’l.
9 Family Planning & Reproductive Health Ass’n. Comment Ltr. 37 (July 31, 2018)
10 (estimating cost per site of at least \$300,000).

11 In the New Rule, HHS reports that “[a]fter receiving public comments,” 84
12 Fed. Reg. at 7718, it increased its central estimate of capital costs from \$20,000 to
13 \$30,000 per facility, *id.* at 7782. Yet even that trivially increased estimate is still
14 more than 10 to 20 times below the estimates submitted by grantees themselves.
15 HHS still does not identify any data source, assumptions, methodology, or literature
16 that supports its estimates. And HHS still has not estimated any of the ongoing costs
17 of the Separation Requirement, which grantees report will cost them millions more
18 on top of the capital expenses. HHS instead insists, without any evidence, that
19 grantees’ estimates were simply too “high,” and HHS vaguely anticipates, again
20 without any evidence, that lower cost methods of compliance will materialize. *Id.* at
21 7781. Ultimately, HHS seeks to fault the commenters for “not provid[ing] sufficient
22 data to estimate these effects.” *Id.* But it is the responsibility of the agency, not of
23 commenters, to consider the “important aspect[s] of the problem” and “examine

1 relevant data.” *Motor Vehicle Mfrs. Ass’n v. State Farm Mut. Auto. Ins. Co.*, 463
2 U.S. 29, 43 (1983). Specifically, under its own guidelines for analysis, it was HHS’s
3 responsibility to “use market data . . . obtained through interviews, literature reviews,
4 review of online merchandise catalogues, or other sources” to accurately assess
5 costs. HHS, *Guidelines* at 32. Here, HHS has instead ignored the best evidence
6 before it (i.e., public comments) and offered no other evidence or reasonable theories
7 of how affected clinics could install new waiting rooms, exam rooms, entrances,
8 websites, and personnel, all for just \$30,000.

9 The New Rule’s analysis of direct compliance costs underestimates capital
10 expenses by an order of magnitude and completely ignores tens or hundreds of
11 millions more in ongoing costs. These serious omissions show that HHS arbitrarily
12 failed to examine relevant data, consider important aspects of the problem, and to
13 otherwise engage in the kind of rational analysis required by the Administrative
14 Procedure Act.

15 **D. The New Rule’s Enumerated Benefits Are Conclusory and Unsupported**
16 **by Evidence**

17 HHS lists a number of expected “benefits” of the New Rule, including an
18 alleged increase in the number of providers seeking to participate in Title X
19 following the erosion of the nondirective mandate, enhanced patient service and
20 care, and increased compliance with Title X’s prohibition on the use of funds for
21 abortion services. *See* 84 Fed. Reg. at 7777. For each of these expected benefits, the
22 agency makes no attempt to provide evidence supporting its likelihood, nor to
23 estimate the magnitude of these alleged effects. This omission is contrary to both

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

10 While HHS claims that the New Rule will result in “increased compliance”
11 with rules guarding against the misuse of Title X funds, the agency presents no
12 evidence of the misapplication of funds under the present regulatory scheme. 84 Fed.
13 Reg. at 7764. As noted in *Circular A-4*, a regulation’s impact can only be measured
14 against an established baseline. *See Circular A-4* at 15. Without this baseline—i.e.,
15 without any analysis or evidence of current misuse of funds—the agency cannot
16 convincingly assert that the New Rule will “enhance” compliance. *See* 84 Fed. Reg.
17 at 7777. In making claims about enhanced compliance without assessing baseline
18 compliance, HHS arbitrarily ignores an “important aspect of the problem.” *State*
19 *Farm*, 463 U.S. at 43.

20 Similarly, HHS provides no evidence for its assertion that the New Rule will
21 result in “an expanded number” of providers entering the Title X program. *See* 84
22 Fed. Reg. at 7777. While HHS acknowledges that it expects some Title X grantees
23 to exit the program in response to the New Rule, the agency argues that they will be

1 replaced by new grantees entering the program now that they are permitted to offer
2 only a limited range of contraception services. *See id.* at 7741. However, the agency
3 provides no evidence to support its claim that a larger number of providers will enter
4 the program as exit. *See id.* at 7782. Moreover, these hypothetical new grantees are
5 unlikely to serve as perfect substitutes for those providers that currently provide a
6 full range of services but must exit the program as their ethical and professional
7 response to the New Rule. As a result, some number of patients will lose access to
8 contraceptive services they have come to rely on. HHS nevertheless argues that
9 enabling Title X funding to support clinics that provide only natural planning
10 methods will, in fact, “decrease unintended pregnancies ... because clients are more
11 likely to visit clinics that respect their views and beliefs.” *Id.* at 7743 (emphasis
12 added). The agency provides no evidence or analysis to estimate how many women,
13 if any, currently do not seek Title X care because of their personal beliefs, nor does
14 the agency provide any rational argument that this body of women outweighs the
15 sizable number that will lose access to the services they current receive under the
16 Title X program.

17 In assessing whether a regulation is supported by the reasoned explanation
18 required under the APA, courts “do not defer to the agency’s conclusory or
19 unsupported suppositions,” *United Techs. Corp. v. Dep’t of Def.*, 601 F.3d 557, 562
20 (D.C. Cir. 2010) (quoting *McDonnell Douglas Corp.*, 375 F.3d at 1187). Here, each
21 of the benefits identified by HHS lack evidentiary support and are contrary to both
22 the record and common sense. That the New Rule’s entire beneficial impact is
23 comprised of “unsupported suppositions” renders the Rule arbitrary and capricious.

1 *Id.*; *see also* State Farm, 463 U.S. at 43 (An agency may not “offe[r] an explanation
2 for its decision that runs counter to the evidence before [it].”).

3 **IV. CONCLUSION**

4 This Court should grant Plaintiffs’ Motion for Preliminary Injunction.

5
6 DATED: April 10, 2019

7
8 LANE POWELL PC

9 By s/ Taylor Washburn
10 Taylor Washburn, WSBA #51524
washburnt@lanepowell.com

11
12 Madison Condon, New York State Bar #5653480
madison.condon@nyu.edu

13 (*pro hac vice pending*)
14 Jason A. Schwartz, Virginia State Bar #73398

jason.schwartz@nyu.edu
15 (*pro hac vice pending*)
16 Institute for Policy Integrity
17 New York University Law School
139 MacDougal St., 3rd Floor
New York, NY 10012

18 T: (212) 998-6239
F: (212) 995-4592

19 *Counsel for Amicus Curiae*
20 *Institute for Policy Integrity*