Nos. 19-1614 & 20-1215

IN THE UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

MAYOR AND CITY COUNCIL OF BALTIMORE,
Plaintiff-Appellee,
v.
ALEX M. AZAR II, in his official capacity as Secretary of the United States Department of Health and Human Services, et al.,
Defendants-Appellants.

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

SUPPLEMENTAL BRIEF FOR APPELLEE

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INTRODUCTION

HHS committed serious errors in promulgating the Rule at the heart of this case. HHS failed to base key estimates and predictions on relevant evidence, failed to acknowledge the existence of countervailing evidence, and failed to explain how it reached the conclusions that it did. HHS erroneously concluded that the Rule is consistent with medical ethics without addressing the unanimous contrary view reflected in the Record, failed to consider any evidence that the Rule would negatively impact Title X patients and providers, and vastly underestimated the costs of the Separation Requirement—the requirement that abortion services, counseling, and referrals must be performed in a separate physical location from Title X services. HHS's errors "compelled" the district court to conclude that the Rule is "inadequately justified and objectively unreasonable." *Mayor & City Council of Baltimore v. Azar*, No. CV RDB-19-1103, 2020 WL 758145, at *1, *2, *6, *8, *11 (D. Md. Feb. 14, 2020) ("Opinion."). This Court should reach the same conclusion and affirm.

Appellants minimize or ignore HHS's errors, and instead try to justify the Rule on the basis of new arguments and evidence that HHS

did not consider and on which HHS did not rely. *See* Supp.Br.17-26. Indeed, some of Appellants' arguments are appearing for the first time in Appellants' Supplemental Brief. *See* Supp.Br.23-24. But reliance on new justifications is impermissible. The lawfulness of HHS's actions "must be measured by what [it] did, not by what it might have done." *SEC v. Chenery Corp.*, 318 U.S. 80, 93-94 (1943); *accord Michigan v. EPA*, 135 S. Ct. 2699, 2711 (2015) (Scalia, J.) (quoting this line of *Chenery*).

Appellants' downplay of HHS's errors overlooks the real-world consequences of the agency's mistakes. HHS's incorrect conclusion about the requirements of medical ethics in the face of overwhelming contrary Record evidence caused Title X's largest provider and numerous States (including Maryland, of which Baltimore is a subgrantee) to withdraw from the program. HHS's failure to consider evidence of the Rule's severe negative repercussions for Title X patients and providers caused HHS to promulgate a Rule with devastating consequences for both. And HHS's miscalculation of the Separation Requirement's costs caused HHS to promulgate a requirement that almost no Title X provider can meet. The Rule has slashed the Title X program's patient capacity in half, jeopardizing care for 1.6 million female patients nationwide.

The district court correctly (1) vacated the Rule, and (2) permanently enjoined the Rule in the State of Maryland. Appellants do not dispute that the district court correctly vacated the Rule. *See* Supp.Br. (not addressing the district court's decision to vacate the Rule); *see also* 5 U.S.C. § 706(2) (requiring reviewing courts to "set aside" unlawful agency action); *O.A. v. Trump*, 404 F. Supp. 3d 109, 152-154 (D.D.C. 2019) (explaining the distinction between vacatur and an injunction).

Appellants dispute the scope of the district court's injunction. Supp.Br.43-48. But the district court's injunction is narrowly tailored and lawful. The City showed below that a statewide injunction is necessary to provide complete relief to the City. Injunctions entered "to provide complete relief" are rooted in historical equity practice and consistent with Article III. *See Madsen v. Women's Health Ctr., Inc.*, 512 U.S. 753, 765 (1994); *see also Califano v. Yamasaki*, 442 U.S. 682, 702 (1979) ("[T]he scope of injunctive relief is dictated by the extent of the violation established, not by the geographical extent of the plaintiff class.").

Appellants further claim that the Rule is severable. Supp.Br.49-50. But it is not. HHS nowhere disputes that there is "substantial doubt" that HHS would have promulgated the Rule without the counseling restrictions and Separation Requirement. *See* Supp.Br. (not addressing the "substantial doubt" test). That test, in which the existence of a severability clause is just one factor, is dispositive in the severability inquiry. Vacating and enjoining the whole Rule is appropriate here because (1) the provisions of HHS's Rule are interlocking (they cross-reference and depend on one another), (2) HHS has never explained which provisions it believes are lawful and severable, and (3) HHS is best positioned to revise and reissue a new Rule in accordance with the Court's judgment.

In any event, Appellants' severability argument is waived. The City argued that the Rule is inseverable at summary judgment and Appellants did not contest it. Appellants' criticism of the district court's severability analysis is misplaced where, as here, Appellants' did not argue the issue below. *See* Pls. Mot. SJ, SJA582-83; Def's Cross Mot. SJ, SJA1110; Pls. Opp. to SJ, SJA1186-1187, 1211; Defs. Reply SJ, SJA1220 n1.

At bottom, HHS erred in its consideration of the evidence before it in this rulemaking and failed to explain its reasoning adequately. Numerous rules are vacated each year for that reason. The district court appropriately vacated the Rule and permanently enjoined it in the State of Maryland. The Court should affirm that judgment.

STATEMENT OF THE CASE

The City relies on the statement of the case in its Petition for Initial Hearing En Banc, Appeal No. 20-1215, Dkt.10, at 3-11, and its Brief for Appellee, Appeal No. 19-1614, Dkt.44, at 13-41.

SUMMARY OF ARGUMENT

I.A. The Rule is arbitrary and capricious for the three reasons given by the District Court. Opinion.*8. *First*, HHS's conclusion that the Rule is consistent with medical ethics is unsupported by the evidence in the Record and inadequately explained. Opinion.*8-*10. *Second*, the Record contradicts HHS's repeated statements in the Rule that there was "no evidence" that the Rule would have an adverse impact on patients or providers in the Title X program. *Id.* at *10. *Third*, no evidence supports HHS's estimate of the costs of the Separation Requirement, and the overwhelming weight of the evidence shows that HHS vastly (and demonstrably) underestimated its costs. *Id.* at *11. All three of those

errors are substantial. Any one of them, standing alone, requires the Rule's vacatur.

Contrary to Appellants' arguments, HHS did not adequately weigh evidence regarding the Rule's consistency with medical ethics, its adverse impacts on Title X patients and providers, or the costs associated with compliance with the Separation Requirement. Supp.Br.12-14. With respect to all three issues, HHS overlooked relevant evidence or failed to rely on any evidence at all. HHS cannot claim deference to its "expert judgment," nor are its conclusions "rationally explained," Supp.Br.12-14, where its reasoning is tainted by basic factual errors.

I.B. Appellants' new argument that the Court must uphold the Rule because it reflects "the better reading," Supp.Br.12, of Title X is waived (Appellants did not raise it below), wrong (it is not "the better reading" of the statute), and not decisive of whether HHS acted arbitrarily and capriciously. HHS considered and relied on its incorrect conclusions regarding the requirements of medical ethics, impacts on providers and patients, and the costs of the Separation Requirement in promulgating the Rule and crafting its key provisions. HHS's errors as to each of those issues is thus grounds for vacatur.

I.C. The Court should decline to follow the Ninth Circuit's reasoning because the Ninth Circuit's decision is marred by errors and is unpersuasive. *First*, with respect to the statutory claims in this case, the Ninth Circuit misinterpreted the Nondirective and Non-Interference Mandates. *Second*, in its review of the adequacy of HHS's consideration of medical ethics, the Ninth Circuit substituted its own view of the requirements of medical ethics for that of HHS, in direct contravention of basic principles of administrative law. *Third*, in its review of the adequacy of HHS's assessment of the likely impacts of the Rule on Title X patients and providers, and of the Separation Requirement's costs, the Ninth Circuit overlooked key errors that HHS committed in its consideration of those issues. The Ninth Circuit did not consider HHS's statements that it had before it "no evidence" or "actual data" showing adverse impacts on the Title X program, nor that HHS's $30,000 compliance cost number is supported by no Record evidence, nor that HHS demonstrably underestimated the cost of the Separation Requirement by over $200 million by failing to appreciate that it would apply to every Title X provider.

II. The Court should affirm the district court's decision to vacate the Rule on additional grounds. The Rule violates (1) the "Nondirective Mandate," *e.g.*, 132 Stat. 2981, 3070-71; (2) the "Non-Interference Mandate," 42 U.S.C. § 18114; (3) Title X's "Voluntary Acceptance Requirement," 42 U.S.C. § 300a-5; 45 Fed. Reg. 37,433, 37,437 (June 3, 1980); (4) the APA's requirement that the public have a "meaningful opportunity to comment," *see* 5 U.S.C. § 706(2)(D); (5) the First Amendment; and (6) the Fifth Amendment.

III. The district court correctly vacated the Rule—a remedy Appellants do not dispute. The district court also entered a lawful and narrow permanent injunction that comports with principles of equity and Article III. The City established at summary judgment that the City suffers harm not only from the loss of its own access to Title X funds but also from the loss of other Title X providers in Maryland. The need to remedy those harms justified the entry of a statewide injunction. The district court also correctly held that the Rule is inseverable because there is "substantial doubt" that HHS would have promulgated the Rule without the counseling restrictions or Separation Requirement.

STANDARD OF REVIEW

This Court reviews a decision to grant a permanent injunction for an abuse of discretion, legal conclusions de novo, and any factual findings for clear error. *See Legend Night Club v. Miller*, 637 F.3d 291, 297 (4th Cir. 2011). The decision to vacate a Rule is reviewed for abuse of discretion. *See Stand Up for California! v. U.S. Dep't of Interior*, 879 F.3d 1177, 1190 (D.C. Cir. 2018).

ARGUMENT

I. The Rule is Arbitrary and Capricious Because it is Inadequately Explained and Objectively Unreasonable

The APA requires courts to "hold unlawful and set aside agency action, findings, and conclusions found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706. In reviewing a rule, courts "must engage in a searching and careful inquiry of the [administrative] record, so that we may consider whether the agency considered the relevant factors and whether a clear error of judgment was made." *Casa De Maryland v. DHS*, 924 F.3d 684, 703 (4th Cir. 2019) (internal quotation marks omitted). An agency rulemaking is arbitrary and capricious if, in coming to its decision, the agency "relied on factors which Congress has not intended it to consider,

entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins.*, 463 U.S. 29, 43 (1983).

A. HHS Erred in its Consideration of Evidence Regarding Medical Ethics, Impacts on Patients and Providers, and the Cost to Comply With the Separation Requirement

1. HHS's Conclusion That the Rule is Consistent With Medical Ethics Is Unsupported by the Record and Inadequately Explained

HHS's conclusion in the Rule that HHS "disagrees" that the Rule infringes on the legal, ethical, and professional obligations of medical professionals, Opinion.*9; *see also* 84 Fed. Reg. at 7724, 7748, is arbitrary and capricious because it is contrary to the evidence before the agency and inadequately explained, Opinion.*1-*2. The Administrative Record is replete with evidence establishing that the Rule's referral limitations—requiring medical providers to withhold information from patients about where to go for further treatment—violate the consensus view of medical ethics in the United States. Opinion.*8-*10. As the district court explained,

> HHS was not required to demonstrate that any professional organization supported the Rule, *but it was required* to provide a reasoned explanation for its disagreement with the medical ethics concerns of every major medical association in the country, while simultaneously finding the Final Rule consistent with medical ethics."

Id. at *10 (emphasis added). This HHS failed to do. Instead, HHS summarily dismissed comments from the American Medical Association and every other comment explaining that the Rule violates medical ethics. HHS stated simply that it "disagree[d]." 84 Fed. Reg. at 7724, 7748.

For example, the American Medical Association (AMA), the organization that issues the *Code of Medical Ethics*, explained to HHS that "[t]he inability to counsel patients about all of their options in the event of a pregnancy *and to provide any and all appropriate referrals*, including for abortion services, are contrary to the AMA's *Code of Medical Ethics*." *See* AMA Comment, SJA189 (emphasis added) (citing Opinion E-1.1.3). HHS did not address the AMA comment.

Similarly, the comments of the American College of Obstetricians and Gynecologists ("ACOG"), an organization representing more than 90% of the board-certified obstetricians and gynecologists ("OBGYNs") in the United States, went unaddressed. ACOG told HHS that the referral

restriction would "place physicians in ethically compromised situations" and violate ACOG's Code of Professional Ethics. Opinion.*8-*9; ACOG Comment, SJA169-174.

The comment of the National Family Planning and Reproductive Health Association ("NFPRHA")—which includes more than 80% of the pre-Rule Title X grantees and 66% of subrecipients—also went unaddressed. NFPRHA informed HHS that the Rule violated numerous ethics codes and HHS's own Quality Family Planning ("QFP") guidelines, which state that the provision of pregnancy test results should be "followed by a discussion of options and appropriate referrals." *See* NFPRHA Comment, SJA273-310.

HHS similarly dismissed comments from a multitude of additional leading medical organizations informing HHS that the Rule violated medical ethics, including the American Academy of Family Physicians ("AAFP"), American Academy of Nursing ("AAN"), American Academy of Pediatrics ("AAP"), and American College of Physicians ("ACP"), among others. *See* AAFP Comment, SJA32; AAN Comment, SJA51; AAP Comment, SJA194-196; ACP Comment, SJA251.

Nor did HHS address comments from physicians with expertise in medical ethics who informed HHS that the referral restriction violated medical ethics. *See* Stahl Comment, AR308621-AR308627; https://bit.ly/3bauUP8 ("I write as an ethicist …. The proposed regulations violate core tenets of medical ethics, including honest information and informed consent…."); Chor Comment, AR196377-AR196378, https://bit.ly/2RXw7SK ("As a board-certified obstetrician-gynecologist, I can attest that this proposal is bad medicine; as a medical ethicist, I can also affirm it is an assault on both the patient-provider relationship and the autonomy of patients and health care providers."); Karlin Comment, AR216127, https://bit.ly/2XUaRBf ("I am a physician … as well as an anthropologist and medical ethicist…. The gag rule violates core ethical standards …."); McGowan Comment, AR282565, https://bit.ly/2RXYWyD ("As an ethicist who has dedicated my career to improving women's health, I oppose this proposed federal rule.").

Finally, HHS also ignored comments from four States and Planned Parenthood ("PPFA") that informed HHS that the Rule violated medical ethics and that the professional and ethical violations would be so profound they would be forced to exit the program if the proposed

regulations were finalized (which they later did). Opinion.*8-*9; SJA371 (explaining that PPFA, Washington, New York, Hawaii, and Oregon would be forced to withdraw). In fact, several commenters explained that numerous Title X providers would have to withdraw because the Rule would place doctors in an ethically compromised position, and as a result, patients would have significantly reduced access to care. Opinion.*8-*9.

Against this compelling and voluminous evidence from the nation's leading medical organizations, collectively representing the overwhelming majority of the nation's board-certified OBGYNs, and rooted in longstanding principles of medical ethics and written medical ethics codes, HHS responded in a mere three paragraphs that cited no evidence of the requirements of medical ethics. *See* 84 Fed. Reg. at 7724, 7748. This superficial response fails for at least nine reasons.

1. Appellants have conceded that the Record reveals no code of medical ethics, no professional medical organization, and no opinion from an expert on medical ethics that supports HHS's conclusion that the Rule is consistent with medical ethics.[1] Appellants concede that the Rule

[1] Appellants designated two comments from Christian medical groups for inclusion in the Supplemental Joint Appendix that they have not before

contradicted the views of medical ethics of literally every major medical organization in the United States and do not dispute that the Rule contradicted HHS's *own* views about the obligations of health care professionals contained in the CDC's Recommendations on Providing Quality Family Planning Services, ("QFP"), including that "referral to appropriate providers of follow-up care should be made at the request of the [pregnant] client."[2] At minimum, HHS's explanation for its conclusion was inadequate. Opinion.*10. "Nodding to concerns raised by commenters only to dismiss them in a conclusory manner is not a

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cited. *See* Christian Medical Association Comment, SJA19-27; National Association of Catholic Nurses Comment, SJA38-47. Those comments do not contradict the district court's finding, Opinion.*8-9 (and Defendants' concession, SJA1263-1264) that the Record shows no professional medical organizations that take the position that the counseling restrictions are consistent with medical ethics. The comments state that some Christian medical providers have conscience objections to referring for abortion. *See* Supp.Br.28-29 (relying on the comments for that proposition). The Rule is substantially broader than needed to address that issue. The Rule prevents *all* Title X providers—not just those with conscientious objections—from making abortion referrals.

[2] *See* CDC, *Providing Quality Family Planning Services: Recommendations of CDC and the U.S. Office of Population Affairs* at 14, 63(4) MMWR (Apr. 25, 2014), https://www.cdc.gov/mmwr/pdf/rr/rr6304.pdf [perma: https://bit.ly/2RQg0q6]; *see also id.* at 13-14 ("Pregnancy Testing and Counseling" section noting that, "[t]he [pregnancy] test results should be presented to the client, followed by a discussion of options and appropriate referrals").

hallmark of reasoned decisionmaking." *Gresham v. Azar*, 950 F.3d 93, 103 (D.C. Cir. 2020) (Sentelle, J.).

2. Appellants' efforts to justify HHS's failure to root its conclusions about medical ethics in evidence about the requirements of medical ethics fail. Appellants are incorrect that HHS reasonably concluded that barring physicians from making abortion referrals "was 'not inconsistent' with 'medical ethics' because it was merely 'a matter of Congress's choice of what activities it will fund.'" Supp.Br.27 (citing Fed. Reg. at 7724). The statement itself is incorrect. Congress—through the Title X statute—does not require HHS to bar abortion referrals. As *Rust v. Sullivan* held, the Title X statute is "ambiguous" on the question. 500 U.S. 173, 184 (1991). The Rule's referral restrictions do not reflect "Congress's choice," but HHS's.

In any event, Appellants' claim is irrelevant because HHS did not in fact state in the rulemaking that the scope of federally-funded services within the Title X program had any bearing on whether the counseling restriction is consistent with medical ethics. *See* 84 Fed. Reg. at 7724, 7748; *but see* Supp.Br.27-28. It would have been irrational if it had. By that logic, HHS could bar doctors in publicly funded programs from

referring patients for emergency prenatal care to save a pregnancy and claim this prohibition was consistent with medical ethics on the grounds that forcing doctors to remain silent was simply "a matter of Congress's choice of what activities it will fund." Supp.Br.27. The scope of a federally funded program has nothing to do with requirements of medical ethics. The two issues are unrelated.

To be sure, not every limitation on the scope of a federally funded program raises medical ethics concerns. *See* Supp.Br.28 (contending HHS must be able to reasonably restrict the activities of doctors in the Title X program). But the overwhelming weight of the evidence in the Record shows that the Rule's *counseling* restrictions raise serious medical ethics concerns. Even if HHS had relied on this reasoning during rulemaking, the mere fact that Title X is a publicly funded program does not thereby make it consistent with medical ethics for HHS to require physicians to deny patients access to relevant medical information even when patients implore them to provide it.

3. Conscience statutes are not relevant to the question whether the Rule's counseling restrictions are ethical. *Contra* Supp.Br.28-29. *First*, *permitting* a physician with a conscience objection to decline an abortion

referral is a fundamentally different thing from *forcing* a physician who believes it is in her patient's best interest to provide such advice (and indeed may feel compelled by her own conscience to provide it) to withhold it. *Second*, doctors with conscience objections to abortion counseling often refer their patients to *other* providers who can engage in such counseling (rather than surreptitiously withholding information about abortion, as the Rule requires), thus respecting both patient autonomy and the doctor's conscience.[3] Conscience statutes simply do not coercively deny patients relevant medical information the way the Rule does. *Third*, legislatures are not bound by the dictates of medical

[3] *See* American College of Obstetricians and Gynecologists Committee on Ethics, *The Limits of Conscientious Refusal in Reproductive Medicine*, No. 385 (November 2007), *reaffirmed* 2019, http://bit.ly/2XRZZ4I ("Conscientious refusals that conflict with patient well-being should be accommodated only if the primary duty to the patient can be fulfilled. All health care providers must provide accurate and unbiased information so that patients can make informed decisions. Where conscience implores physicians to deviate from standard practices, they . . . *have the duty to refer patients in a timely manner to other providers if they do not feel that they can in conscience provide the standard reproductive services that patients request*." (emphasis added)). As the National Association of Catholic Nurses explained in its comment, if a patient determines that her chosen course is abortion, and a provider is unable to offer an abortion referral, the provider should "offer[] a transfer of care to the client." SJA41.

ethics. Conscience statutes by their very nature are *exemptions* from the rules that would otherwise govern physicians' professional conduct. The very existence of conscience statutes supports the proposition that otherwise-applicable rules require abortion counseling. Indeed, nothing in the Rule's discussion of conscience statutes explains why HHS believes they are sound evidence of the requirements of medical ethics. 84 Fed. Reg. at 7716, 7744-48.

4. Appellants and HHS are also incorrect about the import of *Rust*. *Rust* is not evidence of the requirements of medical ethics. *Contra* Supp.Br.29, 31-33. *Rust* never discussed medical ethics; it did not suggest a view on the requirements of medical ethics; and resolving the issue was not necessary to the Court's holding in that case. *See* Opinion.*9. The *Rust* Court held only that the regulations in that case did not so "significantly impinge upon the doctor-patient relationship" that they rose to the level of a First Amendment violation. *Rust*, 500 U.S. at 200; *contra* Supp.Br.29. That is not a holding about the requirements of medical ethics, and it did not purport to be.

Appellants' bizarre argument that *Rust* held that the 1988 Rule was consistent with medical ethics because abortion counseling was outside

the "scope of the [Title X] program," Supp.Br.27,32-33, seemingly arises from Appellants' failure to appreciate that the *Rust* court was discussing the requirements of the First Amendment in that passage, not medical ethics. *See Rust*, 500 U.S. at 200. The 1988 Rule was consistent with the First Amendment, *Rust* held, because limiting the scope of the Title X program did not violate the doctors' First Amendment rights. *See id.* But restrictions on the scope of a publicly funded program can place doctors in the program in an ethically compromised position without violating the First Amendment. *Contra* Supp.Br.27,32-33. Indeed they did in *Rust*.

5. Appellants argue that HHS's analysis of medical ethics here significantly overlaps with the agency's discussion of the issue in promulgating the 1988 rule. Supp.Br.30. But that is irrelevant. The fact that HHS addressed medical ethics concerns in a similar way in 1988 only bolsters the case that no recognized code of medical ethics, no medical organization, and no medical ethicists in fact consider the Rule consistent with medical ethics. Not now and not then. Given that Appellants are raising this argument for the very first time in their

Supplemental Brief, their criticism that "[n]either Baltimore nor the district court" has addressed this issue, *id.*, is misplaced.

6. Appellants' argument that the Rule cannot be unethical because "[t]he majority of incumbent providers have remained in the program without any apparent ethical sanction," Supp.Br.30-31, is both incorrect and irrelevant. It is irrelevant because the Court cannot affirm the Rule on the basis of extra-record evidence that arose in the few months since the new Rule took effect. *See, e.g.*, *Chenery*, 318 U.S. at 87 (explaining that courts can uphold the decision of an administrative agency only on the basis "upon which the record discloses that its action was based"); *accord State Farm*, 463 U.S. at 50 ("[C]ourts may not accept appellate counsel's *post hoc* rationalizations for agency action.").

It is also incorrect because in fact roughly half of incumbent Title X providers *have* withdrawn from the program in response to the Rule. *See* Ruth Dawson, *Domestic Gag Rule Has Slashed the Title X Network's Capacity by Half*, Guttmacher Institute (Feb. 26, 2020), http://bit.ly/3csjZle. Planned Parenthood, which alone served roughly 40 percent of Title X patients, withdrew, and 15 states lost all or some of their Title X funding. *See* Power to Decide, *Impacts of the Domestic Gag*

Rule (Nov. 4, 2019), https://bit.ly/2z8YPti. More than 20 States and the District of Columbia sued HHS to enjoin the Rule before it took effect. *See California v. Azar*, 950 F.3d 1067 (9th Cir. 2020). And, finally, the fact that providers remained in the Title X program once the Rule took effect does not mean that the Rule's counseling restrictions are ethical. Far from it. It means that the providers that were compelled to stay were "force[d] … into a choice with no positive outcome." Dr. Mobley Declaration, SJA964 (explaining the ethical bind providers face when a "program simply cannot survive without Title X funding").

7. Appellants also make the astonishing claim (backed by certain *amici* States, Dkt.112) that HHS was entitled to summarily dismiss evidence of the requirements of medical ethics provided by the nation's leading non-partisan medical organizations, including the AMA, ACOG, AAFP, ACP, AAP, AAN, and numerous other medical organizations and physicians with expertise in medical ethics because their views of medical ethics are "little more than *ipse dixit*." Supp.Br.35; *see id.* at 33-36 (calling these Baltimore's "preferred organizations" even though no organizations in the Record take a contrary view). Those organizations have expertise in this area because they represent hundreds of thousands

of physicians and the overwhelming majority of the nation's OBGYNs. The AMA is the largest association of physicians in the United States. It wrote the *Code of Medical Ethics*. ACOG represents more than 90 percent of board certified OBGYNs. It has issued multiple ethics opinions specifically addressing the intersection of abortion counseling and conscience. *See* Amicus Brief of ACOG, et al., Dkt.53-1. HHS itself relies on ACOG and AAP to set the standard of care for its own Quality Family Planning (QFP) guidelines.[4] When these organizations opined on the Rule, they did so on behalf of hundreds of thousands of doctors. And these organizations did not merely provide the organizations' opinions and stop there. They explained to HHS how the rule contravened longstanding principles of patient autonomy and informed consent, cited numerous medical ethics codes, and cited medical ethics opinions written by committees of doctors who convened to study these issues. *See* AMA

[4] *See* CDC, *Providing Quality Family Planning Services: Recommendations of CDC and the U.S. Office of Population Affairs* at 13, 63(4) MMWR (Apr. 25, 2014), https://www.cdc.gov/mmwr/pdf/rr/rr6304.pdf [perma: https://bit.ly/2RQg0q6] ("Providers of family planning services should offer pregnancy testing and counseling … in accordance with recommendations of major professional medical organizations, such as the American College of Obstetricians and Gynecologists (ACOG) and the American Academy of Pediatrics (AAP).").

Comment, SJA 187-89; ACOG Comment SJA171-74; AAFP Comment, SJA32; AAN Comment, SJA 51; AAP Comment, SJA194-196; ACP Comment, SJA251. In response, HHS cited no relevant medical ethics evidence at all.

8. The Court should reject Appellants' *post hoc* attempt to redefine medical ethics as the rules State medical licensing boards enforce. Supp.Br.34-35. That is not how HHS understood commenters' medical ethics concerns, it is not how the commenters presented their concerns, and it is not consistent with the common understanding of medical ethics. Medical ethics are the basic values that guide the practice of medicine. They are not created by statute. If commenters on "medical ethics" had meant to refer to state medical licensing requirements, they would have referred to them as such. *Contra* Supp.Br.34-35. Instead they commented that the Rule was inconsistent with "medical ethics." *E.g.* SJA78 (New York State Dep't of Health); SJA158 (Guttmacher); SJA171 (ACOG); SJA189 (AMA); SJA197 (AAP); SJA260 (ACLU); SJA278 (NFPRHA); SJA320 (Ctr. Reprod. Rights); 367 PPFA). Indeed, in its comment, the Baltimore City Health Department raised its concerns

about the Rule's inconsistency with state law governing medical practice separately from its concerns about medical ethics. SJA109-10.

In any event the principles of medical ethics propounded by the AMA, ACOG, and the other professional medical organizations in this case is relevant to doctors' legal obligations in Maryland and across the country. Courts rely on these materials to decide the appropriate standard of medical care (and thus the legal duties) of doctors. *See, e.g.*, *Faya v. Almaraz*, 620 A.2d 327, 334 (Md. 1993) (citing and relying on AMA's code of medical ethics in negligence case concerning whether a surgeon infected with the AIDS virus has a legal duty to inform patients of that condition before operating upon them). And as ACOG explained in its *amicus* brief in this case, liability for failing to make a referral is not speculative: "delay or failure to refer a patient for appropriate treatment is a common ground for medical malpractice claims." Amicus Brief of ACOG, *et al.*, Dkt.53-1, at 7.

9. In a similar vein, the Court should reject Appellants' eleventh hour attempt to invoke prohibitions on abortion counseling in certain publicly funded programs as evidence of the requirements of medical ethics. Supp.Br.34-35. HHS did not rely on those restrictions as evidence

of medical ethics, meaning the Court cannot affirm the Rule on that basis. *See, e.g.*, *Chenery*, 318 U.S. at 87; *State Farm*, 463 U.S. at 50. And it would have been arbitrary and capricious if it had. Publicly funded programs are not required to abide by the requirements of medical ethics. HHS's error was not simply that it promulgated a Rule that contravenes medical ethics. Its error was in mistakenly concluding that the Rule is consistent with medical ethics, and promulgating the Rule relying on its erroneous and unfounded belief the Rule did not raise serious ethics concerns. Opinion.*10.

2. The Record Contradicts HHS's Repeated Statements in the Rule That There Was "No Evidence" That the Rule Would Have an Adverse Impact on Patients or Providers

HHS failed to adequately weigh the benefits and burdens of the Rule because HHS mistakenly believed that there was "no evidence" in the Record that providers would withdraw from the program, and no "actual data" that the Rule would negatively impact patients or providers, that it needed to weigh against the Rule's "benefits." HHS said this repeatedly in the Rule. 84 Fed. Reg. at 7749, 7775, 7780, 7785; Opinion.*10. It stated that: "[t]he Department finds no evidence to support the assertion that the final rule will drive current providers from

the Title X program," 84 Fed. Reg. at 7749 (emphasis added); "commenters did not provide evidence that the rule will negatively impact the quality or accessibility of Title X services. And the Department believes that this rule will likely improve quality and accessibility for Title X services," *id.* at 7780 (emphasis added); "[c]ommenters offer no compelling evidence that this rule will increase unintended pregnancies or decrease access to contraception," *id.* at 7785 (emphasis added); and "[the Department is] not aware, either from its own sources or from commenters, of actual data that could demonstrate a causal connection between the type of changes to Title X regulations contemplated in this rulemaking and an increase in unintended pregnancies, births, or costs associated with either," *id.* at 7775 (emphasis added). In reliance on this mistaken belief that it lacked any evidence, HHS asserted that "these final rules will contribute to more clients being served, gaps in service being closed, and improved client care." *Id.* at 7723.

But, as the district court recognized, HHS's claim that "no evidence" supported the view that the Rule would impact providers or patients in the Title X program was contrary to the evidence. Opinion.*10. HHS not

only had *some* evidence "support[ing] the assertion that the final rule [would] drive current providers from the Title X program," 84 Fed. Reg. at 7749, it had significant evidence that the Rule would seriously disrupt existing reliance interests, limit access to Title X care, and force an enormous number of providers out of the Title X program.

For example, several commenters explained that numerous existing Title X providers would likely withdraw from Title X if the Rule took effect. Opinion.*10; *see* Baltimore City Health Dep't Comment, SJA109; City Health Dep't Leaders Comment, SJA112; PPFA Comment, SJA371-76; Guttmacher Comment, SJA151-53; NFPRHA Comment 723, 727; Ryan Health Comment, SJA245; AMA Comment, SJA190. In contrast, HHS relied on only a single letter as evidence that new providers would enter the program to fill gaps in services.[5] *See* 84 Fed. Reg. at 7780 & n.138.

[5] HHS did not cite the comment from the Christian Medical Association as evidence that new providers would join the program. As the Christian Medical Association pointed out "a main reason why" more groups do not participate in the Title X program "is that they find the federal grants process far too complex and intimidating," SJA24, a problem the Rule made worse.

Moreover, commenters not only informed HHS that providers would be forced to withdraw from the program, but also provided HHS with the "actual data" that HHS said it did not have before it—data showing that the Rule would limit access to contraception and other types of reproductive health care, harming women's health, 84 Fed. Reg. at 7780. *See* Brindis Comment, SJA467-68; PPFA Comment, SJA437. Numerous commenters provided HHS with studies showing defunding even one major provider (Planned Parenthood) from a generally available grant program severely negatively impacts patient access to care. *See id.* One commenter provided HHS with a detailed and comprehensive chart showing the impact on contraception access state by state if Planned Parenthood alone withdrew from the Title X program. Guttmacher Comment, SJA163-68. HHS wholly failed to account for these effects. HHS's failure to weigh the evidence of negative impacts violated the APA. *Pub. Citizen v. Fed. Motor Carrier Safety Admin.*, 374 F.3d 1209, 1219 (D.C. Cir. 2004) ("The mere fact that the ... effect[ ] [of a rule] is *uncertain* is no justification for *disregarding* the effect entirely." (emphases in original)).

Appellants ignore HHS's misstatements about the evidence and claim with no support that "HHS expressly and extensively considered the reliance interests at stake, including the Rule's likely effect on incumbent providers and patients." Supp.Br.36; *see also* Supp.Br.37-39 (citing HHS speculation, with no consideration of the contrary "actual data" before it, that roughly the same number of providers would enter the program as would leave, and that on balance, the Rule would have no effect on patients or the number of available providers). HHS's prediction that enough providers would enter the Program to replace any providers that might depart was dead wrong. Roughly half of Title X's incumbent providers and numerous States have been forced out of the Program, *See* Guttmacher, *supra*, http://bit.ly/3csjZle; Power to Decide, *supra*, https://bit.ly/2z8YPti, belying HHS's bald claim that "the vast majority of Title X grantees have remained in the program since the Rule's referral restriction took effect," Supp.Br.39. Such a failure to consider relevant evidence concerning "an important aspect of the problem" is quintessential arbitrary and capricious agency action. *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983). Judicial deference to HHS's "expertise" and "predictive

judgments," Supp.Br.38, does not require the Court to disregard these plain factual errors.

Contrary to Appellants' claim, HHS cannot ignore evidence where it deems that evidence an attempt to "veto" a program change or a threat to "boycott" a program, Supp.Br.39-40. After an exhaustive search of cases in every federal circuit, the City was unable to locate a case in which any court has ever endorsed the view that an agency may simply disregard relevant evidence because it deems it a threat. In any event, in the Rule itself HHS never stated that it was disregarding any evidence on that basis, and Appellants cannot rationalize HHS's failure to consider relevant evidence *post hoc* in litigation briefs. *See, e.g.*, *Chenery*, 318 U.S. at 87; *State Farm*, 463 U.S. at 50. And there is no reason to believe that any of the information commenters provided to HHS about the consequences of the Rule were threats as opposed to honest representations about the Rule's consequences; Appellants do not offer any basis for characterizing commenters' warnings as attempts to "veto" the Rule or threats to "boycott" the program. The fact that non-grantees, including major nonpartisan professional medical organizations, offered much of the evidence demonstrating the Rule's negative consequences,

seriously undermines Appellants' claim that the evidence commenters provided was intended as a threat.

Finally, HHS's failure to weigh relevant evidence cannot be excused on the grounds that the Rule reflects the "best reading of Title X and other policy objectives regardless of the costs." Supp.Br.40. Agencies are almost always required to consider costs before promulgating rules, even when those Rules involve weighing incommensurables. *See Michigan*, 135 S. Ct. at 2706 (Scalia, J.) (an agency acts unreasonably in giving "cost no thought *at all*"); *id.* at 2716 (Kagan, J., dissenting) (agreeing that an agency "acts unreasonably" by disregarding costs "[u]nless Congress provides otherwise"). But the Court need not reach the question. Because HHS purported to consider the costs in this case, the Rule cannot now be affirmed on the grounds that HHS was entitled to ignore costs here. *See, e.g.*, *Chenery*, 318 U.S. at 87; *State Farm*, 463 U.S. at 50.

In light of the overwhelming weight of evidence in the Record, the district court points out the obvious: HHS's categorical assertions that commenters provided "no evidence" and "no data" showing that the Rule would have an adverse impact on providers and patients were wrong. Opinion.*10.

3. No Evidence Supports HHS's Estimate of the Costs of the Separation Requirement, and the Overwhelming Weight of the Evidence Shows That HHS Vastly Underestimated Them

HHS estimated that affected grantees would incur average costs of $30,000 but provided no support for that estimate. 84 Fed. Reg. 7782. HHS has not identified any evidence in the record that supports this number—not one study, not one pilot program, not one expert opinion, not even one comment from the public. The $30,000 number is neither rooted in evidence nor reality. No one—including HHS and Appellants—has any idea where that $30,000 number came from or what expenses it is supposed to cover (i.e., whether it is costs for facilities, recordkeeping, salaries, or other expenses). Appellants' Supplemental Brief sheds no new light on the source of the estimate. *See* Supp.Br.40-43.

The evidence before the agency showed that this unfounded number is nowhere close to the actual cost of compliance: Planned Parenthood, the largest Title X provider, carefully tallied the numbers and estimated average capital costs of nearly $625,000 per affected service site. Opinion.*11. Other commenters pointed to costs of similar amounts. *Id.* Evidence provided by commenters showed that HHS's cost estimates were not simply incorrect—but incorrect by *orders of magnitude*. *See*

Family Planning Council of Iowa Comment, SJA242 (explaining that cost of establishing a site in Iowa was $85,000); Ctr. Reprod. Rights Comment, SJA346 (explaining that "the cost of implementing an additional electronic health record system would cost tens of thousands, if not hundreds of thousands of dollars for large practices"); PPFA Comment, SJA388 (relying on cost estimate studies to estimate average renovation costs of $625,000 for Planned Parenthood sites). Indeed, HHS entirely failed to account for ongoing (not just one-time) costs, including those associated with required duplication of staff and contracts for goods and services—costs that can reach millions of dollars for some grantees. Opinion.*11; *See* PPFA Comment, SJA388-89; City Health Dep't Leaders Comment, SJA111-12; Brown Comment, at 2-3, AR245855-AR245856, https://bit.ly/2PBwvpz.

Even using HHS's own $30,000 number, HHS demonstrably underestimated the financial cost of the Separation Requirement by over $200 million. As Appellants admit, Supp.Br.41, HHS estimated that 15 percent of sites "do not comply with physical separation requirements" because they provide abortions. 84 Fed. Reg. at 7781. HHS multiplied 15 percent of the total Title X sites by its $30,000 per site cost to arrive

at a total estimated cost for the Separation Requirement of $36.08 million. 84 Fed. Reg. at 7782. But the Separation Requirement affected 100 percent of Title X sites, because merely making abortion *referrals* as part of pregnancy counseling violates the separation requirement, *see id.* at 7717, and every Title X grantee made abortion referrals before the Rule took effect. Thus the estimated total cost—even using HHS's own per-site number—should have been $240 million, not the $36 million the agency estimated. Here, again, HHS "entirely failed to consider an important aspect of the problem," *State Farm*, 463 U.S. at 43, and in doing so underestimated the cost of its Rule by roughly seven-fold—by over $200 million. That error warrants vacatur in its own right.

In earlier briefing, Appellants tried to brush off this error by hypothesizing that most Title X providers that chose to remain in the program would stop making abortion referrals—even for patients entirely outside the Title X program—rather than physically separate the parts of their facilities that make abortion referrals from the parts that do not. But HHS did not reach that conclusion and the Court cannot affirm the Rule on that basis. *See, e.g.*, *Chenery*, 318 U.S. at 87; *State Farm*, 463 U.S. at 50.

Finally, contrary to Appellants' claim, the district court did not "substitut[e] its own policy judgment regarding compliance costs" for that of HHS. Supp.Br.43. Quite the opposite. The district court held that HHS failed to root its estimate of the cost of compliance in any evidence and likely vastly underestimated the cost. *See* Opinion.*11.

B. The Rule Cannot Be Upheld on the Grounds That it Reflects "the Better Reading" of Title X

The Court should reject Appellants' new argument that because the Rule reflects "the better reading" of the Title X statute, that "alone" justifies HHS's "adoption of the Rule, regardless of what the Rule's effects and costs might be." Supp.Br.23-24. *First*, the argument is waived because Appellants are making it for the first time in this appeal. *Holland v. Big River Minerals Corp.*, 181 F.3d 597, 605 (4th Cir. 1999) ("Generally, issues that were not raised in the district court will not be addressed on appeal."). *Second*, Appellants concede that HHS weighed the degree to which the new Rule "better" implemented Title X against other factors, including the Rule's consistency with medical ethics, its impacts on patients and providers, and the costs of complying with the Separation Requirement. Supp.Br.24,26,40 (explaining HHS sought to weigh these "incommensurables" against one another). Errors weighing

incommensurables are still errors and are still subject to arbitrary and capricious review. *See* IPI Amicus Brief, Dkt.49, at 19-22 & n.10 (citing, e.g., *Public Citizen v. Fed. Motor Carrier Safety Admin.*, 374 F.3d 1209, 1219 (D.C. Cir. 2004)). *Third*, Title X is not in fact "better" read to restrict referrals for pregnancy termination, and *Rust* did not hold that it was. *Contra* Supp.Br.18. The *Rust* court expressed absolutely no view about which reading of the "ambiguous" statute is the better one. *See Rust*, 500 U.S. at 184–87. In fact, HHS's longstanding interpretation is the better one. It stretches words to their limit to say that abortion "is a method of family planning" in a program that does not provide abortion but only abortion referrals to patients who request them.

1. HHS's Errors About Medical Ethics, Program Impacts, and Compliance Costs Are Relevant Because HHS Relied on Them in Deciding Whether To Promulgate the Rule

It is undisputed that HHS gave some consideration to medical ethics, impacts on patients and providers, and the costs of complying with the Separation Requirement in the Rule, as Appellants spend much of their brief explaining. Supp.Br.26-43. HHS did not respond to comments about medical ethics, impacts, and costs by stating that HHS did not need to consider those issues because HHS's reading of Title X reflected the

"better reading" of the statute. And the Rule cannot be affirmed for reasons that the agency itself did not consider and upon which it did not rely. *See, e.g.*, *Chenery*, 318 U.S. at 87; *State Farm*, 463 U.S. at 50.

No exception or workaround to *Chenery* applies in this case. Appellants were not required to promulgate the Rule. Appellants concede this is not a *Chevron* Step One case where there is only one reasonable way to read the Title X statute. Supp.Br.23 (conceding Title X is an "ambiguous statute"). And this is not an instance where the agency Rule "can be sustained as a matter of law," *GTE S., Inc. v. Morrison*, 199 F.3d 733, 742 (4th Cir. 1999), especially not on the basis that the Rule reflects the "better" reading of Title X.

In short, HHS was not required to promulgate the new Rule and it is impossible to know whether HHS would have promulgated the Rule had it fully grappled with the medical ethics concerns, the devastating impacts on providers and patients, and the significant costs of the Separation Requirement. In circumstances like these, where the agency sought to weigh incommensurables but failed to "examine" "relevant data," *Dep't of Commerce v. New York*, 139 S. Ct. 2551, 2569 (2019), and thus made a "clear error of judgment," *Citizens to Preserve Overton Park,*

Inc. v. Volpe, 401 U.S. 402, 416 (1971), *abrogated on other grounds by Califano v. Sanders*, 430 U.S. 99 (1977), the appropriate result is vacatur and remand. "If judicial review is to be more than an empty ritual, it must demand something better than the explanation offered for the action taken in this case." *Dep't of Commerce*, 139 S. Ct. at 2576.

2. The Rule Does Not Reflect "the Better Reading" of Title X Because Abortion is Not a "Method of Family Planning" in a Program That Provides Patient-Requested Referrals

A Title X program that provides a referral for an abortion when a patient requests one is not best understood as a "program[] where abortion is a method of family planning." 42 U.S.C. § 300a-6. The *Rust* Court did not endorse a contrary view. *Contra* Supp.Br.18. The Court's words were: "we are unable to say that the Secretary's [prohibition on referrals] … is impermissible." *Rust*, 500 U.S. at 184.

A referral for an abortion is not the same as providing an abortion. And a referral provided at the patient's request does not endorse the patient's decision to seek the referral. A program that provides abortion referrals when requested is thus at least two steps removed from a program where abortion "is a method of family planning." Yet the Rule bars physicians from providing abortion referrals in order to implement

that statutory mandate. *Rust* may have held that interpretation of the text is "permissible," 500 U.S. at 184, but it is by no means the "better" reading. Supp.Br.23.

C. The Court Should Reject the Ninth Circuit's Reasoning Because its Decision is Marred by Errors and Unpersuasive

The Court should decline to follow the Ninth Circuit's decision. The Ninth Circuit did not have the full Record before it, *California*, 950 F.3d at 1082-84 & n.11, and so could not "engage in [the required] searching and careful inquiry of the [administrative] record" that is necessary before a court can adequately "consider whether the agency considered the relevant factors and whether a clear error of judgment was made." *Casa de Maryland*, 924 F.3d at 703 (internal quotation marks omitted); *see also* Opinion.*6 (noting the district court in our case conducted "a careful and searching inquiry" of the Record). Perhaps as a result, the Ninth Circuit did not confront the deficiencies in the Record nor address HHS's most serious errors. The Ninth Circuit also mistakenly and impermissibly supplemented HHS's reasoning and substituted its judgment for that of the agency.

The Ninth Circuit's discussion of medical ethics nowhere mentions HHS's failure to justify or explain its conclusion that the Rule is consistent with medical ethics in the face of overwhelming contrary evidence. *California*, 950 F.3d at 1101-03 & n.34. Nor does the Ninth Circuit recognize that HHS failed to cite any evidence supporting its incorrect conclusion. *Id.* The Ninth Circuit instead substituted its own position on the merits of the medical ethics issue for that of HHS. *Id.* That is something courts are not permitted to do. *State Farm*, 463 U.S. at 43.

The Ninth Circuit stated that the AMA misinterpreted its own *Code of Medical Ethics*. *See California*, 950 F.3d at 1088 & n. 34. Even if that were true, that was not the stated basis for HHS's conclusion. *See* 84 Fed. Reg. at 7724, 7748. HHS provided no reason for its decision to "disagree" with the AMA's conclusion, and AMA's interpretation of its own *Code of Medical Ethics* is likely to be correct. If HHS disagreed with the AMA's interpretation of its *Code of Medical Ethics*, HHS needed to provide a reasoned explanation for its disagreement. *State Farm*, 463 U.S. at 43.

The Ninth Circuit also held that *Rust*'s discussion of whether withholding abortion counseling violates a patient's First Amendment rights constituted a holding about the requirements of medical ethics. *California*, 950 F.3d at 1103 & n.36. But, as the City explains above, that misreads *Rust*. *Rust*'s holding regarding First Amendment limits on State interference with the physician-patient relationship says nothing about the medical providers' *ethical* duties. *See Rust*, 500 U.S. at 200.

The Ninth Circuit also failed even to address two more of HHS's patently incorrect claims: (1) HHS's claim that there was "no evidence" that the Rule would have adverse impacts on Title X services or Title X providers, 84 Fed. Reg. at 7749, 7775, 7780, 7785; Opinion.*9; and (2) HHS's underestimation of the cost of the Separation Requirement for existing providers by at least $200 million. The Ninth Circuit did not discuss the fact that HHS repeatedly incorrectly concluded that there was "no evidence"—at all—that the Rule would have adverse impacts on Title X services or Title X providers, when in fact it had overwhelming evidence of such impacts. *See California*, 950 F.3d at 1100. And the Ninth Circuit did not address the fact that HHS underestimated the cost of the Separation Requirement for existing providers by at least $200

million by incorrectly concluding that the Separation Requirement would only apply to Title X grantees who provide abortions (rather than grantees that merely provide referrals). *Id.* at 1101 & n.32.

The Ninth Circuit did not engage in the "thorough, probing, in-depth review," and corresponding "searching and careful" inquiry into the facts, that the APA requires. *Overton Park*, 401 U.S. at 415-416.

II. The Court Should Affirm the District Court's Decision to Vacate the Rule on Additional Grounds

The Court should affirm the district court's decision to vacate the Rule on additional grounds. The Court can affirm the judgment on any ground properly raised below. *See Jones v. United States*, 527 U.S. 373, 396 (1999); *Nw. Airlines, Inc. v. Cty. of Kent, Mich.*, 510 U.S. 355, 364 (1994).

A. The Rule Violates the Nondirective Mandate and Non-Interference Mandates

The Rule violates the Nondirective and Non-Interference Mandates for the reasons given in the City's Brief for the Appellee. *See* Brief for Appellee, Appeal No. 19-1614, Dkt.44.

B. The Rule Violates Title X's "Voluntary Acceptance Requirement"

The Rule violates Title X's requirement that acceptance of Title X services be voluntary. Title X provides in relevant part that: "The acceptance by any individual of [Title X] family planning services or ... information (including educational materials) ... shall be voluntary." 42 U.S.C. § 300a-5 ("Voluntary Acceptance Requirement"). HHS's own *current* regulation interpreting that provision—which has stood since 1980 and which the new Rule did not modify—requires that "each project supported under this part must …. Provide services without subjecting individuals to any coercion … to employ or not to employ any particular methods of family planning." 42 C.F.R. § 59.5(a)(2). Thus, 42 U.S.C. § 300a-5 and 42 C.F.R. § 59.5(a)(2) both prohibit Title X grantees from coercing patients into having an abortion or foregoing one.

The Rule violates both 42 U.S.C. § 300a-5 and 42 C.F.R. § 59.5(a)(2) because the Rule's requirements that physicians withhold abortion referrals (even if a patient asks for one) and make prenatal care referrals (even if a patient says she does not want one) are intended to coerce, and do in fact coerce, patients to obtain prenatal care and not abortion services.

C. The Rule Violates the APA's Rulemaking Requirements

The Rule should be vacated and remanded to the agency because the agency failed to give the City and the public a meaningful opportunity to comment. Appellants structured the rulemaking process to take regulated parties by surprise and deprive them of a "meaningful opportunity for comment" in violation of this Court's precedents. *N.C. Growers' Ass'n, Inc. v. United Farm Workers*, 702 F.3d 755, 770 (4th Cir. 2012).

The Rule is complex and extremely consequential. Yet in promulgating the Rule, HHS violated multiple Executive Orders and controlling OMB guidance specifically designed to give stakeholders advance notice of proposed rulemaking. Harris & Hassan Comment, SJA470-71; "About the Unified Agenda," SJA1079. Those orders and guidance mean regulated parties are virtually always afforded many months, or even years, of advance notice of a proposed rule—time they use to begin investigating facts and law relevant to a proposed rule. But because of HHS's violations of those orders and guidance even the most vigilant stakeholders here at best had 70 days to prepare comments because notice that a proposed rule was even contemplated was first

made public only ten days before the comment period opened. SJA1187-88. Numerous commenters including Baltimore, blindsided by the proposed rule's sudden announcement, requested more time to comment, but HHS refused. *E.g.* Md. Cong. Delegation Comment (quoting Baltimore City Health Department), SJA54-55; Conn. Comment, SJA28; Legal Voice Comment, SJA30; New York Comment, SJA36; Universal Healthcare Comment, SJA257; PPFA Comment, SJA430-31; Harris & Hassan Comment, SJA470-42. HHS's extraordinary departures from the standard rulemaking process deprived commenters of a meaningful opportunity to comment.

D. The Rule Violates the First Amendment

The Rule violates the First Amendment rights of doctors and patients. *Rust* held that Title X—as it was then structured—permissibly "used private speakers to transmit specific information pertaining to its own program" and that the counseling restrictions were "appropriate steps to ensure that its message [was] neither garbled nor distorted by the grantee." *Rosenberger v. Rector & Visitors of Univ. of Va.*, 515 U.S. 819, 833 (1995); *see Legal Services Corp. v. Velazquez*, 531 U.S. 533, 541 (2001) (making the same point). But Congress has modified the Title X

Program in important respects since *Rust*, specifically by enacting the Nondirective and Non-Interference Mandates. As a consequence of the enactment of those provisions, the Title X Program is no longer a program designed to convey a government message, but rather a program designed to promote an open doctor-patient dialogue. Thus, the limitations on physician speech in the Rule are controlled by *Rosenberger*'s strict scrutiny test, 515 U.S. at 830-37, not *Rust*, and fail under that test.

E. The Rule Violates the Fifth Amendment Because it Discriminates Against Women on the Basis of Sex

State policies that entrench stereotypes of what women *should* be are illegal.[6] *See, e.g.*, *United States v. Virginia,* 518 U.S. 515, 533-34 (1996), (physical differences "may not be used, as they once were, to create or perpetuate the legal, social, and economic inferiority of women."); *id.* at 542 n.12. More recently, the Court made clear that certain laws and policies awarding benefits based on reproductive capacity impose sex-based stereotypes in violation of the equal protection

[6] *See generally* Cary Franklin, *The Anti-Stereotyping Principle in Constitutional Sex Discrimination Law*, 85 N.Y.U. L. Rev. 83 (2010); Neil S. Siegel & Reva B. Siegel, *Pregnancy and Sex Role Stereotyping: From* Struck *to* Carhart, 70 OHIO ST. L.J. 1095 (2009).

clause. *Nev. Dep't of Human Resources v. Hibbs*, 538 U.S. 721, 730-36 (2003). Chief Justice Rehnquist explained that policies that discriminate based on pregnancy and enforce sex-based assumptions about women's role as mothers are a paradigmatic example unlawful sex-stereotyping in violation of the Due Process Clauses' guarantee of sex equality. *Id.* at 724-25, 731, 736 (pattern of state laws justifying differential parental leave policies based on pregnancy was unconstitutional sex discrimination because it entrenched sex-based stereotypes).

Geduldig v. Aiello, 417 U.S. 484 (1974), decided almost thirty years before *Hibbs*, when constitutional sex discrimination jurisprudence—not to mention understandings of women's equality—was in its nascent stage, is not to the contrary. In *Geduldig*, the Court left open the proposition that *some* pregnancy classifications are sex-based. *Id.* at 496-97 n.20 (holding that "[w]hile it is true that only women can become pregnant it does not follow that *every* legislative classification concerning pregnancy is a sex-based classification" (emphasis added)). *Hibbs* answered the question left open by *Geduldig*: pregnancy classifications are sex-based and violate constitutional sex equality guarantees when they entrench sex-role stereotypes.

The Rule is such a classification. It treats pregnant patients differently from other patients in a manner that entrenches stereotypes about women. Policies that restrict women's autonomy to end an unwanted pregnancy enforce an unlawful stereotype—that women's place is in the home while men are responsible for civic engagement. Haugeberg Decl., SJA601-02 ¶¶15-17; *id.* at SJA 604-05 (discussing history of laws regulating reproductive health care, designed to enforce "women's obligations as wives and mothers", and "women's place in the home"). Moreover, the Rule's prohibition on referrals for abortion and mandatory referrals for prenatal care—like old laws restricting information about family planning methods—reveals "a deep mistrust of women's abilities to make informed and responsible judgments." *Id.* SJA629-30 ¶¶84-85.

Because the Rule classifies based on pregnancy in a way that constitutes sex discrimination, the Government must meet heightened scrutiny by coming forward with persuasive evidence that there is an "exceedingly persuasive" justification for the Rule and that it "serves 'important governmental objectives and that the discriminatory means employed' are 'substantially related to the achievement of those

objectives.'" *Virginia*, 518 U.S. at 533 (internal citations omitted). That it cannot do. The claim that the Rule is needed to enforce the statutory ban on funding for abortion activities is false. And any attempt to justify the Rule as protecting women is neither an "exceedingly persuasive" justification serving important governmental objectives, nor would the Rule be substantially related to the achievement of those objectives. In fact, such a justification would further confirm that the Rule is intended to enforce outdated sex-role stereotypes in violation of the Fifth Amendment.

III. The Court Should Affirm the District Court's Decision To Vacate and Permanently Enjoin the Rule

The district court entered appropriate relief in this case. The court correctly vacated the Rule—a point Appellants do not dispute and have thus conceded.[7] The permanent injunction is not overbroad. And the district court correctly vacated and enjoined the entire Rule because it is inseverable.

[7] *United States v. Al-Hamdi*, 356 F.3d 564, 571 n.8 (4th Cir. 2004) ("It is a well settled rule that contentions not raised in the argument section of the opening brief are abandoned.").

A. Appellants Do Not Dispute That the District Court Correctly Vacated the Rule

The district court correctly vacated the Rule. Injunctive relief and vacatur are distinct remedies. *See Monsanto Co. v. Geertson Seed Farms*, 561 U.S. 139, 165-66 (2010). At the final judgment stage of a case, vacatur is the presumptive remedy for an APA violation. *See* 5 U.S.C. § 706(2); *Sierra Club v. U.S. Army Corps of Eng'rs*, 909 F.3d 635, 655 (4th Cir. 2018); *Nat'l Mining Ass'n v. U.S. Army Corps of Eng'rs*, 145 F.3d 1399, 1409 (D.C. Cir. 1998) ("[W]hen a reviewing court determines that agency regulations are unlawful, the ordinary result is that the rules are vacated—not that their application to the individual petitioners is proscribed." (internal quotation marks omitted)). An injunction is a more significant remedy than vacatur. *Monsanto*, 561 U.S. at 165. A court is not remiss in ordering vacatur alone without an accompanying injunction. *Id.* at 165-66. In this case, the district court concluded that vacatur *and* an accompanying permanent injunction were warranted. Order, SJA1330-31 (granting permanent injunction); Mem. Order, SJA1335-38 (clarifying vacatur was also granted).

Vacatur does not operate like an injunction. The APA requires courts to "set aside" unlawful agency action. 5 U.S.C. § 706(2). When

agency action is set aside, it is "vacate[d]," "annul[led]," "render[ed] void," "deprive[d] of force," and "ma[d]e of no authority or validity." *Action on Smoking & Health v. Civil Aeronautics Bd.*, 713 F.2d 795, 797 (D.C. Cir. 1983) (per curiam). And where the challenged agency action is unlawful on a program-wide basis, the APA requires that action to be "set aside" on a program-wide basis. *See Harmon v. Thornburgh*, 878 F.2d 484, 495 n.21 (D.C. Cir. 1989). As the Supreme Court has recognized, a single adversely affected plaintiff can "of course" challenge final agency actions that apply "across the board" and thereby "affect[]" the "entire" agency program. *Lujan v. Nat'l Wildlife Fed'n*, 497 U.S. 871, 890 n.2 (1990). Because vacatur is the remedy the APA provides, the district court correctly vacated the Rule.

B. The Court Should Hold That Vacatur by its Nature Cannot Be Limited Geographically

The district court erred in one respect, however, by purporting to limit the geographic scope of the vacatur to Maryland. It does not make sense to speak of "vacatur" in party-based or geographic terms. *See O.A.*, 404 F. Supp. 3d at 152-54. Vacatur, by its very nature, is a holding that a rule is unlawful. When a rule is vacated the rule ceases to be effective. That is, the agency has been told that the rule is unenforceable. It is

analogous to the Supreme Court "vacating" an opinion by a court of appeals. When the opinion is vacated it no longer carries legal significance, not just for the parties to that case, but for all purposes. There is no way for an agency to lawfully enforce a vacated rule once an Article III court has held that the rule is invalid. An order vacating a rule is not an injunction—it does not carry the threat of contempt or court sanctions—but is nonetheless sufficient to defeat its legality in use.

Thus, every court to expressly consider the issue—until now—has concluded that an order vacating agency action under 5 U.S.C. § 706(2) cannot be restricted geographically or to the parties. *See City & Cty. of S.F. v. Azar*, 411 F. Supp. 3d 1001, 1025 (N.D. Cal. 2019), *appeal filed*, No. 20-15398 (9th Cir. Mar. 9, 2020); *O.A.*, 404 F. Supp. 3d at 152-54, *appeal filed*, No. 19-5272 (D.C. Cir. Oct. 11, 2019); *N.M. Health Connections v. HHS*, 340 F. Supp. 3d 1112, 1183 (D.N.M. 2018), *rev'd on other grounds*, 946 F.3d 1138 (10th Cir. 2019); *Desert Survivors v. U.S. Dep't of the Interior*, 336 F. Supp. 3d 1131, 1134 (N.D. Cal. 2018); *see also E. Bay Sanctuary Covenant v. Trump*, __ F.3d ___, Nos. 18-17274, 18-17436, 2020 WL 962336, *24 (9th Cir. Feb. 28, 2020).

This Court's decision in *Virginia Society for Human Life, Inc. v. Federal Election Commission* (*VSHL*), 263 F.3d 379 (4th Cir. 2001), is not to the contrary. *VSHL* concerned the appropriate scope of an injunction, not vacatur. *See id.* at 394. After the Federal Election Commission denied a petition for a rulemaking to repeal an FEC regulation, the plaintiff sued for a declaratory judgment and injunctive relief. The district court held that the regulation violated the First Amendment and entered a nationwide injunction enjoining its enforcement, without reaching VSHL's APA claims. *Va. Soc'y for Human Life v. Fed. Election Comm'n*, 83 F. Supp. 2d 668, 676-77 (E.D. Va. 2000). This Court affirmed the district court on the merits—solely on constitutional grounds, *see* 263 F.3d at 381, 392—but determined that the injunction should be limited to enjoining the FEC from enforcing the regulation against the plaintiff, *id.* at 393-94. The *VSHL* court stated that "[n]othing in the language of the APA … requires us to exercise such far-reaching power." *Id.* at 394. But the "far-reaching power" to which the *VSHL* court referred was the power to enter a nationwide injunction, not to vacate a rule. Vacatur does not operate in geographic or party-based terms, and therefore, vacating a rule is not the exercise of "far-reaching power" but instead the

exercise of the power Congress determined was appropriate to ensure orderly and effective judicial review of agency action. *See O.A.*, 404 F. Supp. 3d 109, 152-154 (D.D.C. 2019) ("What would it mean to 'vacate' a rule as to some but not other members of the public? What would appear in the Code of Federal Regulations?").

The district court denied the City's request to amend the district court's vacatur order to eliminate the geographic limitation on its scope. *See Mayor & City Council of Baltimore v. Azar*, 2020 WL 1873947 (D. Md. Apr. 15, 2020). This Court has the power to correct that error and should do so. In this Circuit "the cross-appeal requirement [is] one of practice, not a strict jurisdictional requirement." *Am. Roll-On Roll-Off Carrier, LLC v. P & O Ports Baltimore, Inc.*, 479 F.3d 288, 295 (4th Cir. 2007); *Greenlaw v. United States*, 554 U.S. 237, 245 (2008) (discussing and declining to disturb the Circuit's rule). In any event, holding that vacatur cannot be geographically limited would not implicate the cross-appeal rule because it would not alter the judgment below. Such a holding would not eliminate the purported geographic limitation in the vacatur order, but merely explain that the geographic limitation is not

legally significant.[8] The Court should hold that vacatur is not a geographically limited remedy.

C. The Injunction Is Not Overbroad and Comports With Longstanding Principles of Equity and Article III

Appellants agree that the district court's injunction is lawful as long as it was "necessary to provide complete relief" to the City. Supp.Br.45-46 (internal quotation marks omitted). The City provided persuasive, unrebutted evidence below that a Maryland-wide injunction would be necessary to prevent irreparable harm to the City.[9] That was sufficient to justify the court's injunction under the deferential abuse-of-discretion standard this Court applies to the entry of permanent injunctions. In further support of this argument, the City directs the Court to the

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[8] As explained above, the Court can clarify the nature of the vacatur remedy without a cross-appeal. For that reason, and because cross-appealing would make this case more complex, the City has not cross-appealed. But if the Court believes a cross-appeal is needed, the City will promptly cross-appeal. The City has until June 15, 2020 to file a cross-appeal.

[9] *See, e.g.*, Dr. Mobley Declaration, SJA961 ("The kind of care mandated by the Final Rule would damage the patient-provider relationship" and "thus cause many patients to delay or avoid seeking necessary medical care in the future."); Hager Decl., SJA972 ("Baltimore's public health services will have to spend more non-Title X funds due to the loss of Title X funds by providers in Maryland and neighboring states.").

relevant section of its Brief for the Appellee explaining the City's need for a statewide preliminary injunction. *See* Brief for Appellee, Appeal No. 19-1614, Dkt.44, at 67-68.

D. The Rule Is Inseverable

Appellants' severability argument is waived. Appellants did not argue severability below. *See Holland*, 181 F.3d at 605. The City argued at summary judgment that the Rule is inseverable. Pls. Mot. SJ, SJA582-83. In their cross-motion for summary judgment, Appellants noted that the Rule contained a severability clause but did not argue anywhere that the Rule is inseverable. *See* Def's Cross Mot. SJ, SJA1110. In its response, the City noted the waiver and explained the prejudice that would result if Appellants were permitted to raise severability for the first time in their reply. Pls. Opp. to SJ, SJA1186-1187, 1211. In Appellants' reply, rather than argue the issue, Appellants instead, in a footnote "incorporate[d] by reference their [severability] argument[s]" from their opposition to the City's motion for a preliminary injunction. Defs. Reply SJ, SJA1220 n.1. Issues raised only in reply, and only in footnotes, are not properly raised. *Hunt v. Nuth*, 57 F.3d 1327, 1338 (4th Cir. 1995) (finding issue raised only in reply waived); *Wahi v. Charleston*

Area Med. Ctr., Inc., 562 F.3d 599, 607 (4th Cir. 2009) (finding issue raised only in footnote waived).

In any event, the district court correctly concluded that the Rule is inseverable. Appellants do not dispute that the governing test is whether there is "substantial doubt" that the issuing agency would have promulgated the rule in the absence of the challenged provisions. *North Carolina v. FERC*, 730 F.2d 790, 795-96 (D.C. Cir. 1984) (citing *FPC v. Idaho Power Co.*, 344 U.S. 17, 20-21 (1952)); *accord Nat'l Treasury Emps. Union v. Chertoff*, 452 F.3d 839, 867 (D.C. Cir. 2006). Nor do Appellants dispute "the ultimate determination of severability will rarely turn on the presence or absence" of a severability clause. *Cmty. for Creative Non-Violence v. Turner*, 893 F.2d 1387, 1394 (D.C. Cir. 1990) (quoting *United States v. Jackson*, 390 U.S. 570, 585 n.27 (1968)). Nor do Appellants anywhere contend that HHS would have in fact promulgated the Rule without the counseling restrictions and Separation Requirement. *See* Supp.Br.49-50. There are thus no grounds for severing the Rule here.

Indeed, severing the Rule in this case would be particularly inappropriate because HHS's APA violations in this case are fundamental. HHS's violation of at least two statutory restrictions on its

authority and three serious errors in considering the evidence before it calls into question the validity and integrity of the entire rulemaking venture. A severability clause—without more—is not enough to justify severing a Rule in these circumstances. Such a clause is "an aid merely; not an inexorable command," *Whole Woman's Health v. Hellerstedt*, 136 S. Ct. 2292, 2319 (2016) (internal quotation marks omitted), and does not give a court license to "devise a judicial remedy that ... entail[s] quintessentially legislative work," *Ayotte v. Planned Parenthood of N. New England*, 546 U.S. 320, 329 (2006). Severing in circumstances like these "would inflict enormous costs on *both courts and litigants*." *Whole Woman's Health*, 136 S. Ct. at 2319 (emphasis added); *see* Supp.Br.50 (arguing that the parties and the Court should canvass the Rule line by line to determine which provisions are inseverable).

Preserving isolated parts of the Rule likely deviates from the course HHS would have chosen in the face of the invalidation of the Rule's core provisions. Vacating the entire rule thus respects "the fundamental principle that agency policy is to be made, in the first instance, by the agency itself—not by courts, and not by agency counsel." *Harmon*, 878 F.2d at 494. Thus, "Courts ordinarily do not attempt, even with the

assistance of agency counsel, to fashion a valid regulation from the remnants of the old rule." *Id.* (footnotes omitted). The Court should affirm the district court's holding that the Rule is inseverable.

CONCLUSION

The Court should clarify that vacatur has no geographic limitations, but otherwise affirm the district court's decision.

April 24, 2020

Respectfully submitted,

s/ *Andrew Tutt*

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing response in opposition to motion for stay pending appeal was filed electronically on April 24, 2020 and will, therefore, be served electronically upon all counsel.

s/ *Andrew Tutt*
Andrew T. Tutt

CERTIFICATE OF COMPLIANCE

Pursuant to Federal Rules of Appellate Procedure 32(a) and 32(g), the undersigned counsel for appellee certifies that this brief:

1. This brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7) because this brief contains 11,926 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(f).

2. This brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and (6) because this brief has been prepared using Microsoft Office Word and is set in Century Schoolbook font in a size equivalent to 14 points or larger.

s/ *Andrew Tutt*
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