IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

MAYOR AND CITY COUNCIL OF BALTIMORE, *Plaintiff*, v. ALEX M. AZAR II, in his official capacity as the Secretary of Health and Human Services; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; DIANE FOLEY, M.D., in her official capacity as the Deputy Assistant Secretary, Office of Population Affairs; OFFICE OF POPULATION AFFAIRS, *Defendants*.	Case No. 1:19-cv-01103 RDB

PLAINTIFF'S MEMORANDUM IN OPPOSITION TO DEFENDANTS' CROSS MOTION FOR SUMMARY JUDGMENT AND REPLY IN SUPPORT OF PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Cases **Page(s)**

Statutes, Rules & Regulations

Other Authorities

OPPOSITION AND REPLY

The Court should grant Baltimore City summary judgment and vacate the Rule in its entirety. The Rule violates three statutes, is arbitrary and capricious, was adopted through a rushed and procedurally flawed process that prejudiced Baltimore City, violates the First Amendment, and violates the equal protection component of the Fifth Amendment's Due Process Clause.

I. Defendants Do Not Dispute Key Material Facts and Legal Arguments

A "party waives an issue at summary judgment when it fails to argue or brief the issue." *Nzabandora v. Rectors & Visitors of Univ. of Va.*, 749 F. App'x 173, 176 n.3 (4th Cir. 2018) (citing *Cox v. SNAP, Inc.*, 859 F.3d 304, 308 n.2 (4th Cir. 2017)); *see also Slovinec v. Am. Univ.*, 520 F. Supp. 2d 107, 111 (D.D.C. 2007) ("[I]f a [party] files an opposition to a ... motion and addresses only certain arguments raised by the [opponent], a court may treat those arguments that the [party] failed to address as conceded." (internal quotation marks omitted)).

The principle is one of basic fairness. This Opposition and Reply is Plaintiff's last opportunity to address arguments and issues raised by the Defendants. If Defendants bring forward *new* evidence and *new* arguments on Reply, Baltimore will have no opportunity to respond to them. That is not only unfair to Baltimore, but risks an improvident or ill-advised opinion from the Court. *See Sanders v. Callender*, No. DKC 17-1721, 2018 WL 337756, at *7 n.5 (D. Md. Jan. 9, 2018) ("[R]uling on an issue minimally addressed is unfair" to an opposing party and "risk[s] an improvident or ill-advised opinion on the legal issues raised." (quoting *Hunt v. Nuth*, 57 F.3d 1327, 1338 (4th Cir. 1995)).

Defendants do not dispute the following material facts and legal arguments raised in Plaintiff's Motion for Summary Judgment.

A. Defendants Do Not Dispute that the Rule is Inseverable

Defendants do not dispute that the Rule is inseverable. ECF 81-1 ("MSJ"), at 34-35. Therefore, if the Court determines that either the Rule's counseling restrictions or its separation requirements are unlawful, Defendants do not dispute that the appropriate remedy is to vacate the Rule in its entirety.

B. Defendants Do Not Dispute That No Medical Organizations, Codes of Medical Ethics, Or Medical Professionals Consider the Rule Consistent with Medical Ethics and Have Pointed to No Record Evidence Supporting the Conclusion

Defendants do not dispute that the Rule requires medical providers to violate codes of medical ethics, including statutory codes of ethics. MSJ at 8. Defendants do not dispute that HHS has not identified any code of medical ethics under which the Rule's counseling restrictions would be considered ethical. MSJ at 8-9. Defendants do not dispute that HHS has not identified any professional medical organization that takes the position that it is ethical to withhold relevant medical information from a patient who is requesting it. MSJ at 8-9. Defendants do not dispute that HHS has not identified a single physician who believes it is consistent with medical ethics for a physician to obstruct a patient's access to safe and legal medical treatment because the physician disagrees with the patient's decision to pursue that treatment. MSJ at 8-9. And Defendants have pointed to no record evidence whatsoever supporting the agency's conclusion.

C. Defendants Do Not Dispute That The Rulemaking Process Violated Executive Orders and OMB Guidance, And That The Earliest That Stakeholders Became Aware of the Proposed Rule Was May 22, 2018—Ten Days Before The Comment Period Opened

Defendants do not dispute that the Proposed Rule never appeared on the Fall 2017 or Spring 2018 Regulatory Agendas. MSJ at 9. Defendants do not dispute that the Rulemaking process involved no early outreach to affected stakeholders. *Id.* Defendants do not dispute that the earliest that stakeholders became aware of the Proposed Rule was May 22, 2018, ten days before

the comment period opened. *Id.* at 9-10; ECF 83 ("CMSJ") at 26. Defendants do not dispute that HHS's actions violated Executive Orders 12,866 and 13,563 and OMB Guidance. MSJ at 9-10; CMSJ at 28-29.

D. Defendants Do Not Dispute That The Agency Failed to Explain Key Departures From Its Existing Legal Interpretations and Factual Conclusions

Defendants do not dispute that HHS did not acknowledge or explain in the Rule that the agency was changing its position on the appropriate interpretation of the Nondirective Mandate. CMSJ 21-22. Defendants do not dispute that the Rule does not explain why HHS departed from its own evidence-based assessment of the importance of nondirective counseling and medically appropriate referrals in its Quality Family Planning Guidelines. MSJ at 17; CMSJ at 23. Defendants do not dispute that the Rule does not explain why HHS changed its view, expressed in the 2000 Rule, that medical ethics require nondirective counseling and referral. MSJ at 17; CMSJ at 23.

E. Defendants Do Not Dispute That HHS Had Evidence Before It Relevant to the Rule's Negative Consequences for Access to Title X Services, Directly Contradicting HHS's Claims In the Rulemaking That It Had "No Evidence"

Defendants do not dispute that HHS had evidence before it that supported the conclusion that the Rule would drive current providers from the Title X program, directly contradicting HHS's assertion in the Rule that it had "no evidence." MSJ at 19; CMSJ at 23. Defendants do not dispute that commenters provided evidence that the rule would negatively impact the quality and accessibility of Title X services, directly contradicting HHS's assertion in the Rule that commenters "did not provide" such evidence. MSJ at 19-21; CMSJ at 23. Defendants do not dispute that commenters provided actual data demonstrating a causal connection between the type of changes contemplated by the Rule and an increase in unintended pregnancies, births, or costs,

MSJ at 19-21; CMSJ at 23, directly contradicting HHS's assertion in the Rule that HHS was "not aware" of any such "actual data." 84 Fed. Reg. at 7724.

II. *Rust v. Sullivan* Does Not Foreclose Baltimore's Arguments

Defendants are incorrect that Baltimore's claims are foreclosed by *Rust v. Sullivan*, 500 U.S. 173 (1991). *See generally* CMSJ. *Rust* does not foreclose any of Baltimore's claims, as this Court has already held. Op. on Mot. Dis. at 12-13, ECF 74 ("MTD Op."). *Rust* is not binding precedent for issues that were not argued or decided in that case. *See, e.g.*, *United States v. Verdugo-Urquidez*, 494 U.S. 259, 272 (1990) (explaining that Supreme Court decisions should not be interpreted to "encompass" issues beyond the "[t]he question presented for decision"); *United States v. L.A. Tucker Truck Lines, Inc.*, 344 U.S. 33, 37-38 (1952) (explaining that where a point "was not ... raised in briefs or argument nor discussed in the opinion of the Court ... the case is not a binding precedent on this point"); *United States v. More*, 7 U.S. 159, 172 (1805) (Marshall, C. J.); *see also Legal Servs. Corp. v. Velazquez*, 531 U.S. 533, 557 (2001) (Scalia, J., dissenting) ("Judicial decisions do not stand as binding 'precedent' for points that were not raised, not argued, and hence not analyzed.").

None of Baltimore's claims were at issue—much less analyzed or decided—in *Rust*. The Nondirective Mandate and the Non-Interference Mandate were enacted after *Rust* and do not conflict with *Rust*. Op. on Prelim Inj., ECF 43 ("PI Op."), at 16, 19; MTD Opp. at 13. The Rule's substantive reasonableness, the adequacy of HHS's justification for it, and the adequacy of the public procedures used to craft it are to be tested against the actions of the agency *today*, not 30 years ago. *See* PI Op. at 22. Finally, Baltimore's other claims—that the Rule violates Title X itself and Equal Protection, and the particular First Amendment claims Baltimore now raises—were not analyzed or decided in *Rust.*

III. Baltimore City Is Entitled To Summary Judgment On All of Its Claims

A. The Rule Violates the Non-Interference Mandate (Count I)

The Rule violates the Non-Interference Mandate for the reasons stated in Plaintiff's Motion for Summary Judgment, MSJ at 12-13, Plaintiff's Motion for Preliminary Injunction, ECF 11-1 ("PI Mot.") at 15-19, Plaintiff's Reply in Support of that motion, ("PI Reply"), ECF 34, at 6-13, and in the Court's opinion granting the Preliminary Injunction, PI Op. at 17-18.

Defendants still press waiver. CMSJ at 11-12. But waiver has never barred Plaintiff's Non-Interference Mandate claim, and it certainly has no relevance now that HHS is "applying the Rule" to all Title X grantees—including Baltimore City. Defendants do not dispute that commenters raised the "substance of the issues covered" by the Non-Interference Mandate during the rulemaking. CMSJ at 11. That is all that was necessary. *See 1000 Friends of Md. v. Browner*, 265 F.3d 216, 228 (4th Cir. 2001); *see California v. Azar*, 385 F. Supp. 3d 960, 993–95 (N.D. Cal. 2019) (collecting comments). Requiring commenters to raise issues with precise legal citations would elevate form over substance, and undermine the fundamental public participation purposes that underlie notice and comment rulemaking. The commenters on the Rule who explained that the Rule violates medical ethics were doctors, not lawyers, and their comments should be construed in that light. Notice and comment is supposed to be a meaningful opportunity for give-and-take between the agency and the public, not a word game.

Moreover, Defendants do not dispute that HHS considered the ACA—including § 1554—during the rulemaking. CMSJ at 12 n.1. Nor could they, because Defendants' reproduced § 1554 in the administrative record and represented that HHS relied on it.[1] Waiver does not apply where

[1] Defendants' contend that HHS relied on the ACA but "not § 1554 in particular." CMSJ at 12 n.1. But Defendants reproduced the entire ACA in the administrative record, including § 1554, and represented that they relied on the ACA (which, by definition, includes § 1554). That reasonably means HHS relied on the whole law, including § 1554.

the agency in fact addressed an issue in crafting the Rule. *See Koretoff v. Vilsack*, 707 F.3d 394, 400 n.3 (D.C. Cir. 2013) (Williams, J., concurring). Moreover, contrary to Defendants' claim, CMSJ at 12, which relies on citation to a concurrence in a D.C. Circuit case, in *this* circuit, purely legal questions, like those raised by the Non-Interference Mandate, are not subject to waiver. *See Cowpasture River Pres. Ass'n v. Forest Serv.*, 911 F.3d 150, 182 (4th Cir. 2018).

But, the Court need not reach any of these questions because HHS is "applying the Rule" to all Title X grantees—including Baltimore City—and therefore waiver simply has no application at all. CMSJ at 11. Defendants' are wrong that "applying the Rule" is restricted to some kind of judicial enforcement proceeding—Title X does not have enforcement proceedings. Failure to comply results in the termination of grant funding, not a prosecution. Under Defendants' view, if parties fail to raise an issue during notice and comment on a Title X rule they would *never* be able to challenge it because HHS does not enforce Title X through enforcement proceedings. Instead, as Defendants' own best authority states, waiver is inapplicable "where an agency may act without affording a pre-deprivation hearing and the affected party can and does immediately challenge the action in court." *Koretoff v. Vilsack*, 707 F.3d at 400 (Williams, J., concurring). That is what happened in this case: Baltimore sued for a preliminary injunction to *avoid* the termination of its Title X grant funding. Because this is a challenge where HHS is "applying the Rule" to Baltimore City, that is yet another reason that waiver does not bar Plaintiff's claim.

Defendants' other arguments, CMSJ at 10-14, have already been addressed extensively in other briefing and are unpersuasive. The Non-Interference Mandate is not an "obscure" provision of the ACA; applying it would not impliedly repeal *Rust*; it plainly applies to any regulation the Secretary promulgates (including those involving grant funds); and the Rule violates the Mandate by requiring healthcare providers to violate the ethical standards of healthcare

professionals, by interfering with doctor-patient communications, and by imposing unreasonable barriers to access and care.

B. The Rule Violates the Nondirective Mandate (Count II)

The Rule violates the Nondirective Mandate for the reasons stated in Plaintiff's Motion for Summary Judgment, MSJ at 13-14, Plaintiff's Motion for Preliminary Injunction, PI Mot. at 19-21, Plaintiff's Reply in Support of that motion, PI Reply at13-16, and in the Court's opinion granting the Preliminary Injunction, PI Op. at 18-20. Defendants' arguments, CMSJ at 14-19, have already been addressed extensively in other briefing and are unpersuasive. The Nondirective Mandate did not impliedly repeal *Rust* (indeed, HHS itself believes the Mandate requires Title X grantees to engage in nondirective pregnancy counseling, *see* CMSJ at 22); "referrals"—advice about where to go for further treatment—are unambiguously "counseling" (as usage in dictionaries, the medical community, by Congress in other statutes, and even by HHS in this rulemaking all show); and the Rule's requirement that providers make referrals for prenatal care (even when a patient does not want it) and withhold referrals for pregnancy termination (even when a patient requests it) each violate the Nondirective Mandate because they are coercive, not nondirective. *See* PI Op. at 20.

C. The Rule Violates Title X's Requirement That Title X Services Be "Voluntary" and Non-Coercive (Count III)

The Rule violates Title X's requirement that Title X services be voluntary.[2] 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.

[2] The statute does not, as Defendants' misleadingly altered quotation of the statue would have it, "require[] *only* that Title X services be 'voluntary' *in the sense that* accepting family planning services under the program 'shall not be a prerequisite to eligibility for or receipt of any other service of assistance.'" MSJ at 19 (emphasis added). The unaltered text is clear that services "shall be voluntary ***and*** shall not be a prerequisite" for other services. 42 U.S.C. § 300a-5.

HHS's own *current* regulation interpreting that provision—which has apparently 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).

Rust does not foreclose this argument because *Rust* did not address this argument. To Plaintiff's knowledge, no party in *Rust* brought to the Court's attention the existence of 42 U.S.C. § 300a-5 or the agency's interpretation of it in 42 C.F.R. § 59.5(a)(2). Neither the *Rust* majority nor the *Rust* dissent cite to either provision at any point, and the Briefs available on Westlaw do not appear to include references to them either. As explained above, *Rust* is not a precedent for points not argued and not decided in that case. Nor would it make sense for courts to ignore controlling authority that was not brought to the Supreme Court's attention in an earlier case.

Defendants do not dispute that 42 U.S.C. § 300a-5 and 42 C.F.R. § 59.5(a)(2) prohibit Title X grantees from coercing patients into having an abortion or foregoing one.[3] CMSJ at 19-20 & n.4. Defendants instead argue that the Rule's mandatory prenatal referrals and ban on abortion referrals are not coercive. *See id.* But this Court has already held that the Rule's referral restrictions are "coercive." MSJ at 15 (citing PI Op. at 20). And they certainly are. The patients served in the Title X program are among the most vulnerable, and even small barriers placed in

[3] Defendants stress that HHS did not intend to depart "from HHS's prior interpretation" of 42 U.S.C. § 300a-5. CMSJ at 20 n.4. But because the Rule does, in fact, "subject individuals to … coercion … not to employ [a] particular method[] of family planning"—in direct contravention of 42 C.F.R. § 59.5(a)(2)—HHS's unexplained departure from its own existing regulation is both contrary to law and arbitrary and capricious because the agency show no "awareness that it is changing position." *Encino Motorcars, LLC v. Navarro,* 136 S. Ct. 2117, 2126 (2016) (explaining that an agency acts arbitrarily and capriciously where it fails to "display awareness that it is changing position" and "show that there are good reasons for the new policy" (quotation marks omitted)).

their path can be insurmountable obstacles. Hager Decl., PEP385, PEP395; MFP Comm't, PEP439; IPI Comm't, PEP490, PEP494, Guttmacher Comm't, PEP564.

D. The Rule Is Arbitrary and Capricious Because It Is Inadequately Explained and Substantively Unreasonable (Counts VII & VIII)

The Rule is arbitrary and capricious for numerous reasons. Five are so stark and uncomplicated that it is almost impossible to reach a contrary conclusion. HHS (1) diametrically reversed its earlier interpretation of the requirements of the Nondirective Mandate without displaying any awareness that it was doing so, much less offering any explanation; (2) concluded that the Rule is consistent with medical ethics, without considering relevant evidence or displaying any awareness that it was changing its position; (3) stated that HHS had "no evidence" that the Rule would have adverse impacts on patient access to any Title X services when in fact it had overwhelming evidence of such impacts; (4) erred in its weighing of the benefits and costs of the Separation Requirement, including by estimating that the cost to comply with the Separation Requirement would be a one-time cost of $30,000 and would apply to only 15% of providers, though neither number is supported by evidence in the record; and (5) limited who may engage in nondirective counseling in the Title X program to individuals with advanced degrees without any explanation for the decision and even though there is no reason (or evidence) supporting the limitation.

1. HHS Reversed Its Interpretation of the Nondirective Mandate Without Recognizing It Was Doing So. Defendants admit that "HHS continues to recognize" the Nondirective Mandate "requires that if pregnancy counseling is offered it must be nondirective." CMSJ at 22. But Defendants (and HHS) have insisted that the nondirective mandate does not require nondirective referrals, because "referrals" are not "counseling." *See* CMSJ at 15-17. That marks a diametric reversal of the agency's position in the 2000 Rule. The relevant page of the preamble reads in relevant part:

> A number of comments argued that the regulatory text should reflect the requirement for nondirective counseling and referral …. [A leading medical organization] pointed out that it is essential that the program regulations contain specific language about the counseling and referral requirements, and recommended the incorporation of sections of the 1981 Title X program guidelines into the regulations so as to be absolutely clear that pregnancy counseling and referral must be provided to patients facing an unwanted pregnancy upon request. *Congress has also repeatedly indicated that it considers this requirement to be an important one*: the program's four most recent appropriations, Pub. L. 104–208 (110 Stat. 300–243), Pub. L. 105–78 (111 Stat. 1478), Pub. L. 105–277 (112 Stat. 2681), and Pub. L. 106–113 (113 Stat. 1501–225), required that pregnancy counseling in the Title X program be "nondirective." Consequently, *the Secretary has decided to reflect this fundamental program policy in the regulatory text. See,* § 59.5(a)(5) below.

65 Fed. Reg. 41270, 41273 (July 3, 2000) (emphasis added). In turn, HHS revised § 59.5(a)(5) to require "nondirective counseling on each of the options, and referral upon request." *Id.* at 41279.

That passage, together with other passages in the 2000 Rule, shows that HHS then believed that the Nondirective Mandate required Title X grantees to provide referrals as part of nondirective counseling. *See* MSJ at 16-17. At minimum, it shows that HHS believed that the Nondirective Mandate *authorized* HHS to permit Title X grantees to make referrals as part of nondirective counseling. Defendants are therefore incorrect that HHS's new interpretation of the Nondirective Mandate is consistent with its interpretation of the Mandate in the 2000 Rule. *See* CMSJ at 21-22. HHS failed to grapple with its previous interpretation of the Nondirective Mandate as covering referrals. *See* MSJ at 16-17. Simply put, in the 2000 Rule HHS said that the Nondirective Mandate applies to referrals; in the new Rule HHS said that it did not, without acknowledging or explaining that it was reversing its position. That violates the principle, reaffirmed in *Encino Motorcars, LLC v. Navarro*, that an agency acts arbitrarily and capriciously where it fails to "display awareness that it is changing position" and "show that there are good reasons" for the change. 136 S. Ct. 2117, 2126 (2016).

2. HHS Concluded That the Rule is Consistent with Medical Evidence In the Face of Overwhelming Contrary Evidence. Defendants do not dispute that HHS's entire discussion of the Rule's consistency with medical ethics appears in two brief passages in the Rule. *See* CMSJ at 22 (citing 84 Fed. Reg. at 7724, 7748). And Defendants admit that HHS's entire justification for stating that the Rule is consistent with medical ethics is that *Rust* would not have upheld the Rule if it were not consistent with medical ethics, and that Congress would not enact conscience statutes if they were inconsistent with medical ethics. *See id.* Those inferences are plainly irrational. No inferences about the requirements of medical ethics can be drawn from *Rust* because the Court never analyzed whether the Rule was consistent with medical ethics in *Rust*. No inferences about the requirements of medical ethics can be drawn from conscience statutes because there is no reason to believe that Congress enacts conscience statutes because they reflect medical ethics. In fact, the opposite inference is the better one—Congress would have little need to enact conscience statutes if medical ethics already permitted healthcare providers to decline to provide care as a result of conscience objections.[4] Moreover, Defendants do not dispute that the conclusion that the Rule is consistent with medical ethics is contrary to the overwhelming weight of the evidence in the record. HHS has not identified any code of medical ethics, any medical

[4] *See, e.g.*, 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 must provide potential patients with accurate and prior notice of their personal moral commitments. *Physicians and other health care providers 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.* In resource-poor areas, access to safe and legal reproductive services should be maintained." (emphasis added)).

organization, or even any medical provider who believes that medical ethics permit healthcare providers to make misleading medical referrals or refuse to provide them altogether.

As minimum, HHS failed to display an awareness that it was changing its earlier factual conclusions about the requirements of medical ethics. Defendants do not dispute that HHS did not display any awareness in the Rule that HHS was changing its view that requiring grantees to provide nondirective referrals—even in the face of conscience objections—is "consistent with the prevailing medical standards" as recommended by "national medical groups." 65 Fed. Reg. at 41273; *see* CMSJ at 23 (not addressing this point). HHS also failed to discuss anywhere in the Rule that it was departing from the ethical conclusions—not to mention the required standard of care—set forth in its own Quality Family Planning Guidelines ("QFP"). *See* MSJ at 17; CMSJ at 23. Defendants do not dispute that HHS nowhere discussed the inconsistency between the Rule and the QFP. Indeed, Defendants did not even rely on the QFP in developing the Rule (Defendants did not include the QFP in the Administrative Record). Defendants argue that HHS did not need to consider the QFP in crafting the Rule because HHS said in the Rule that it was "departing from its prior approach under the 2000 regulations." CMSJ at 23. But the QFP reflects considered, long-held, and specific conclusions about the requirements of medical ethics. *See* Center for Disease Control and Prevention, Providing Quality Family Planning Services (2014), http://bit.ly/2M2P4kW; Kost Decl., PEP111-112; Mobley Decl., PEP368-369; NPHRA Comm't, PEP696; PP Comm't, PEP789-790. HHS's decision to adopt a diametrically opposite view of medical ethics, without even acknowledging that the conclusion departed from its own longstanding unrescinded guidance, was arbitrary and capricious. *See Encino Motorcars, LLC v. Navarro*, 136 S. Ct. 2117, 2126 (2016).

3. HHS Reached An Erroneous Conclusion About The Likely Consequences of the Rule By Repeatedly Incorrectly Stating That It Lacked Any Contrary Evidence. Defendants admit that HHS adopted the Rule because "HHS concluded that the Rule would 'contribute to more clients being served, gaps in service being closed, and improved care.'" CMSJ at 23 (quoting 84 Fed. Reg. at 7723). But Defendants do not dispute that HHS reached that conclusion on the basis of a completely erroneous view of the evidence in the record—with HHS stating on multiple occasions that the record contained "no evidence" or no "actual data" supporting a contrary conclusion.[5] *See* MSJ 18-21. As Plaintiff has explained, an enormous amount of persuasive evidence in the record supported the conclusion that the new Rule would severely disrupt access to Title X services, leaving millions of individuals with reduced access to healthcare.

Defendants are incorrect that HHS would be permitted to totally disregard relevant evidence because HHS deemed the evidence a "threat." CMSJ 23. After an exhaustive search of cases in every federal circuit, Plaintiff was unable to locate a single case in which any court has ever endorsed Defendants' view. In any event, in the Rule itself HHS never said it was disregarding any evidence on that basis, and Defendants cannot rationalize HHS's failure to consider relevant evidence *post hoc* in litigation briefs. Moreover, there is no reason to believe that any of the information about the consequences of the Rule were "threats" as opposed to honest representations about the Rule's consequences; neither HHS nor Defendants have ever offered any basis for the

[5] For example, HHS 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, that "commenters did not provide evidence that the rule will negatively impact the quality or accessibility of Title X services," *id.* at 7780, that "[c]ommenters offer no compelling evidence that this rule will increase unintended pregnancies or decrease access to contraception," *id.* at 7785, and that HHS was "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 rule-making and an increase in unintended pregnancies, births, or costs associated with either," *id.* at 7775.

aspersion. The fact that non-grantees, including major medical organizations, offered much of the evidence of the Rule's negative consequences, seriously undermines Defendants' claim that the evidence of the disruption to the program that would result from the Rule was a "threat."

4. HHS's Weighing of the Benefits and Costs of the Physical and Financial Separation Requirement Was Demonstrably Flawed. Defendants admit that the only benefit HHS identified from adopting the separation requirement was "to address the risk and perception that Title X funds would be used for other prohibited purposes." CMSJ at 23. Defendants also admit that the purpose of the physical and financial separation requirement to carry out "the statutorily mandated assurance that taxpayer dollars are not being used to fund projects where abortion is a method of family planning" under § 1008. CMSJ at 24. Thus, HHS has no statutory mandate (or authority) to adopt a requirement in the program to combat an erroneous "perception" of misuse of funds; and the record is devoid of any evidence that any grantee has used Title X funds contrary to § 1008 in the last 20 years (while the 2000 Regulations were in effect). There was, in the most literal sense, no need to adopt the Separation Requirement.

HHS also showed no awareness of, and gave no explanation for, its dramatic reversal of view about the severe negative impacts of the separation requirement on Title X services. In the 2000 Rule, HHS explained:

> [I]n the light of the enforcement history noted above, it is not unreasonable to say that the standard of "physical" separation has, as a practical matter, had little relevance or applicability in the Title X program to date. Moreover, *the practical difficulty of drawing lines in this area*, both as experienced prior to 1988 and as evident in the history of the Gag Rule itself, *suggests that this legal interpretation is not likely ever to result in an enforceable compliance policy that is consistent with the efficient and cost-effective delivery of family planning services*.

65 Fed. Reg. 41276 (emphasis added). That is a significant and definitive factual conclusion. According to HHS in 2000, the separation requirement was "not likely *ever* to result" in a compliance policy consistent with the efficient and cost-effective delivery of family planning services.

Id. In the new Rule, HHS did not reference that conclusion or provide a reasoned justification for reversing it.

As for the costs of the separation requirement, Defendants do not dispute that there is no record evidence supporting the agency's estimate of the cost of compliance as a one-time cost of $30,000. *See* CMSJ at 24 (citing no evidence). HHS apparently pulled the financial cost number to achieve physical separation out of thin air. The overwhelming weight of the evidence in the record shows that a one-time cost of $30,000 is drastically too low. Hiring and paying even one new front desk staff member and a single clinician to staff newly separate facilities would quickly cost *annual* multiples of $30,000, *see* CRR Comm't, PEP765, before even counting additional costs for obtaining the physical space, configuring it, furnishing it, and setting up electronic systems—yet all of those components are part of "physical separation" under the Rule. Numerous commenters, including those with experience in setting up and equipping Title X and other health care facilities, emphasized to HHS that its numbers were orders of magnitude too low.[6] And commenters provided specific evidence to substantiate the inadequacy of HHS's number.[7] But HHS ignored that evidence and simply finalized the Rule using a critical cost number that was irrational and contrary to the record evidence.

[6] *See, e.g.*, FPCI Comm't PEP655 ("it typically costs hundreds of thousands, or even millions, of dollars to locate and open any health care facilities (and would also cost much more than $10,000-30,000 to establish even an extremely simple and limited office), staff it, purchase separate workstations, set up record-keeping systems, etc."); PPFA Comm't PEP 862-864; NFPRHA Comm't, PEP726-727.

[7] *See, e.g.*, CRR Comm't, PEP765 n.144 (cost of electronic health records system alone over $160,000 for small practice); FPCI Comm't, PEP655 (Title X subrecipient's additional physical site cost $85,000 in March 2018); PPFA Comm't, PEP862-864 (describing health center construction or renovation costs in detail). And many called on HHS to undertake an actual assessment of the cost components of "physical separation" under Section 59.15. *See, e.g.*, ACP Comm't, PEP667 (ACP "calls on HHS to analyze the financial, time, and quality of care impacts" of physical separation); IPI Comm't, PEP484-485.

Finally, Defendants do not dispute that HHS erred by concluding that only 15 percent of Title X providers (those that also provide abortions outside the Title X program) would be affected by the Rule, rather than the 100 percent of Title X providers who previously made ethically required referrals for abortion, and would need to engage in physical and financial separation to continue to do so for their services outside the Title X programs. MSJ at 23; *see* CMSJ at 24. Thus, Defendants do not dispute that HHS's overall estimate of compliance costs arising from the Rule should have been (even using its own $30,000 one-time compliance cost estimate) closer to $240 million than the $36 million the agency estimated, a cost more than six times higher than the agency estimated.

5. No Evidence or Explanation Supported HHS's Decision to Limit Pregnancy Counseling to "Advanced Practice Providers" ("APPs"). Defendants do not dispute that HHS failed to explain why an advanced degree is necessary to engage in pregnancy counseling. Defendants also do not dispute that no evidence in the record supports HHS's conclusion that pregnancy counseling requires that individuals have "advanced medical degrees, licensing, and certification requirements." 84 Fed. Reg. at 7728 n.41. Instead, in response to the Proposed Rule, which limited pregnancy counseling to physicians, numerous commenters explained that nurses, social workers, and other individuals at Title X providers were similarly qualified to engage in pregnancy counseling. *See* MSJ at 24 n.14. The Rule's limitation on pregnancy counseling to APPs replaces one arbitrary distinction set forth in the proposed rule (between physicians and all others), with another (between APPs, physicians, and all others). But the distinction is still unexplained and irrational. MSJ at 23-24.

E. HHS's Rulemaking Process Deprived the Public of a Meaningful Opportunity to Participate in Violation of the Administrative Procedure Act (Count IX)

1. HHS Deprived The Public of a Meaningful Opportunity to Comment

The Rule must be vacated and remanded to the agency because the agency failed to give Baltimore City and the public a meaningful opportunity to comment.[8] Even Defendants admit that an agency violates the APA "where the agency's structuring of the notice-and-comment process deprived the public of a meaningful opportunity to comment." CMSJ at 26. Thus, the only relevant question is whether HHS deprived Baltimore City and other stakeholders of a "meaningful opportunity to comment."

The evidence establishes that HHS's structuring of the rulemaking process in this case deprived Baltimore City and other stakeholders of a meaningful opportunity to comment. Defendants do not dispute that HHS radically departed from rulemaking procedures, engaged in zero outreach about the Proposed Rule, failed to place the Proposed Rule on the Regulatory Agenda, and rushed the Proposed Rule through OIRA. *See* CMSJ at 28-29. Defendants do not dispute that even extremely vigilant stakeholders at best had 70 days (rather than 60 days) to prepare comments on the Rule because the Rule was first revealed publicly on May 22, 2018. *See* CMSJ at 26. Plaintiff has already demonstrated that the Rule is complex and extremely consequential. MSJ at 26. The fact that the Executive Branch has multiple Executive Orders and OMB guidance

[8] The Court should again reject Defendants' argument that Plaintiff failed to plead this claim, CMSJ at 25—as it did at the Motion to Dismiss. *See* MTD Op. at 19 ("Baltimore City has made a plausible claim that the public was deprived of a meaningful opportunity to comment on the Proposed Rule and departed from proper rulemaking procedures."); *see also* ECF 1, at 64 ("COUNT IX VIOLATION OF APA—WITHOUT OBSERVANCE OF PROCEDURE REQUIRED BY LAW"); *id.* at ¶¶ 224-26 ("The APA requires agencies to publish notice of all proposed rulemakings in a manner that gives interested persons an opportunity to participate in the rule making through submission of written data, views, or arguments …. The regulations as drafted must be set aside as in violation of 5 U.S.C. § 706(2)(D) … Such regulations adopted without the notice-and-comment procedure required by 5 U.S.C. § 553 of the APA are invalid." (cleaned up)).

specifically designed to provide *public notice* of an upcoming rulemaking is strong evidence that the Executive Branch considers pre-comment-period notice crucial to ensuring stakeholders have a meaningful opportunity to comment on proposed Rules. In turn, the fact that HHS violated those Executive Orders and that OMB guidance (a fact Defendants do not dispute), is powerful evidence that stakeholders are thereby *denied* a meaningful opportunity to comment when the Executive Branch fails to comply with those directives.

Contrary to Defendants' arguments, HHS's structuring of the notice-and-comment process deprived commenters of a meaningful opportunity to comment. HHS received over 500,000 comments. CMSJ at 27-28. But the number of comments HHS received is not an appropriate measure of the harm from HHS's procedural violation. HHS's lack of prior notice forced stakeholders to reduce the quality of their comments, depriving them of the opportunity to fully explore relevant statutory authorities and of the ability to marshal more and better evidence of the Rule's likely consequences. Defendants point to cases where Courts have upheld 60-day and 30-day (and even shorter) comment periods. But the APA requires courts to look to the circumstances of the rulemaking—including the agency's actions leading up to the announcement of the rulemaking, the complexity and importance of the rule, whether commenters sought extensions during the comment period for valid reasons, and the degree of prejudice arising from the failure to hold open the comment period longer, among other equitable factors—in determining whether an agency deprived stakeholders of the opportunity to comment in a meaningful manner. *See N. Carolina Growers' Ass'n, Inc. v. United Farm Workers*, 702 F.3d 755, 769-70 (4th Cir. 2012).

Here, Plaintiff has demonstrated—in light of the manner in which HHS structured the notice and comment process—that 60 days was too short.[9]

HHS's violation of multiple Executive Orders and controlling OMB guidance—all of which were designed to give stakeholders advance notice of proposed rulemaking, *see* MSJ at 9-11—is centrally relevant to whether HHS provided stakeholders a meaningful opportunity to comment. *See* MSJ at 26-27. Defendants are incorrect that taking those violations into account would impose additional procedural requirements beyond those found in the APA. *See* CMSJ at 29. The Fourth Circuit considered and rejected a variant of this very argument in *North Carolina Growers' Association*. *See* 702 F.3d at 769.

2. The Rule's Restriction of Pregnancy Counseling To Advanced Practice Providers (APPs) Is Not a "Logical Outgrowth" of the Proposed Rule

The Rule's limitation of pregnancy counseling to APPs was not a logical outgrowth of the proposed Rule. The parties agree on the legal standard, *see* MSJ at 27; CMSJ at 29-30. But commenters could not have anticipated the agency's decision, and indeed, Defendants do not and cannot point to a single comment in the record addressing whether counseling should be limited to APPs, and if so, who should qualify as an APP. An "agency does not have carte blanche to establish a rule contrary to its original proposal simply because it receives suggestions to alter it during the comment period." *Chocolate Mfrs. Ass'n of U.S. v. Block*, 755 F.2d 1098, 1104 (4th Cir. 1985); *see also Kennecott v. EPA*, 780 F.2d 445, 452 (4th Cir. 1985) ("It is not acceptable for an agency to set unachievable limits, and then when the [regulated entities] object[], to pull a curative [measure] out of its hat. This sort of conduct would frustrate the purpose of the

[9] Moreover, ordering the agency to reopen the comment period is not a severe imposition on HHS. Data show that "remands cause[] relatively little interference with agency attempts to achieve regulatory goals." William S. Jordan, III, *Ossification Revisited: Does Arbitrary and Capricious Review Significantly Interfere with Agency Ability to Achieve Regulatory Goals Through Informal Rulemaking?*, 94 Nw. U. L. Rev. 393, 424 (2000).

procedural safeguards in the administrative process, and replace participatory rulemaking with rulemaking by ambush.").

F. The Rule Violates the First Amendment (Count V)

The Rule violates the First Amendment rights of doctors and patients. Defendants' contrary arguments are unpersuasive. Concededly, *Rust* forecloses some First Amendment challenges. *Rust* held that the 1988 Rule did not impermissibly discriminate against healthcare providers based on viewpoint. *Rust*, 500 U.S. at 192; CMSJ at 31. As the Supreme Court has explained, *Rust* held that the government had 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). As the Supreme Court further explained in *Legal Services Corporation v. Velazquez*,

> The Court in *Rust* did not place explicit reliance on the rationale that the counseling activities of the doctors under Title X amounted to governmental speech; when interpreting the holding in later cases, however, we have explained *Rust* on this understanding. We have said that viewpoint-based funding decisions can be sustained in instances in which the government is itself the speaker, *see Bd. of Regents of Univ. of Wis. System v. Southworth*, 529 U.S. 217, 229 (2000), or instances, like *Rust*, in which the government "used private speakers to transmit specific information pertaining to its own program." *Rosenberger v. Rector and Visitors of Univ. of Va.*, 515 U.S. 819, 833 (1995).

531 U.S. 533, 541 (2001). Thus, *Rust* forecloses challenges to government-messaging programs on the basis that they unconstitutionally discriminate on the basis of viewpoint.

But the new Rule violates the First Amendment for reasons that are not foreclosed by *Rust*. *First*, it violates the First Amendment because it unconstitutionally impinges on the doctor-patient relationship. *Rust* left this question open, stating it did not need to decide it because the

1988 Rule did not, in fact, impinge on the doctor-patient relationship.[10] *See Rust*, 500 U.S. at 200. But since *Rust*, patients in the Title X program have become more reliant on their doctors, and the Rule's impingement on the relationship between doctors and patients in the Title X program is more significant today than it was thirty years ago. Indeed, all the (unrebutted) evidence before the Court shows that the Rule *does* in fact significantly impinge on the doctor-patient relationship. *See* MSJ at 28. And if the Court concludes that the Rule significantly impinges on the doctor-patient relationship, both *Velazquez* and *Rust* itself support striking it down. *See* MSJ at 28-29.

Second, the Rule violates the First Amendment because, as *Velazquez* and *Rosenberger* make clear, *Rust*'s holding depended on the degree to which the 1988 Rule helped the government to convey a Government message without that message being "garbled nor distorted by the grantee." *Rosenberger*, 515 U.S. at 833. But Congress has modified the Title X Program in important respects after *Rust*, by enacting the Nondirective and Non-Interference Mandates. Defendants do not dispute this. *See* CMSJ at 32. As a consequence, the Title X Program is no longer best understood as a program designed to convey a government message favoring childbirth over abortion as it was in *Rust*; rather, in light of the two Mandates, it is best understood as a program designed to facilitate physician speech that puts the patient's interest first, and does not favor any particular method of family planning over another. Thus, *Rust* does

[10] In *Velazquez* the Supreme Court decided the question *Rust* left open, holding that, indeed, the government cannot interfere with traditional relationships—like the attorney-client relationship—even as part of a government subsidy program. 531 U.S. at 542-44. Justice Scalia recognized that, after *Velazquez*, *Rust*'s factual conclusion that the 1988 Rule did not unconstitutionally impinge on the doctor-patient relationship was in serious doubt. *Id.* at 553-54 (Scalia, J., dissenting). As Scalia explained, the statutory schemes in *Rust* and *Velazquez* were "in all relevant respects indistinguishable" and "the majority's contention that the subsidized speech in these cases is not government speech because the lawyers have a professional obligation to represent the interests of their clients founders on the reality that the doctors in *Rust* had a professional obligation to serve the interests of their patients." *Id.*

not control the First Amendment analysis now that Congress has changed Title X from a government messaging program into a program that explicitly *prohibits* the delivery of a government message regarding a patient's pregnancy options. Instead, limitations on physician speech in the program are controlled by *Rosenberger*'s strict scrutiny test. 515 U.S. at 830-37 (applying strict scrutiny to efforts to curtail private speech on the basis of viewpoint where government program was intended to fund private speech, not a government message). Defendants' only response to this argument is to note that the holding in *Rust*—that the government does not engage in unconstitutional viewpoint discrimination when it creates and funds a government-messaging program—has been reaffirmed. CMSJ at 32. But Defendants do not respond to the more crucial point that Congress's intent with respect to Title X has changed and with it the line of authority (*Rosenberger* rather than *Rust*) that provides the appropriate lens through which to analyze the Rule's restrictions on physician speech. *See* CMSJ at 32.

Third, the Rule violates the First Amendment rights of patients by selectively withholding information from patients on the basis of its viewpoint. No patient-centered First Amendment claims were raised or analyzed in *Rust* and therefore *Rust* does not foreclose them. Defendants are simply incorrect that because the Supreme Court stated that it was rejecting "First Amendment" claims in *Rust* that means the Court rejected every conceivable argument that the Rule, and any future similar Rule, could violate the First Amendment. CMSJ at 33. There is a long history in this country of courts applying the First Amendment to bar the political branches from co-opting public institutions like schools and libraries—institutions similar in critical respects to healthcare providers—from becoming mouthpieces for particular government-favored viewpoints. *Bd. of Educ., Island Trees Union Free Sch. Dist. No. 26 v. Pico*, 457 U.S. 853, 870-72 (1982) (plurality); *Keyishian v. Bd. of Regents of Univ. of State of N.Y.*, 385 U.S. 589, 603

(1967); *Meyer v. Nebraska*, 262 U.S. 390, 399-403 (1923); *accord Rosenberger*, 515 U.S. at 830-37. Patients accessing government-subsidized healthcare, much like students accessing government-subsidized education, have a First Amendment right to access that care free from government orthodoxy. *See Keyishian*, 385 U.S. at 603; *W. Va. State Bd. of Educ. v. Barnette*, 319 U.S. 624, 642 (1943) (students may not be expelled from public schools for refusing to endorse a pro-government viewpoint).

Fourth, the Rule violates the First Amendment rights of patients to receive information. Contrary to Defendants' assertion, the Rule *does* withhold information by requiring healthcare providers to withhold certain referrals—*i.e.*, to withhold information about where to receive further treatment. *Contra* CMSJ at 33. The Supreme Court has increasingly recognized that government efforts to suppress the information that people receive violates the First Amendment. *See* MSJ at 30-31. The only reason that the Rule withholds information from patients is because they might use it to seek out a lawful treatment. As the Supreme Court has held, that is not a valid reason to restrict access to information, *see Meese v. Keene*, 481 U.S. 465, 482 (1987), especially in a healthcare setting, *see Nat'l Inst. of Family & Life Advocates v. Becerra*, 138 S. Ct. 2361, 2374 (2018) ("[W]hen the government polices the content of professional speech, it can fail to preserve an uninhibited marketplace of ideas in which truth will ultimately prevail." (marks and alterations omitted)); *id.* at 2372 (noting the particular First Amendment concerns with government regulation of speech about the "controversial" topic of abortion).

G. The Rule Violates the Equal Protection Component of the Fifth Amendment's Due Process Clause (Count VI)

The Rule violates the equal protection component of the Fifth Amendment's Due Process Clause because it (1) is a sex-based classification and (2) classifies on the basis of pregnancy to

promote sex stereotypes.[11] Defendants do not dispute that *Rust* does not foreclose this claim, nor could they, as *Rust* did not involve a sex-discrimination claim under the Fifth Amendment. As explained in Plaintiff's motion for summary judgment, classification on the basis of sex (or pregnancy when it furthers sex-based stereotypes) triggers an obligation for Defendants to come forward and prove an "exceedingly persuasive justification" for the Rule. *See* MSJ at 31-32. Defendants do not dispute that they cannot meet that burden. *See* CMSJ at 33-35. Therefore, the only relevant question is whether the Rule is an impermissible sex classification that in fact triggers this heightened scrutiny.

The Rule is a sex-based classification because it determines who is subject to counseling and referral restrictions on the basis of sex. Defendants are incorrect that the Rule does not classify on the basis of sex because it only restricts counseling and referrals related to abortion. *Contra* CMSJ at 34. The relevant question for purposes of determining whether the Rule is a sex-based classification is whether, but for the person's sex, that person would be treated differently under the Rule.[12] It is immaterial that what is denied happens to be a referral for abortion. Defendants would not dispute that if the Rule denied contraceptives to women, but not to men, the Rule would constitute an impermissible sex-based classification. Defendants could not get around that conclusion by instead denying women access to tubal ligation, while still providing men access

[11] The Court should reject Defendants' suggestion that Baltimore City lacks standing to raise its equal protection claim. CMSJ at 33. The argument is so underdeveloped that it provides Baltimore City no meaningful opportunity to contest it. The Court should therefore treat the argument as waived.

[12] *See Weinberger v. Wiesenfeld*, 420 U.S. 636, 640-41 (1975) ("If he had been a woman, he would have [been treated differently] …."); *Frontiero v. Richardson*, 411 U.S. 677, 678-79 (1973) ("[A] serviceman may claim his wife as a 'dependent' without regard to whether she is in fact dependent upon him for any part of her support …. A servicewoman, on the other hand, may not …."); *L.A. Dept. of Water & Power v. Manhart*, 435 U.S. 702, 711 (1978) (explaining that Title VII sex discrimination involves "treatment of a person in a manner which but for that person's sex would be different").

to vasectomies, then claim that the Rule is not discriminatory because it discriminates on the basis of those who need tubal ligations and those who do not (rather than on the basis of sex). The Rule denies some healthcare services to women, but does not deny any services to men. The Rule is thus a sex-based classification subject to heightened scrutiny. *See* MSJ at 32 & n.15. It is as simple as that.

At minimum, the Rule is a classification based on pregnancy that furthers sex stereotypes. As Plaintiff demonstrated, the Rule treats pregnant women differently from other patients because of stereotypes about women. *See* MSJ at 33-34. Even if the Rule did not already meet the "but for" test for a classification on the basis of sex, it would meet the standard for an impermissible classification on the basis of pregnancy that promotes sex stereotypes. MSJ at 33-34.

Defendants' argument that abortion restrictions are immune to sex-discrimination challenges is both irrelevant and incorrect. The claim is *irrelevant* because the Rule is a sex-based classification because it treats women differently from men, not because it treats abortion differently from other healthcare. The claim is also *incorrect* because the cases cited by Defendants for the proposition that sex-discrimination claims cannot be brought to challenge abortion restrictions, CMSJ at 33-34, simply do not stand for that proposition. *Bray v. Alexandria Women's Health Clinic* did not involve constitutional sex discrimination claims. *See* 506 U.S. 263, at 266-68 (1993) (holding that 42 U.S.C. § 1985(3) did not provide a federal cause of action against private persons obstructing access to abortion clinics). The quote Defendants use from *Bray* cites to two cases challenging bans on Medicaid funding for abortion, neither of which involved sex discrimination claims. *Bray* at 273 (citing *Maher v. Roe*, 432 U.S. 464 (1977); *Harris v. McRae*, 448 U.S. 297 (1980)). In any event, Title X does not involve government funding for abortion; it involves whether doctors may provide complete counseling to patients.

IV. The Rule Is Inseverable

For the reasons stated in Plaintiff's Motion for Summary Judgment, the Rule is inseverable. *See* MSJ at 34-35. If any portion is deemed unlawful, the whole Rule should be vacated. Defendants do not dispute this point.

CONCLUSION

For the foregoing reasons, Plaintiff respectfully requests that the Court grant Plaintiff's Motion for Summary Judgment and deny Defendants' Cross Motion for Summary Judgment.

Dated: December 2, 2019

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that on December 2, 2019, I filed the foregoing with the Clerk of the Court using the ECF System which will send notification of such filing to the registered participants identified on the Notice of Electronic Filing.

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