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UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF WASHINGTON
AT YAKIMA

STATE OF WASHINGTON,

Plaintiff,

v.

ALEX M. AZAR II, et al.,

Defendants.

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

Plaintiffs,

v.

ALEX M. AZAR II, et al.,

Defendants.

NO. 1:19-cv-3040-SAB

REPLY IN SUPPORT OF STATE OF WASHINGTON'S MOTION FOR PRELIMINARY INJUNCTION

NOTED FOR: April 25, 2019
With oral argument at 10:00 a.m.

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I. INTRODUCTION

Defendants show absolutely no sign of grasping the real-life consequences of the Final Rule. Over half of Washington counties will lose Title X care and thousands of already underserved Washingtonians will lose access to contraception, perversely undermining the core objective of Title X in pursuit of a narrow Administration goal. This is truly a case of an exception swallowing the rule, and here Defendants do not even heed the limits of the exception, with grave consequences to Washington. Irreparable harm is not seriously contested.

The only legal support for this abandonment of Title X fails. Defendants insist that *Rust v. Sullivan*, 500 U.S. 173 (1991), controls the outcome. That cannot be so, because *Rust* merely held that section 1008 of Title X was "ambiguous"; later-enacted statutes removed that ambiguity; and *Rust* was decided on a now thirty-year-old rulemaking record that did not account for present-day issues, including statewide network destruction. *Rust* does not forever shield HHS from later-enacted laws clarifying Title X and limiting the agency's rulemaking authority, nor does it somehow absolve HHS from considering its own evidence-backed program requirements, input from major medical associations and practitioners, practical realities on the ground, and substantiated cost assessments, in assessing factors Congress identified as important. Defendants repeatedly misconstrue the State's position, *Rust*'s holding, and even HHS's own Final Rule, all to no avail. Injunctive relief is warranted.

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II. ARGUMENT

A. The Final Rule Is Contrary to Law

1. *Rust* does not dictate the outcome of this case

Defendants' insistence that *Rust* controls is meritless. *Rust* preceded both the Nondirective Mandate and section 1554 of the ACA, which clarify section 1008 and limit HHS's discretionary authority. *Rust* did not address all the issues raised here. Moreover, HHS failed to adequately consider the extensive record *in this case*, which differs from the thirty-year-old record at issue in *Rust*.

Defendants argue that the Nondirective Mandate and section 1554 are inapplicable because they did not "silently overrule[]" *Rust*. Opp. at 2, 18, 20, 21, 26, 30. But no one argues that they did, and they are not inconsistent with *Rust*. Contrary to Defendants' misstatements of its holding, *Rust* established no "authoritative interpretation" of section 1008. Opp. at 2, 19, 20, 21. Rather, *Rust* held that section 1008 was "ambiguous," leaving the Court "unable to say" as of 1991 that the gag rule was "impermissible." 500 U.S. at 184. After *Rust* (and after the anomalous gag rule was rescinded), Congress made clear that section 1008 *cannot* be construed to prohibit nondirective counseling, enshrining that longtime understanding in the law (and reenacting it annually through the present). Mot. at 6 & n.15; *id.* at 8. In 2010, Congress further restricted HHS's rulemaking authority by enacting section 1554 of the ACA. These statutes make clear that (1) section 1008 does not prohibit nondirective pregnancy counseling—in fact, funding is *conditioned* on any counseling being nondirective; and (2) HHS lacks

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authority to promulgate any regulation that interferes with patients' access to medical information and care or mandates unethical practices. HHS's promulgation of the Final Rule in spite of these statutes is now clearly unlawful.

Defendants' authority is far off the mark. The "presumption against implied repeals" applies where two *statutes* contain conflicting language, *Nat'l Ass'n of Home Builders v. Defs. of Wildlife*, 551 U.S. 644 (2007) (Opp. at 19)—not where, as here, Congress foreclosed an agency interpretation by clarifying an ambiguity. Similarly, the other cases Defendants cite involved "clear, authoritative" *judicial* constructions of a statute, not *agency* interpretations of an ambiguous statute. *TC Heartland LLC v. Kraft Foods Grp. Brands LLC*, 137 S. Ct. 1514 (2017); *Forest Grove Sch. Dist. v. T.A.*, 557 U.S. 230 (2009) (Opp. at 20). Agency interpretations are not set in stone,[1] and certainly cannot override Congress's clarification of an ambiguity. *See Chevron, U.S.A., Inc. v. Nat. Res. Defense Council, Inc.*, 467 U.S. 837, 843 (1984) (courts "must give effect to the unambiguously expressed intent of Congress"); *Branch*

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[1] *See I.N.S. v. Cardoza-Fonseca*, 480 U.S. 421, 446 n.30 (1987); *United States v. Mead Corp.*, 533 U.S. 218, 247 (2001) (Scalia, J., dissenting) ("Where *Chevron* applies, statutory ambiguities remain ambiguities" and "create a space, so to speak, for the exercise of continuing agency discretion."). Such exercise of discretion remains reviewable for both reasonableness *and* arbitrariness. *Humane Soc'y of U.S. v. Zinke*, 865 F.3d 585, 605 (D.C. Cir. 2017).

v. Smith, 538 U.S. 254, 281 (2003) (plurality op.) ("courts do not interpret statutes in isolation, but in the context of the *corpus juris* of which they are a part, including later-enacted statutes"); SCALIA & GARNER, READING LAW 330 (2012).

Moreover, Defendants' *post hoc* litigation position contradicts HHS's own prior position: HHS conceded in the Final Rule that the Nondirective Mandate clarified the law and is binding. *See, e.g.*, 84 Fed. Reg. 7747 (acknowledging that "projects must comply with Congress's requirement that pregnancy counseling be nondirective, and the Department must enforce that requirement"). The fact that the Nondirective Mandate was enacted through consecutive appropriations acts is irrelevant. Mot. at 22; NFPRHA Mot. at 12.[2]

In short, the Court need not grapple with whether the Nondirective Mandate and section 1554 "silently overruled" *Rust* because no party contends that they did, and Defendants' characterization of the State's position is false. Both statutes simply clarify the law and limit HHS's rulemaking authority—and, moreover, are perfectly consistent with Title X's successful operation throughout

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[2] *See also Strawser v. Atkins*, 290 F.3d 720, 734 (4th Cir. 2002) (courts must "follow Congress's last word on the matter even in an appropriations law"). *Calloway* (Opp. at 2, 21) is inapposite, as it states only that implied statutory repeals through appropriations acts are "disfavored." 216 F.3d 1, 9 (D.C. Cir. 2000). Here, there is no statutory inconsistency and no "repeal" has occurred.

its fifty-year history and with the Current Regulations (which were in place when both statutes were enacted).[3] It is *HHS's* impermissible new interpretation of section 1008 that effects a "major change" and creates a conflict where none exists. Opp. at 2; *see Ass'n of Am. R.R. v. S. Coast Air Quality Mgmt. Dist.*, 622 F.3d 1094, 1097 (9th Cir. 2010) (courts must strive to harmonize laws that purportedly conflict); *see also Morton v. Mancari*, 417 U.S. 535, 551 (1974) (courts may not "pick and choose among congressional enactments," but must "give effect to both").

Even setting these later-enacted statutes aside, *Rust* cannot control the outcome of this case because the record before HHS in 2018 was different from the record before it in 1988. Defendants assert that *Rust* "rejected" claims "indistinguishable" from the State's claims here, but even if that were true (it is not), HHS is not somehow absolved from having to consider "the administrative record before the agency at the time the agency made its decision." *Nat'l Wildlife Fed'n v. U.S. Army Corps of Eng'rs*, 384 F.3d 1163, 1170 (9th Cir. 2004); Mot. at 28. A rulemaking cannot survive judicial review if the agency failed to consider important factors, acted counter to the evidence in the record, or offered no reasoned analysis based on the record. Mot. at 28. Here, HHS ignored

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[3] Defendants mis-quote the State's brief: the *Current Regulations* "reinstated the pre-*Rust* status quo"; the Final Rule is an aberration. Opp. at 11; Mot. at 8.

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extensive evidence and failed to consider numerous present-day issues that were not at issue in *Rust*—including that the Final Rule will dismantle Washington's statewide Title X network and diminish or eliminate patients' access to Title X services.

Defendants also make much of overlap between the 1988 gag rule and the Final Rule. Opp. at 12–17. Any similarities are irrelevant in light of superseding statutes and HHS's failure to engage in a reasoned decisionmaking process based on the record before it. But in any event, the Final Rule makes a prenatal care referral mandatory and deems it "medically necessary," imposes stricter physical separation requirements on a broader range of activity, removes the longstanding requirements that contraceptive services be "medically approved" and that patients be referred for any "medically indicated" care, adds a burdensome new "comprehensive health services" requirement, limits the use of Title X funds in contravention of the statute, and gives HHS discretion to reject grant applications prior to merits review. Mot. at 10–12. The Final Rule is a different rule.

2. The Nondirective Mandate renders the Final Rule unlawful

Defendants' attempt to reconcile the Final Rule with the Nondirective Mandate is riddled with logical flaws and textual errors, and contradicts Congress's express inclusion of "referral" within "nondirective counseling" for Title X purposes. The Final Rule brazenly violates the Nondirective Mandate.

To begin with, Defendants mischaracterize *HHS's own rule* by claiming it "requir[es]" any pregnancy counseling to be nondirective. Opp. at 22, 27–28. In

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fact, the Final Rule does the opposite: it expressly permits *directive* counseling about "maintaining the health of the mother and unborn child during pregnancy" (§ 59.14(b)(1)(iv)). Contrary to Defendants' *post hoc* litigation position (which misconstrues the State's argument), *see* Opp. at 26, HHS conceded that presenting *one* option as the "only option" "violates" the Nondirective Mandate. 84 Fed. Reg. 7747. Yet the Final Rule makes purportedly "nondirective" counseling just one of *four* optional types of "counseling and/or information" that projects may provide to pregnant patients (§ 59.14(b)(1)). This violates the mandate that *all* pregnancy counseling "shall be nondirective," Pub. L. No. 115-245, and betrays its guarantee to patients that they will not be coerced into unwanted or unneeded medical treatment. Defendants fundamentally misunderstand the concept of patient-centered care reflected in the Nondirective Mandate: their invocation of the purported rights of "other entities" to provide directive counseling, Opp. at 26–27, ignores *patients'* guaranteed rights to receive nondirective counseling about all options they are considering (and not about options they are not considering). Mot. at 8–9, 21–22, 24–26.

Even if practitioners elect to give purportedly "nondirective" counseling, the Final Rule deprives their patients of the Nondirective Mandate's guarantee by requiring coercive referrals. Defendants cannot credibly argue that counseling accompanied by a mandatory referral is truly "nondirective," and they fail to defend HHS's arbitrary and irrational conclusion that prenatal care is "medically

necessary" for *all* pregnant patients.[4] *See* Opp. at 21–25. As a matter of clinical practice and medical standards, counseling and referral are complementary aspects of the same patient-centered care process—as HHS's own program requirements establish, and as multiple commenters pointed out. *See, e.g.*, QFP at 14 (pregnancy test results "should be presented to the client, followed by a discussion of options and appropriate referrals"); AAN cmt. at 4; ACNM cmt. at 2; ACOG cmt. at 5–6; AMA cmt. at 2–3; APHA cmt. at 2; CA cmt. at 7–8; Dr. Steinauer cmt.; Guttmacher cmt. at 6–8; GW Fac. cmt. at 4–5; JIWH cmt. at 3; MO FHC cmt. at 3; NFPRHA cmt. at 3–5, 7–9; NIRH cmt. at 3–4; NWLC cmt. at 2; PPFA cmt. at 3–7, 10–14, 20; WA cmt. at 10–11.

It is no surprise, then, that Congress has expressly defined "nondirective counseling" to *include* "referrals" in the related context of infant adoption programs, as HHS acknowledged. 84 Fed. Reg. 7744 n.72 ("information and referrals" are "included in nondirective counseling to pregnant women" (quoting 42 U.S.C. § 254c–6)); *id.* at 7733 ("Congress has expressed its intent that postconception adoption information *and referrals* be included *as part of any nondirective counseling* in Title X projects") (emphasis added); *id.* at 7730

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[4] This unsupported assertion is divorced from any medical standard of care. *See* ECF No. 34-1 (ACOG *Amicus* Br.) at 12 ("[p]renatal care is not medically indicated for patients who wish to terminate their pregnancies"); Mot. at 32 & n.91.

(same; referring to counseling and "corresponding referrals"). Congress enacted these provisions a decade *after* using slightly different terminology in the never-enacted Family Planning Amendments Act. *See* Opp. at 23–24. Moreover, Congress reenacted the Nondirective Mandate twenty-four years in a row while the Current Regulations were in effect, further demonstrating its agreement that referrals are part of, or must at least be consistent with, nondirective counseling. "Congress is presumed to be aware of an *administrative* or judicial interpretation of a statute and to adopt that interpretation when it re-enacts a statute without change." *Forest Grove*, 557 U.S. at 239–40 (emphasis added) (Opp. at 20). HHS, too, recognized that "counseling, information, and referral" are "part of nondirective postconception counseling" within Title X. 84 Fed. Reg. 7733–34; *see also id.* at 7747 (acknowledging that referrals are made "during" counseling).

Because Congress has made clear (and HHS has acknowledged) that referral is "part of" nondirective counseling, Defendants' resort to Black's Law Dictionary and a decades-old bill that never became law to support their *post hoc* litigation position is unavailing. *See* Opp. at 23–24; Mot. at 20. Defendants do not seek, and are not entitled to, any deference to their new-found interpretation of "counseling" as entirely severable and distinct from referral. *See* Mot. at 20 (no deference owed to interpretation advanced for the first time in litigation); *see also State v. U.S. Bureau of Land Mgmt.*, 277 F. Supp. 3d 1106, 1117 (N.D. Cal. 2017), *appeal dismissed*, 2018 WL 2735410 (9th Cir. Mar. 15, 2018)

(no deference owed to agency interpretation absent delegated authority to administer *the statute it is interpreting*) (citing *Mead*, 533 U.S. at 226–27).

3. Section 1554 of the ACA renders the Final Rule unlawful

Section 1554 provides that HHS "shall not promulgate any regulation" that interferes with patients' access to medical information and care or violates principles of medical ethics. 42 U.S.C. § 18114. The Final Rule violates these commands in multiple respects, rendering it unlawful. Mot. at 22–25; *see Nat'l Ass'n of Home Builders*, 551 U.S. at 662 ("shall" denotes a statutory "command that admits of no discretion" on the agency's part). Notably, Defendants propose *no* construction of section 1554 that would accommodate the Final Rule; they argue only that section 1554 should not apply. Each of their arguments fails.

First, Defendants' assertion that section 1554 either "repealed" section 1008 or has no meaning at all, Opp. at 30, is meritless for the reasons discussed above. *Supra* at 2–5. Section 1554 prohibits HHS from adopting "any" regulation that impedes access to care, interferes with patient–provider communications, or mandates unethical practices—which the Final Rule does. Mot. at 22–25. By its plain language, section 1554 does not exempt public benefits programs from its limitations on HHS's authority, as Defendants argue. Opp. at 31. Whether in a federally funded grant program or in any other HHS regulatory context, section 1554 establishes patient protections that HHS is forbidden to violate. The *Rust* Court's finding that the 1988 rule was permissible thirty years ago has no bearing on whether the Final Rule violates section 1554.

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Second, HHS cannot evade section 1554 on the grounds that it applies "notwithstanding any other provision" of the ACA. Opp. at 30, 31–32. This "reading of the '[n]otwithstanding any other provision of this title' language is implausible." *United States v. Trucking Mgmt., Inc.*, 662 F.2d 36, 43 (D.C. Cir. 1981) (same statutory language established Congress's "simple and unequivocal intent" to foreclose contrary agency interpretation of an executive order). That Congress chose not to supersede *all* provisions of law on the books as of 2010, *see* Opp. at 32, does not permit HHS to violate section 1554, which on its face prohibits "any" HHS regulation inconsistent with its provisions, and is not limited to the ACA. In fact, the "notwithstanding" language confirms Congress's intent that section 1554 have legal "force" that "supersedes" any contrary provisions of the ACA, *see World Duty Free Americas, Inc. v. Summers*, 94 F. Supp. 2d 61, 66 (D.D.C. 2000), defeating Defendants' theory that this is one of the "rare instances" in which there is "no law to apply." Opp. at 32–33; *Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 410 (1971). *See also Nat'l Ass'n of Mfrs. v. Dep't of Defense*, 138 S. Ct. 617, 632 (2018) (courts must "give effect" to all statutory provisions); *Gonzales v. Oregon*, 546 U.S. 243, 274 (2006) (courts look to whole statutory scheme to determine scope of agency's authority). It would make no sense for Congress to have "committed the decisionmaking to the agency's judgment *absolutely*," leaving "no law to apply," *Heckler v. Chaney*, 470 U.S. 821, 830 (1985) (emphasis added), because section 1554's entire purpose is to *limit* HHS's rulemaking authority. *See* 42 U.S.C. § 18114.

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Third, Defendants' unsupported argument that section 1554 does not apply because it does not specifically mention "abortion or even pregnancy" is meritless. Opp. at 30, 33. Section 1554 plainly applies generally to "medical care," "health care services," "communications . . . between the patient and the provider," and "principles of informed consent and the ethical standards of health care professionals." 42 U.S.C. § 18114. It does not exempt reproductive health care from these general provisions, and nothing suggests that Congress intended to exempt this (or any) type of care *sub silentio*. *See Seed Co. Ltd. v. Westerman*, 266 F. Supp. 3d 143, 148 (D.C. Cir. 2017) ("general terms should be accorded 'their full and fair scope' and not be 'arbitrarily limited'") (quoting SCALIA & GARNER, *supra*, at 101) (general-terms canon). Section 1554 acknowledges and enshrines modern principles of ethical, patient-centered care in *all* medical contexts, guaranteeing freedom from regulatory intrusion into the exam room. Defendants misapply the "general/specific" interpretive canon, Opp. at 33–34, which only applies where a general permission is *contradicted* by a specific prohibition or permission, or where one statute renders another superfluous. *See RadLAX Gateway Hotel, LLC v. Amalgamated Bank*, 566 U.S. 639, 645 (2012). Here, again, the statutes are in harmony; it is *HHS's* unlawful interpretation of section 1008 that creates a conflict. *Supra* at 4–5. Since at least 1996, Congress has required Title X care to be consistent with modern, ethical, patient-centered principles per the Nondirective Mandate, and section 1554 continues that trend, giving these principles the force of law with respect to all types of medical care.

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Finally, Defendants' "waiver" theory, Opp. at 28–29, is a nonstarter because section 1554 is a statutory limitation on HHS's legal authority. "[T]he waiver rule does not apply to preclude argument where the scope of the agency's power to act is concerned," and it is the *agency's* "obligation to examine its own authority and not to promulgate implementing regulations in a way that exceeds its scope." *Sierra Club v. Pruitt*, 293 F. Supp. 3d 1050, 1061 (N.D. Cal. 2018) (waiver rule did not preclude challenge to EPA's authority to extend compliance deadline); *Nat. Res. Def. Council v. EPA*, 755 F.3d 1010, 1023 (D.C. Cir. 2014) (rejecting waiver argument because agency must justify its exercise of authority "even if no one objects to it during the comment period"). HHS was well aware that section 1554 limited its authority. *See* 83 Fed. Reg. 57552 (Nov. 15, 2018).

Furthermore, waiver in the APA context is a prudential doctrine that "should be interpreted broadly"; in this Circuit, commenters need only raise an issue "with sufficient clarity to allow the decision maker to understand and rule on the issue raised." *Nat'l Parks & Conservation Ass'n v. Bureau of Land Mgmt.*, 606 F.3d 1058, 1065 (9th Cir. 2010). Washington (and many others) put HHS on notice that the Final Rule would create unreasonable barriers to care, impede timely access to services, interfere with patient–provider communications, and violate principles of informed consent and medical ethics. *See* Mot. at 23–25 (citing public comments). If no commenter cited section 1554, this is of no moment because the *issues* it implicates were "adequately before the agency for consideration." *Pruitt*, 293 F. Supp. 3d 1060 (no waiver where record was

"replete with comments" opposing extension of compliance deadline, even though comments did not challenge EPA's *authority* to extend deadline).

Notably, Defendants do not claim to be surprised by the invocation of section 1554, and do not indicate they would have adjusted the Final Rule to account for it if a citation had been provided. *See* Opp. at 28–29. Citing the statute would have been futile, since HHS chose to disregard the issues it covers.

4. Title X itself renders the Final Rule unlawful

Defendants' failure to meaningfully defend the Final Rule's violations of Title X's text and purpose is significant: these violations are dispositive as to multiple key provisions of the Final Rule. *See* Mot. at 25–27. Defendants' heavy reliance on *Rust* is again unavailing. Opp. at 34, 35. While *Rust* did include a quote that referenced "Title X voluntariness," 500 U.S. at 177, it did not analyze, apply, or base its holding on that principle, and the issue was not before the Supreme Court. Its ruling on section *1008* does not somehow foreclose the State's arguments based on section *1007*. Similarly, any discussion of Title X's overall purpose in *Rust* (which was minimal at most), *see* Opp. at 35, did not account for *this* rule's unique provisions or the present-day issues reflected in *this* rulemaking record. *See* Mot. at 25–27.

Rust did not confront statewide network destruction, as Washington faces. Washington does not merely assert that the Final Rule is inconsistent with legislative history, *see* Opp. at 35, but that it defies the statute's "central objective." *Stewart v. Azar*, --- F. Supp. 2d ----, No. 18-152 (JEB), 2019 WL

1375496, at *7 (D.D.C. Mar. 27, 2019). HHS's interpretation cannot stand because it is not "reasonably approximated toward enhancing the provision" of family planning services. *Id*.; *see infra* at 19–22. Courts will not "rubber-stamp" rules that are "inconsistent with a statutory mandate or that frustrate the congressional policy underlying a statute." *ATF v. Fed. Labor Relations Auth.*, 464 U.S. 89, 97 (1983).

Defendants argue for an unduly narrow, atextual reading of Title X's "voluntary" requirement. *See* Opp. at 34–35. Section 1007 provides in full:

> The acceptance by any individual of family planning services or family planning or population growth information (including educational materials) provided through financial assistance under this title (whether by grant or contract) shall be voluntary ***and*** shall not be a prerequisite to eligibility for or receipt of any other service or assistance from, or to participation in, any other program of the entity or individual that provided such service or information.

42 U.S.C. § 300a-5 (emphasis added). Defendants' reading improperly renders the entire first clause (before "and") superfluous, *see Nat'l Ass'n of Mfrs.*, 138 S. Ct. at 632 (courts must "give effect, if possible, to every word Congress used"); ignores the plain meaning of "voluntary"; and ignores legislative history that comports with the plain meaning. *See* Compl. ¶ 23 (citing S. Rep. No. 91-1004, at 12) (Congress intended to "insure that the acceptance of family planning services and information relating thereto must be on a purely voluntary basis").

B. The Final Rule Is Arbitrary and Capricious

1. Defendants' reliance on *Rust* is unavailing thirty years later

Defendants dispute that the Final Rule is arbitrary and capricious, but their

arguments are fundamentally flawed: they repeatedly conflate *this rulemaking record* with the thirty-year-old record at issue in *Rust*. Opp. at 36–37, 41, 44, 45, 47. They assert that the Final Rule is "not arbitrary and capricious" "under *Rust*," though *Rust* addressed a different rule on a different record from last century. *Id.* at 36. They offer no authority for the proposition that *Rust* somehow shields them from ever having to consider different facts on a new record. Remarkably, Defendants do not cite or submit *any portion* of the rulemaking record to support their arguments, though judicial review "is based on the administrative record and the basis for the agency's decision must come from the record." *Ass'n of Irritated Residents v. E.P.A.*, 790 F.3d 934, 942 (9th Cir. 2015); *see also Nat'l Wildlife Fed'n*, 384 F.3d at 1170. Defendants also repeatedly speak of HHS's "interpretation" of section 1008 as though this were somehow dispositive, Opp. at 36–37, 41, 43, 46. But this interpretation is foreclosed by intervening statutes, and is not based on any binding judicial construction of Title X. *See Zinke*, 865 F.3d at 605 (agency rulemaking is always reviewable for arbitrariness). With these fundamental flaws accounted for, the defense of the Final Rule crumbles in the face of HHS's evident failure to consider important factors, examine the record, or draw a rational connection between the facts found and the choice made on *this record*.

2. HHS is not at liberty to disregard important issues

As discussed at length in the Motion, HHS arbitrarily and capriciously disregarded many important issues it was obligated to consider. Mot. at 27–39.

Defendants insist that HHS's flawed interpretation of section 1008 is the *only* relevant consideration. Opp. at 36 ("HHS had a simple and compelling basis for promulgating the Final Rule: to ensure compliance" with its interpretation). They assert the same "risks" of commingling and public misperception invoked in *Rust*—albeit without the same supporting evidence[5]—to the exclusion of all other factors. Opp. at 38–41. But HHS is not at liberty to focus on its own policy preferences while disregarding Title X's core purposes and "important aspect[s] of the problem" that Congress identified, and it must rationally base its decision on evidence in the "whole" record. Mot. at 27–29; 5 U.S.C. § 706; *see also Nat'l Fuel Gas Supply Corp. v. FERC*, 468 F.3d 831, 841 (D.C. Cir. 2006) (vacating rule where agency "provided no evidence of a real problem").

Courts have recently struck down similarly deficient HHS rules for these very reasons. In March 2019, HHS's approvals of state-imposed Medicaid work requirements were vacated because HHS "did not engage with" public comments pointing to harmful effects that would undermine Medicaid's "core" purpose. *Gresham v. Azar*, --- F. Supp. 3d ----, No. 18-1900 (JEB), 2019 WL 1375241, at *8 (D.D.C. Mar. 27, 2019); *Stewart*, 2019 WL 1375496. As the court held, HHS may not act to further purposes that "are not stand-alone objectives of the statute

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[5] Unlike in *Rust*, HHS cited no "reports of the General Accounting Office" or any other evidence, 500 U.S. at 187, and ignored the monitoring and compliance systems put in place under the Current Regulations. Mot. at 38.

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in the first instance," while ignoring Congress's expressed purposes. *Stewart*, 2019 WL 1375496, at *8. Similarly, here, Title X's core purpose is to make "comprehensive," "effective," and "voluntary" family planning services "readily available to all," Mot. at 4–5 & n.9, yet HHS subordinated this purpose to its own narrow policy preferences by adopting an expansive new interpretation of section 1008 that swallows the whole statute and disregards multiple important issues. Mot. at 25–26, 29–38.

Paying lip service to important factors is not enough. *See* Opp. at 44–49 (repeatedly asserting, with no meaningful support, that HHS "considered" issues raised by commenters). Merely "stating that a factor was considered is not a substitute for considering it." *Gresham*, 2019 WL 1375241, at *9 (quoting *Getty v. Fed. Savs. & Loan Ins. Corp.*, 805 F.2d 1050, 1055 (D.C. Cir. 1986)) (brackets and ellipses omitted). *See also Nat'l Lifeline Ass'n v. F.C.C.*, --- F.3d ----, No. 18-1026, 2019 WL 1549886, at *7 (D.C. Cir. Feb. 1, 2019) (agency action was arbitrary and capricious where it "did not meaningfully address comments and evidence that undercut its conclusion"); *Am. Wild Horse Preservation Campaign v. Perdue*, 873 F.3d 914, 932 (D.C. Cir. 2017) (agency action was arbitrary and capricious where it failed to "adequately analyze" important factor). It is "well established that 'conclusory or unsupported suppositions' do not satisfy the agency's obligation to engage in reasoned decisionmaking," particularly "in the face of numerous comments taking the opposite position." *Gresham*, 2019 WL 1375241, at *10 (quoting *McDonnell Douglass Corp. v. U.S. Dep't of Air Force*,

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375 F.3d 1182, 1187 (D.C. Cir. 2004); citing public comments by ACOG). Here, as in the Medicaid cases, HHS merely "spoke generally" of its "beliefs" and "conclusions" that the Final Rule would not impact patients' access to care or pose ethical problems, *see* Opp. at 44, 46, 48, 51, but "cited no research or evidence" to support these "beliefs." *Stewart*, 2019 WL 1375496, at *10, 14; *see* Mot. at 15, 29–30, 36–38. Even if agencies have no "general obligation" in every rulemaking to "produce empirical evidence," Opp. at 41–42, they are not free to base a rulemaking exclusively on their own assertions that are not "based on the administrative record[.]" *Ass'n of Irritated Residents*, 790 F.3d at 942; *see also, e.g.*, *Choice Care Health Plan, Inc. v. Azar*, 315 F. Supp. 3d 440, 443 (D.D.C. 2018) (to survive APA review, "the facts on which the agency purports to have relied" must "have some basis in the record").

3. HHS's unsupported conclusions cannot survive judicial review

Defendants give short shrift to the many problems with the Final Rule raised by the State that render it arbitrary and capricious. *See* Opp. at 41–53. In most cases, Defendants offer a "response [that is] no answer at all," *Stewart*, 2019 WL 1375496, at *10, merely restating the Final Rule's unsupported conclusions.

Medical ethics and patient-focused care. The Final Rule's intrusion into the patient–provider relationship to mandate unethical care—which HHS must consider in *any* rulemaking, *see* 42 U.S.C. § 18114(5)—is arbitrary and capricious. Mot. at 29–32. Defendants fail to explain *why* HHS "adopted a different view" from the major medical associations that unanimously opposed

the Final Rule on ethical grounds, and point to no evidence in the record supporting HHS's contrary "view." Opp. at 44–45, 46; *cf. Sierra Forest Legacy v. Sherman*, 646 F.3d 1161, 1185–86 (9th Cir. 2011) (no deference owed to agency in fields where government lacks "unique expertise"). They offer no defense of HHS's failure to address the *specific* ethical issues raised by commenters—including issues related to informed consent and ethical referrals for medically indicated and appropriate care, Mot. at 24–25 & n.77, 29–30—and instead quote a passage from the preamble that responds to an inaccurate, incomplete, and self-serving characterization of medical ethics requirements. *See id.*; Opp. at 44. Again, merely *stating* that HHS "considered" medical ethics, Opp. at 45, is "not a substitute for considering it." *Gresham*, 2019 WL 1375241, at *9.

Defendants also fail to engage with the multiple reasons why "conscience" statutes are an irrational justification for mandating unethical care, *see* Mot. at 30–31, instead quoting portions of the preamble that do not respond to these points. Opp. at 44–45; *see also id.* at 40–41. They again invoke *Rust*, which did not address or base its holding on medical ethics and was decided on a different record (which would have reflected, if anything, ethical standards and supporting data from thirty years ago). *Id.* at 44. Defendants also offer no rationale *whatsoever* for HHS's removal of the requirement that patients be referred for any "medically indicated" care, its baseless assertion that prenatal care is somehow "medically necessary" for *all* pregnant patients, or its prohibition on "nondirective" pregnancy counseling by qualified Title X personnel who are not

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doctors or "APPs." *See* Mot. at 31–32. In failing to defend these provisions of the Final Rule, Defendants tacitly concede they are arbitrary and capricious.

Program requirements and standards of care. It is difficult to overstate the significance of HHS's *sub silentio* reversal of its Program Requirements as reflected in the QFP, its own summary of best practices for providing quality family planning services as of December 2017. Mot. at 9, 32–34. The QFP provides a solid evidentiary basis for the policies reflected in the Current Regulations; HHS developed it "by conducting an extensive review of published evidence, seeking expert opinion, and synthesizing existing recommendations" from the CDC and other agencies, ACOG, and AAP. QFP update at 1.

The Final Rule requires care that is contrary to the QFP, yet Defendants *admit* that HHS made no "factual findings that contradict those which underlay" the QFP. Opp. at 43 (quoting *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009)). Because the extensive factual basis for the QFP has not changed, HHS cannot—and did not—"supply a reasoned analysis" justifying its departures from the QFP, or for ignoring public comments on the consequences of doing so. Mot. at 33–34; *see also Organized Village of Kake v. U.S. Dep't of Agriculture*, 795 F.3d 956, 966 (9th Cir. 2015) ("an agency may not simply disregard prior factual findings without a reasoned explanation"); *State v. Bureau of Land Mgmt.*, 286 F. Supp. 3d 1054, 1068 (N.D. Cal. 2018) (agency "must provide at least some basis—indeed, a 'detailed justification'—to explain why it is changing course" after "years of study and deliberation"); *Ctr. for Biological Diversity v. Lohn*,

296 F. Supp. 2d 1223, 1239 (W.D. Wash. 2003) (agency action was arbitrary and capricious where it "ignored its experts' conclusions"). Defendants' only response is that "HHS was entitled" to reinterpret section 1008 contrary to Congress's expressed intent. This argument fails for the reasons discussed above, and moreover offers "no answer at all" that would justify HHS's drastic departure from the QFP and disregard of numerous public comments. *See* Mot. at 32–34.

Defendants fail to respond to Washington's argument that the Final Rule is arbitrary and capricious because it will expand eligibility for Title X funds to "diverse" providers who are no longer obligated to offer "medically approved" contraception, which undermines Title X's objective of increasing access to a "broad range" of "effective" contraception. Mot. at 26, 30–31, 32–33; *see* Opp. at 51–52, 53. The QFP emphasizes that clinics should offer a "full range of FDA-approved contraceptive methods," from the most effective (e.g., IUDs and implants) to the least effective (e.g., fertility-awareness based methods), Mot. at 35; QFP at 10 (Fig. 3), and Defendants offer no rational justification for funding the provision of even less effective, non-medically approved services. Defendants *entirely* fail to defend the Final Rule's limitations on the use of Title X funds for core program activities like purchasing contraceptives, training staff, and developing educational materials, Mot. at 27, again conceding the point.

Network destruction and unnecessary burdens. Defendants do not dispute that access to care and network adequacy are "important factors" that HHS must consider. Mot. at 37–38. They insist that HHS *did* consider these factors, but do

not connect the record to HHS's unsubstantiated "conclusions," "expectations," and "anticipation" that the Final Rule will somehow have no impact on access to Title X services. Opp. at 46–48; *see* Mot. at 36–37. Again, "the basis for the agency's decision must come from the record," *Ass'n of Irritated Residents*, 790 F.3d at 942, and here Defendants point to nothing supporting HHS's conclusions.

Contrary to HHS's belief that the Final Rule will "increase the number of providers in the program," Opp. at 46, the unanimous opposition from major medical associations on ethical grounds is itself strong evidence that many practitioners will feel they cannot ethically comply with the rule. *See supra* at 19–20. HHS's "conclusion" that more "applicants" will seek Title X funds and the number of "facilities" will not decrease under the Final Rule is completely unsubstantiated, Opp. at 46–47, 48, and furthermore fails to account for the number of *patients* who will be left without care when major providers are forced to depart. In Washington, almost *ninety percent* of Title X patients will lose their provider because of the Final Rule. Mot. at 13–15, 40–41. Contrary to Defendants' assertion that HSS "considered" Washington's state-specific concerns, they point to nothing in the record addressing the matter of statewide network destruction. Opp. at 47–48. There is no evidence that conscience objectors can possibly fill the massive gap in the network, *see* Opp. at 46–47; Mot. at 14–15—and even if they could, their patients would receive substandard

care inconsistent with Title X's purposes.[6] Mot. at 12, 16, 30–31. Accounting for these problems does not give grantees "veto power" over HHS, Opp. at 47, but it *does* mean that the Final Rule is arbitrary and capricious because it fails to consider factors Congress deemed important and is contrary to Congress's intent.

Defendants offer no response to Washington's arguments that the Final Rule will force providers out of the State's network because the "physical separation" provisions (including costly EHR separation), the "comprehensive primary health care" requirement, and the initial grant eligibility hurdle are excessively burdensome. Mot. at 35; *see* Opp. at 48–52. Though the extreme costs associated with the various separation requirements are well documented in the public record, Mot. at 11–12 & n.36; *id.* at 37–38 & n.109, Defendants devote just half a page of their brief to addressing this issue and do not mention Washington at all. Opp. at 48–49. They fail to explain why or how commenters' substantiated estimates of the Final Rule's costs are not "sufficient," Opp. at 49, and fail to show that HHS's cost estimate is anything more than an "arbitrary assumption." *Bureau of Land Mgmt.*, 286 F. Supp. at 1069, 1072 (agency cannot rely on its own cost analysis and selectively "deny comments about the financial

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[6] For similar reasons, the fact that some *amici* "do not want to assist in the funding of entities linked to abortion," ECF No. 43-1, is immaterial to Congress's intent as reflected in Title X, the Nondirective Mandate, and the ACA, and does not somehow render the unlawful rule valid.

and economic burden" imposed by the rule). Overall, HHS's cost analysis fell far short of the standards for conducting regulatory impact analyses. *See generally* ECF No. 38-1 (*Amicus* Brief of Inst. for Policy Integrity).

Defendants get nowhere by citing "data from the Congressional Research Service," i.e., an estimate that 10% of Title X clinics "offer abortion . . . in addition to Title X-funded activities," 84 Fed. Reg. 7781. Opp. at 49. This figure ignores clinics that must physically separate newly prohibited activities like abortion referrals, and ignores grantees like Washington, which will have to separate its Olympia-based *administration* of the statewide Title X program from any abortion-related activities—an enormous burden HHS did not address. Mot. at 15–16, 23, 26. This figure also ignores the numbers of *patients* served by affected clinics; just 35 of 85 clinics served almost *ninety percent* of Washington Title X patients in 2017, and their departure will leave more than half the State's counties without a Title X provider. Mot. at 5–6, 13–14. Defendants also fail to respond to Washington's arguments that the "comprehensive primary health services" requirement is *ultra vires*, ill defined, self-contradictory, costly, and counterproductive. Mot. at 12; Compl. ¶¶ 114–20; *see* Opp. at 49–50. They fail to defend the new grant eligibility hurdle, which permits HHS to arbitrarily reject funding applications *prior* to merits review, increasing uncertainty and the cost of compliance. Mot. at 35; Compl. ¶¶ 126–29; *see* Opp. at 52.

Reliance interests. Defendants argue that the reliance interests identified by the State are not "legally cognizable" because Title X grants are awarded

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annually. Opp. at 42. But as Defendants acknowledge, the Final Rule changes the *conditions* for Title X funding, requiring programs to provide unethical, substandard care. *See id.* Regardless of who the grantee is, patients and providers rely on being able to receive and give ethical, patient-centered care within a Title X program, and the Final Rule undisputedly disregarded those interests. *See id.* Substandard care will harm public health, which harms the State itself. Mot. at 13–18. Washington also relies on not being disqualified by virtue of its program providing ethical and high-quality care. Mot. at 38–39. *Janus* is inapposite, as it did not involve an agency rulemaking, and balanced First Amendment interests "in perpetuity" against time-limited contract provisions. *Janus v. Am. Fed'n of State, Cnty. & Mun. Emps., Council 31*, 138 S. Ct. 2448, 2484 (2018).

C. Defendants Fail to Refute the State's Evidence of Irreparable Harm

Defendants do not factually or legally dispute that Washington will suffer irreparable harm because the Final Rule will destroy its statewide program and cause uncompensable financial and public health harms. *See* Opp. at 54–55. Nor could they, for the sufficiency of such harm is well established. *See* Mot. at 40–45; *California v. Azar*, 911 F.3d 558, 571, 581 (9th Cir. 2018) (irreparable harm based on "women losing employer-sponsored contraceptive coverage, which will then result in economic harm to the states"); *Regents of Univ. of Cal. v. U.S. Dep't of Homeland Sec.*, 279 F. Supp. 3d 1011, 1033, 1046 (N.D. Cal.), *aff'd*, 908 F.3d 476 (9th Cir. 2018) (irreparable harm based on "loss of specific tax revenues" and "detrimental impact on . . . public health . . . and safety"); *County of Santa*

Clara v. Trump, 250 F. Supp. 3d 497, 537 (N.D. Cal. 2017) (irreparable harm where rule would obligate counties to "take steps to mitigate the risk of losing millions of dollars in federal funding"); *Texas v. United States*, 86 F. Supp. 3d 591, 673 (N.D. Tex. 2015), *aff'd*, 787 F.3d 733 (5th Cir. 2015) (irreparable harm where "there are millions of dollars at stake in the form of unrecoverable costs to the States"). Washington's evidence of the same types of harm is dispositive.

Defendants offer no evidence to refute the harms the Final Rule will impose on real people in Washington and on the State itself. Mot. at 13–18, 41-44. There is nothing "uncertain" about these consequences. *See, e.g.*, *Pennsylvania v. Trump*, 281 F. Supp. 3d 553, 583 (E.D. Pa. 2017) ("[e]ighty five percent of women who do not use any form of contraceptive services and who do not want to become pregnant, become pregnant in one year"); Kost Decl. ¶ 35.

Defendants' only response is a legal argument that conflates injury with standing:[7] they claim the State is not harmed by injury to state residents. Opp. at 54. But courts have repeatedly enjoined this Administration's actions based on irreparable harm to state residents. *See Washington v. Trump*, 847 F.3d 1151, 1169 (9th Cir. 2017); *California v. HHS*, 351 F. Supp. 3d 1267, 1297 (N.D. Cal. 2019); *Pennsylvania v. Trump*, 281 F. Supp. 3d 553, 582 (E.D. Pa. 2017); *Bureau of Land Mgmt.*, 286 F. Supp. 3d at 1075 (N.D. Cal. 2018); *Regents*, 279 F. Supp.

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[7] Defendants do not dispute Washington's standing as a grantee, *see* Mot. at 5 n.10, but superfluously challenge its standing as *parens patriae*. Opp. at 54.

3d at 1034 (N.D. Cal. 2018). As in those cases, the Final Rule irreparably harms Washington because it harms its residents and will have disastrous public health results. Mot. at 13–15. Defendants also argue that Washington's injury is speculative or legally deficient because it is based on third-party subrecipients leaving the network. Opp. at 54–55. This ignores record evidence that they have *already* announced their departure if the Final Rule is not enjoined, and it ignores Washington's own programmatic injury. Mot. at 40–41; Harris Decl. ¶ 60; *see also* Cantrell Decl. ¶ 36; Eastlund Decl. ¶ 8; Kruse Decl. ¶ 40; Maisen Decl. ¶ 42. There is nothing "speculative" about the subrecipients' announcements, or about the harm their absence will cause. *See* Mot. at 13–18, 39–44. Courts routinely enjoin agency actions targeting third parties that cause irreparable injury to states. *See, e.g.*, *California*, 911 F.3d at 581; *Washington*, 847 F.3d at 1169; *California*, 351 F. Supp. 3d at 1297; *Pennsylvania*, 281 F. Supp. 3d at 582–83; *Regents*, 279 F. Supp. 3d at 1033.

D. The Court Should Enjoin the Final Rule in Full

"The basic function of a preliminary injunction is to preserve the status quo pending a determination of the action on the merits." *Chalk v. U.S. Dist. Court Cent. Dist. Cal.*, 840 F.2d 701, 704 (9th Cir. 1988). Any questions about severance are premature; at this early stage, the Final Rule should be enjoined in full pending merits review. In any event, severance is unworkable because the Final Rule is comprised of interrelated provisions that further one overarching purpose: "to ensure compliance" with HHS's new interpretation of section 1008,

Opp. at 36. *See MD/DC/DE Broad. Ass'n v. FCC*, 236 F.3d 13, 22–23 (D.C. Cir. 2001) (regardless of agency intent, unlawful portions of regulation are not severable where they would "undercut the whole structure of the rule").

Nationwide relief is warranted as well. Cases involving federal grant programs are particularly suitable for "programmatic" relief to ensure consistent, fair standards. *Cty. of Los Angeles v. Sessions*, 293 F. Supp. 3d 1087 (C.D. Cal. 2018). Nationwide injunctions are "commonplace in APA cases" and supported by an "uncontroverted line of precedent." *E. Bay Sanctuary Covenant v. Trump*, 909 F.3d 1219, 1256 (9th Cir. 2018). Both the Supreme Court and the Ninth Circuit have been "unpersuaded" by the Justice Department's new policy[8] of opposing *all* requests for nationwide relief, which Defendants follow here. *Cty. & County of San Francisco v. Trump*, 897 F.3d 1225, 1244–45 (9th Cir. 2018); *Trump v. Int'l Refugee Assist. Project*, 137 S. Ct. 2080 (2017) (staying executive order as to parties *and* "similarly situated" persons); *accord E. Bay Sanctuary*, 909 F.3d at 1256; *Hawaii v. Trump*, 878 F.3d 662, 701 (9th Cir. 2017) (per curiam), *rev'd on other grounds*, 138 S. Ct. 2392 (2018); *Washington*, 847 F.3d at 1166–67.

Here, as in *City of Los Angeles*, all applicants for Title X funds should be on an "even playing field." 293 F. Supp. 3d at 1101. Subjecting Washington and

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[8]https://www.justice.gov/opa/pr/attorney-general-sessions-releases-memorandum-litigation-guidelines-nationwide-injunctions.

other grantees to different rules would alter HHS's distribution of Title X appropriations, and Defendants offer no proposal for fairly allocating funding in such a scenario. *See E. Bay Sanctuary*, 909 F.3d at 1256 (upholding nationwide injunction where Administration "fail[ed] to explain" how "a narrower [remedy]" would provide complete relief).

Defendants incorrectly characterize the scope of the injunctive relief granted in the lead-up to *Rust*, which was not "limited . . . to the parties before" the district courts. Opp. at 61; *see Massachusetts v. Bowen*, 679 F. Supp. 137, 148 (D. Mass. 1988) (injunction in favor of NFPRHA and other plaintiffs, as to all "entities they represent, in any manner either directly or indirectly, anywhere within the United States"); *Planned Parenthood Fed'n of Am. v. Bowen*, 687 F. Supp. 540, 544 (D. Colo. 1988) (injunction applicable to plaintiffs "as well as all other parties named in the Preliminary Injunction," a reference to all Planned Parenthood clinics nationwide). Defendants also contend that nationwide relief would somehow preclude other courts from passing on separate challenges to the Final Rule, Opp. at 64, but there is no reason that preliminary programmatic relief in this case would suddenly halt the trajectory of other plaintiffs' cases. Nationwide relief (or alternatively, a stay under 5 U.S.C. § 705, Mot. at 45) is needed to provide complete relief.

III. CONCLUSION

For the reasons above and in the Motion, the State requests that the Court preliminarily enjoin Defendants from implementing or enforcing the Final Rule.

DATED this 19th day of April, 2019.

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DECLARATION OF SERVICE

I hereby declare that on this day I caused the foregoing document to be electronically filed with the Clerk of the Court using the Court's CM/ECF System which will serve a copy of this document upon all counsel of record.

DATED this 19th day of April, 2019, at Seattle, Washington.

/s/ Jeffrey T. Sprung
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Assistant Attorney General