No. 19-35394

UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

NATIONAL FAMILY PLANNING & REPRODUCTIVE HEALTH ASSOCIATION, ET AL.,
Plaintiffs-Appellees,

v.

ALEX M. AZAR II, in his official capacity as the Secretary of Health and Human Services, ET AL.,
Defendants-Appellants.

On Appeal from the United States District Court
for the Eastern District of Washington Nos. 19-cv-3040, 19-cv-3045 (Bastian, J.)

PLAINTIFFS-APPELLEES' ANSWERING BRIEF

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CORPORATE DISCLOSURE STATEMENT

Under Federal Rule of Appellate Procedure 26.1, the corporate Plaintiffs—National Family Planning & Reproductive Health Association; and Feminist Women's Health Center—disclose that they have no parent corporation, nor is there a publicly held corporation that owns 10% or more of their stock.

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INTRODUCTION

The federal Title X grant program serves to equalize access to quality family planning care, ensuring that those with limited economic resources have the same up-to-date clinical care as those with more resources. *See* ER118-20 (injunction order). Since the program's creation in 1970, Title X grants have helped build a highly effective network of health care providers that serves more than four million patients each year. This Title X network reaches a population with income at or near the federal poverty level, that is disproportionately Black and Latino/a, and that has low rates of English proficiency and health literacy.

In 2019, the Department of Health and Human Services and its co-defendants (collectively, "HHS") sought to remake the longstanding rules that have governed the Title X program. The district court recognized that if HHS's sweeping new regulations, 84 Fed. Reg. 7714-91 (Mar. 4, 2019) (the "Rule"), took effect, even briefly, the Title X program, the hundreds of Title X provider organizations before the court, and their vulnerable patients would face immediate, serious irreparable harms. ER127-29. The court found Plaintiffs likely to succeed on not just one, but numerous legal claims. ER125-27. Applying the correct standard, the district court appropriately exercised its discretion and entered a preliminary injunction to preserve the status quo of almost five decades. ER129.

Contrary to HHS's portrayal, this case is not an effort to evade *Rust v. Sullivan*, 500 U.S. 173 (1991), or an effort to sanction the misuse of taxpayer funds, but rather involves the fate of Title X patients and their continued access to quality health care while Plaintiffs litigate to enforce Congress's dictates for this

program. Since *Rust*, Congress has made explicit, for example, that in addition to "preconception family planning," HHS's Opening Brief ("HHS Br.") at 1, Title X also provides pregnancy testing and counseling, and must in all instances do so in a neutral, nondirective manner. This case is not *Rust* redux, but instead presents different statutory claims, including based on statutes that did not exist at the time of *Rust*; different and more expansive challenged regulations; and a different, present-day rulemaking record. HHS has identified no reason to disturb the district court's well-founded findings of fact, application of law, and exercise of discretion to protect Plaintiffs and preserve the status quo during the pendency of this litigation.

STATEMENT OF THE ISSUES

1. Whether the district court, after finding Plaintiffs had shown that "all four factors tip in their favor" (ER125), acted within its discretion to preliminarily enjoin HHS's enforcement of the new Title X regulations.

2. Whether the full scope of the preliminary injunction should remain in force to protect the Plaintiffs from irreparable harm and preserve the longstanding status quo until a final merits determination occurs.

PERTINENT STATUTES AND REGULATIONS

The Supplemental Addendum includes a relevant section of the Title X statute that is not included in HHS's Addendum.

STATEMENT OF THE CASE

A. The Title X Program and the Patients It Serves

1. The Title X Statute. Congress enacted Title X to give low-income persons equal access to modern, quality family planning care, including the then-new contraceptives like "the Pill," so that they could better take control of their reproductive lives. *See* S. Rep. No-91-1004 at 9-12 (1970) (describing Congress's concern for the "medically indigent" and the need for all to have access to quality services); SER7-9. Congress sought to make "comprehensive voluntary family planning services readily available" and "to enable public and nonprofit private entities to plan and develop comprehensive programs of family planning services." Pub. L. 91-572, 84 Stat. 1504 § 2 (1970).

Under Title X, HHS's Office of Population Affairs ("OPA") is to award grants to state or local government and nonprofit entities through a merits-based process that considers, *inter alia*, patient need and an entity's "capacity to make rapid and effective use of such assistance." 42 U.S.C. § 300(b); *see also id.* § 300(a) (funding "to assist in the establishment and operation of voluntary family planning projects"). Each grant funds a Title X "program or project," *id.* § 300a-4(a), consisting of clinical and educational activities based in ordinary health care facilities (where non-Title X care also often occurs), as well as administrative and oversight functions. Title X projects must prioritize low-income patients and provide services at no cost to them. *Id.* § 300a-4(c).

Title X further requires that projects "shall offer a broad range of acceptable and effective family planning methods and services" to their patients. 42 U.S.C. § 300. According to OPA's most recent Program Requirements for Title X,

> All Title X-funded projects are required to offer a broad range of acceptable and effective medically (U.S. Food and Drug Administration (FDA)) approved contraceptive methods and related services on a voluntary and confidential basis.

SER71. Title X projects also provide cervical and breast cancer screening; sexually transmitted disease (STD) and human immunodeficiency virus (HIV) testing and services; pregnancy testing and counseling; and basic infertility services. *See id.*; 42 U.S.C. § 300. Title X services do not include abortions; the statute specifies that no grant funds "shall be used in programs where abortion is a method of family planning." 42 U.S.C. § 300a-6 ("Section 1008"). Consistent with that limit, however, Title X care since the program's inception has taken place in health care facilities where abortions also occur and been provided by entities that also offer abortion care, distinct from their Title X project and with non-Title X funds. SER41.

Congress recognized that Title X—which provides highly personal health care and serves vulnerable patients—required "explicit safeguards to insure that the acceptance of family planning services and information relating thereto must be on a purely voluntary basis by the individuals involved." S. Rep. No. 91-1004 at 12. The statute repeatedly references the voluntary nature of Title X programs and provides in particular that "acceptance by any individual of family planning services or family planning or population growth information (including

educational materials) … *shall be voluntary* and shall not be a prerequisite" for other services or assistance. 42 U.S.C. § 300a-5(a) (emphasis added).

2. Congress's Nondirective Mandate for Title X. Beginning in 1996 and to the present day, Congress has annually placed additional conditions on the operation of Title X programs through appropriations statutes that require, *inter alia*, that "all pregnancy counseling [in Title X projects] shall be nondirective." Pub. L. No. 115-245, 132 Stat. 2981, 3070-71 (2018) (the "Nondirective Mandate"). With the Nondirective Mandate, Congress has made explicit that pregnancy counseling is a Title X service and has required that no aspect of it be directive. *Id*.

3. Congress's Limits on Any HHS Rulemaking to Protect Patients. In addition, Congress in the 2010 Patient Protection and Affordable Care Act ("ACA") has required that the Secretary of HHS "shall not promulgate any regulation" that:

> (1) creates any unreasonable barriers to the ability of individuals to obtain appropriate medical care;
>
> (2) impedes timely access to health care services;
>
> (3) interferes with communications regarding a full range of treatment options between the patient and the provider;
>
> (4) restricts the ability of health care providers to provide full disclosure of all relevant information to patients making health care decisions; [or]
>
> (5) violates the principles of informed consent and the ethical standards of health care professionals; ….

42 U.S.C. § 18114(1)-(5). This provision limits HHS's rulemaking authority in all contexts.

4. The Regulations Now Governing the Title X Program. The longstanding Title X regulations, finalized in 2000, are consistent with the program's operation throughout its almost five-decade history. *See* 42 C.F.R. §§ 59.1-59.12 (2000). They foster long-term "establishment and operation of voluntary family planning projects." 42 C.F.R. § 59.1. For example, the regulations specify that project periods will "usually be for three to five years" and not require a project to "recompete for funds" each year. 42 C.F.R. § 59.8(a) . Programs are to undertake outreach and education that promotes "continued participation in the project by persons to whom family planning services may be beneficial" and to engage the community in ongoing program implementation and evaluation. 42 C.F.R. §§ 59.5(b)(3), (4), (8), (10); *see also* §§ 59.5(a)(10)-(11), 59.6.

All Title X projects must also secure other funding, in addition to their federal grant. The regulations specify that "[n]o grant may be made for an amount equal to 100 percent" of the project's costs. 42 C.F.R. § 59.7(c). Though federal funding does not cover the full cost, all of a project's activities must comply with Title X's program requirements and legal limitations. In addition, Title X grants require pre-approval of budgets and project plans, and strict reporting and grants management steps, to ensure that "[a]ny funds granted under this subpart shall be expended solely for the purpose for which the funds were granted." 42 C.F.R. § 59.9; *see also* §§ 59.4, 10. Under OPA-approved project plans, Title X grants typically help pay for supplies, staff, training, equipment, electronic systems, rent, and other necessities for building and sustaining quality health care projects. SER29-32, SER230-31.

Among many program requirements, each Title X project must "[n]ot provide abortion as a method of family planning," but must offer pregnant women the opportunity to receive "neutral, factual information and nondirective counseling" regarding each of the following options:

> (A) Prenatal care and delivery;
> (B) Infant care, foster care, or adoption; and
> (C) Pregnancy termination.

42 C.F.R. § 59.5(a)(5)(i). Each pregnant Title X patient receives any such counseling on any option she desires, including "referral upon request, except with respect to any option(s) about which the pregnant woman indicates she does not wish to receive such information and counseling." 42 C.F.R. § 59.5(a)(5)(ii). This regulation reflects the same nondirective approach that HHS approved in the 1970s, that HHS required in its 1981 Program Guidelines, and that Title X operated under even before the 2000 regulations were finalized. *See* 65 Fed. Reg. 41,270. As discussed below, in 1988 HHS attempted to end pregnant Title X patients' access to neutral information and referral upon request, but those changes never were implemented nationwide.

5. HHS's National Clinical Standards for Family Planning. From 2010 to 2014, HHS's Centers for Disease Control and Prevention ("CDC") and OPA convened expert panels, undertook extensive literature review, and developed evidence-based national clinical recommendations for family planning care. The resulting joint CDC/OPA publication, "Providing Quality Family Planning Services" ("the QFP") receives periodic supplementation and continues to govern health care today. SER89-144. The QFP's clinical guidelines apply to "all current

or potential providers of family planning services," including but not limited to Title X providers. SER92. OPA's Title X Program Requirements incorporate the QFP into the explicit requirements for Title X projects. SER71.

The QFP directs that family planning providers should take a "client-centered approach," whereby care is responsive to "individual client preferences, needs, and values; client values guide all clinical decisions." SER92, 94. The QFP section on "Pregnancy Testing and Counseling" specifies that "test results should be presented to the client, followed by a discussion of options and appropriate referrals." SER103-04. The QFP directs that those services be provided according to the recommendations of "major professional medical organizations, such as the American College of Obstetricians and Gynecologists (ACOG)." SER103. The type of referral is "at the request of the client" and prenatal counseling is *not* to be provided to all pregnant patients, because not all patients are considering or plan to continue the pregnancy. SER104.

6. The Title X Network and the Patients It Serves. Title X's merits-based grant-making and focus on providing under-resourced communities with quality family planning care has led to a well-distributed, high-performance network of providers. Title X today funds roughly 90 projects, each headed by the grantee that administers the overall project and may also provide services; within those 90 projects, more than 1000 different provider entities (i.e., grantees and subgrantees) serve Title X patients at almost 4000 health care sites. SER169. Approximately 70% of Title X provider sites are specialized, reproductive health-focused practices. SER170. Among their many strengths, Title X providers typically offer

a greater number of contraceptive options than do non-Title X providers and are more likely to offer contraceptive methods onsite, rather than requiring a patient to go to a pharmacy or another provider (e.g., for insertion of an implant). SER152-53, SER161-64. In 2015, the most recent year for which this data is available, Title X providers helped women avoid an estimated 822,000 unintended pregnancies. SER160.

As an Institute of Medicine review of the Title X program explained:

> [M]ost current grantees have been Title X grantees for many years … [and] are often refunded through many cycles. They have demonstrated understanding of the needs of the geographic area to be served, success in developing networks of care and serving patients in their communities, the interest and skills necessary to carry out the subcontracting required, and the ability to meet [OPA] standards in collecting data and monitoring the performance of [subrecipients]. Continuing with high-performing grantees ensures continuity in service delivery through a well-established and -functioning network.

Institute of Medicine, *A Review of the HHS Family Planning Program* (2009) at 112; *see also* SER37-38.

Of the four million patients served in 2017, 90% had incomes at or below 250% of the federal poverty level. OPA, *Title X Family Planning Annual Report* (2017) ("FPAR") at 21. Those patients are disproportionately Black (20% self-identified as Black or African-American) and Latino/a (33%). FPAR at 12. Many patients lack access (outside Title X) to accurate health information. SER22, SER260-62. Large numbers of Title X patients visit their Title X provider multiple times in one year and year after year. SER21, SER253. For approximately six in

ten patients, their Title X clinician is the only health care provider they see all year. SER166.

B. The Challenged 2019 HHS Rulemaking

1. HHS's 2018-2019 Effort to Remake the Program. In June 2018, HHS issued proposed regulations to change the Title X program dramatically—though it identified no triggering event or evidence that the program required change. During the comment period, the agency received an outpouring of objections from the country's leading medical, family planning, and public health experts that cataloged and substantiated the destructiveness of the proposal.[1] Despite the overwhelming evidence of harm, HHS nonetheless promulgated the Rule. The Rule adds or amends dozens of provisions to diminish Title X family planning care and to empower HHS to serve the "conscience" objections of possible future providers, contrary to Title X's purpose of giving the most vulnerable equal access to quality clinical services. *See* 84 Fed. Reg. 7714-91; ER198-232 (NFPRHA Complaint regarding specifics of Rule).

The Rule imposes a new, complex scheme for Title X pregnancy counseling that purports to allow some "nondirective pregnancy counseling" and the optional provision of some information about abortion. Section 59.14.[2] But in fact, its

[1] *See, e.g.*, SER307-10 (index of representative comments to HHS that Plaintiffs relied on for preliminary injunction motion). Full citations for comments cited herein appear in the Table of Authorities.

[2] The Rule's components are cited by "Section" citations, and set forth at Add.74-79. The longstanding Title X regulations that will continue to govern under the preliminary injunction are cited by "42 C.F.R. §" references.

provisions (a) require all pregnant patients to be steered toward keeping their pregnancy; (b) empower individual providers to dictate the contents of Title X counseling based on the providers' preferences, including to omit any mention of abortion regardless of the patient's preferences; and (c) conflict with the QFP's clinical standards. The Rule, for example, erroneously deems prenatal referral "medically necessary" for all pregnant patients, but forbids referral to abortion at patient request. *See* Sections 59.2, 59.5(a)(5), (b)(1) & (8), 59.13-59.18.

The Rule requires all Title X grant administrators and service providers at every Title X site to separate, *inter alia*, their physical locations, staff, electronic health records, websites and email from any *non-Title X* abortion-related activity (including non-Title X clinicians discussing abortion or government employees administering other programs under the same roof). *See* Sections 59.13-59.16. These "physical separation" provisions alone would cause enormous and untenable duplication for Title X-funded government and non-profit entities. But the Rule adds another restriction, forbidding any infrastructure spending "for purposes prohibited" by HHS. *See* Section 59.18 (also limiting funds to "direct implementation" of purposes "expressly permitted" in the regulations). HHS explains that, under the physical separation and infrastructure spending limits combined, "Title X projects would not share any infrastructure with abortion-related activities." 84 Fed. Reg. 7774.

The Rule also makes numerous other changes to support hypothetical, future Title X providers that *oppose* core Title X services, such as biomedical contraceptives and neutral pregnancy counseling, and to divert Title X funds from

serving their purpose. *See, e.g.*, Sections 59.5(a)(1), (12), 59.7(c)(2). The Rule adds intrusive requirements for minors seeking confidential access to family planning care (beyond state and local abuse reporting and other statutory requirements that already cover Title X providers), and it prioritizes serving women of any income whose employers have conscience objections to providing contraceptive care through their private insurance plans. *See, e.g.*, Sections 59.2, 59.5(a)(14), 59.17. The Rule creates excessive, often duplicative levels of record-keeping, reporting, and "transparency" steps where there is no compliance problem. *See, e.g.*, Sections 59.5(a)(13), 59.7(b), 59.17(d), 59.18. And the Rule overhauls the Title X application review and grant-making process, creating a new step whereby HHS can weed out applicants before merits-based review and changing the grant-making criteria that have governed the program for decades. These grant-making changes newly prioritize a diversity of grant subrecipients (especially "non-traditional" Title X providers) for its own sake and would favor entities that HHS sees as especially far removed from any abortion-related activities. *See* Section 59.7; 84 Fed. Reg. 7754.

2. Differences from the 1988 Rulemaking. HHS's primary contention, in its rulemaking and in this litigation, is that the 2019 regulations "in all respects challenged here, reinstated" 1988 regulations; it asserts that "materially indistinguishable regulations" were ruled on in *Rust*. HHS Br. at 1-2. But this false mantra of "materially indistinguishable" ignores important differences between the 1988 attempt to alter Title X and today's.

First, in 1988 HHS excluded from the scope of Title X any post-conception service, including pregnancy counseling. It premised its 1988 rulemaking and its litigation defense of it on the notion that Title X had the "limited function of funding *pre*-pregnancy family planning services." 1990 WL 10012655, Resp. Br. in *Rust* at *6; *see also* 53 Fed. Reg. 2944. Upon a client's pregnancy, HHS said, "the project must direct the client to a prenatal care facility *that, unlike a Title X project, can provide pregnancy counseling* and obstetric or other pregnancy-related care." Resp. Br. in *Rust* at *6 (emphasis added); *Rust*, 500 U.S. at 200. But the 2019 Rule does not and could not rest on such a premise, because Congress has since made clear in the Nondirective Mandate that pregnancy counseling *is* a proper Title X service.

Second, and relatedly, the 1988 regulations imposed a total bar on Title X projects giving information about abortion to their pregnant patients. By contrast, the 2019 Rule imposes a complex new counseling scheme. This scheme puts Title X patients at the mercy of the values of the specific Title X provider they happen to visit. And it insidiously subjects *all* pregnant patients to various directive requirements during what appears to them to be an expert's medical counseling. The 2019 Rule requires any such counseling to depart from current professional standards and to pretend that prenatal care is "medically necessary" for all. Section 59.14.

Third, the 2019 Rule includes "physical separation" requirements that go farther than any 1988 counterparts. The 2019 Rule includes separation factors that attempt to require an even more extreme level of distance and duplication:

separate office entrances and exits, workstations, phone numbers, email addresses, and electronic health records, for example. Section 59.15. Notably, such factors had been in the proposed 1988 rule, but then were *removed* when it was promulgated. *Compare* 52 Fed. Reg. 33214 (proposing separation of medical records systems, office equipment, telephone numbers, entrances and exits) *with* 53 Fed. Reg. 2945 (absence of those factors). Likewise, the 2019 Rule directs that Title X projects must rid themselves of any material, whether for staff or otherwise, that even "referenc[es] abortion," whereas the 1988 regulations sought separation only from material "*promoting* abortion." *Compare* Section 59.15 *with* 53 Fed. Reg. 2945 (emphasis added). Moreover, the 2019 Rule includes novel infrastructure spending rules to forbid any linked infrastructure of any kind. *See* 84 Fed. Reg. 7774.

Fourth, the 2019 Rule explicitly seeks to advance individual providers' (and employers') wishes *not* to offer biomedical contraceptives and/or to avoid neutral pregnancy counseling for pregnant patients. 84 Fed. Reg. 7736, 7743, 7746, 7790. HHS attempts to rely on inapposite religious refusal statutes that it did not invoke in 1988; two did not exist then. *See* 84 Fed. Reg. 7716.

Finally, to attempt to serve the above ends, the 2019 Rule affects many more aspects of the Title X program than occurred in 1988. The 2019 Rule changes numerous longstanding program requirements, adds to and scrambles the program's grant-making criteria, and straps Title X providers with additional, unnecessary, and unjustified processes that will further burden and interfere with Title X patient care. *See supra* at 11-12; ER220-40.

3. NFPRHA's Suit. On March 7, 2019, the National Family Planning & Reproductive Health Association ("NFPRHA") and its named co-plaintiffs sued HHS to challenge the 2019 Rule on behalf of all its Title X-funded members, their clinicians, and their patients. NFPRHA has Title X-funded members in every state and two territories, including more than 65 Title X grantees and almost 700 grant subrecipients. ER127. Its challenge to the Rule was consolidated with Washington State's, and both sought a preliminary injunction.

C. The District Court's Preliminary Injunction

After extensive written submissions on the motions, the district court heard oral argument for almost three hours on April 25, 2019. ER10-101. Given the Rule's impending May 3, 2019, effective date, the court issued a preliminary injunction from the bench. ER102-110. A written order followed. ER112-30.

As set forth in the Order and discussed below, the court applied the Ninth Circuit's governing four-factor test for a preliminary injunction and required Plaintiffs to make a clear showing they were entitled to that relief. ER115-16. Reflecting the Circuit's "sliding scale" approach, the district court held that "[a]lthough Plaintiffs have met their burden of showing that all four factors tip in their favor, the irreparable harm and balance of equities factors tip so strongly in Plaintiffs' favor that a strong showing of likelihood [of success] on the merits was not necessary." ER125.

The court emphasized that the ultimate merits of Plaintiffs' legal claims would be decided later, but that on each claim it considered, Plaintiffs had shown "a claim that has merit and a likely chance of success." ER125. It found that

Plaintiffs met that threshold for their claims that the Rule violates the Nondirective Mandate; violates subsections (1) through (5) of Section 1554; is contrary to Title X's central purpose "to equalize access to comprehensive, evidence-based, and voluntary family planning;" and is arbitrary and insufficiently reasoned on multiple scores. ER125-26; *see also* ER117-18 (discussing Administrative Procedure Act ("APA") requirements for reasoned rulemaking), ER122-23 (discussing Congress's Nondirective Mandate and Section 1554).

Among Plaintiffs' arbitrary and capricious claims, the court highlighted that Plaintiffs had satisfied the likelihood-of-success factor by presenting facts and argument that the Rule "reverses long-standing positions of the Department without proper consideration of sound medical opinions and the economic and non-economic consequences." ER126. The court also endorsed Plaintiffs' showings that the Rule's new pregnancy counseling scheme is "inconsistent with ethical, comprehensive, and evidence-based health care" and that its new separation provisions "more likely than not increase [Title X provider] expenses unnecessarily and unreasonably." ER125-26. Finally, the district court acknowledged Plaintiffs' sufficient showing for a preliminary injunction that HHS had:

> failed to consider important factors, acted counter to and in disregard of the evidence in the administrative record and offered no reasoned analysis based on the record. Rather, it seems the Department has relied on the record made 30 years ago, but not the record made in 2018-19.

ER126-27.

The court then credited the "substantial evidence" from fifteen declarants intimately familiar with the Title X program that "demonstrated [Plaintiffs] are likely to suffer irreparable harm in the absence of a preliminary injunction." ER127-29. The court found that the Rule would immediately leave all of the Plaintiff Title X providers (including the over 750 Title X-funded organizations participating as Plaintiffs through NFRPHA) with a Hobson's Choice, ER127—by imposing substandard pregnancy care, untenable restrictions, and unworkable costs—that forces them to either: (1) suffer damage to Title X providers' missions, reputations, and patients, or (2) leave Title X care altogether, triggering those same types of harms to mission and reputation and an even greater loss of free, quality family planning care. *See* ER127-29, SER4-5, SER47-63. The court credited Plaintiffs' showing that the Title X provider network "carefully knit together over the past 45 years" faced "serious" disruption or destruction. ER127. The court found HHS's response to Plaintiffs' claims and impending harms "dismissive, speculative, and not based on any evidence presented in the record before this Court." ER129.

HHS offered no evidence of harm it would face from a preliminary injunction. The court found "no evidence presented" by HHS that Section 1008 of Title X "is being violated or ignored by this network of providers." ER127. It found that "[p]reserving the status quo will not harm the Government," that "there is no hurry" for the Rule to become effective, and that the May 3, 2019, effective date was arbitrary. ER129. Thus, the balance of the equities and public interest tipped strongly in Plaintiffs' favor. ER125. The district court found "substantial

equity and public interest in continuing the existing structure and network of health care providers" while the legality of the Rule is decided. ER129.

The district court also employed the correct Ninth Circuit standard for the scope of its injunction. Its touchstone was the scope of relief "necessary to provide complete relief to the plaintiffs[] before the Court." ER116-17. In this case, where the Plaintiff organizations provide Title X care in every state, do so within Title X projects that operate with both Plaintiffs and non-Plaintiffs, and compete nationwide for a limited amount of Title X funds, enjoining any enforcement anywhere of the Rule by HHS was necessary to protect Plaintiffs from its irreparable harms. ER116-17, ER129-30.

Shortly after the district court issued the preliminary injunction, two other courts in this Circuit also preliminarily enjoined the Rule. *California v. Azar*, 2019 WL 1877392, at *44 (N.D. Cal. April 26, 2019); *Oregon v. Azar*, 2019 WL 1897475, at *16 (D. Or. April 29, 2019). Another district court has enjoined the Rule in Maryland. *Mayor & City Council of Baltimore v. Azar*, 2019 WL 2298808, at *14 (D. Md. May 30, 2019).

D. Additional Procedural History

HHS moved in both the district court and this Court for a stay of the preliminary injunction pending appeal. On June 3, 2019, the district court denied the stay request. SER311-13. In that ruling, the court reiterated its previous conclusions that "it is Plaintiffs, not Defendants, that have a likelihood of success on the merits, and Plaintiffs, not Defendants, that would suffer irreparable harm if the preliminary injunction" does not remain in place. SER313.

On June 20, 2019, a motions panel of this Court (Leavy, Callahan, Bea, JJ.) stayed all three preliminary injunctions issued against the Rule in this circuit. Dkt. No. 34. Plaintiffs immediately moved for an administrative stay, Dkt. No. 35, and then moved for reconsideration en banc of the motions panel order, Dkt. No. 37. Both of those emergency motions are still pending at the time of this filing.[3]

STANDARD OF REVIEW

A preliminary injunction is reviewed for abuse of discretion. *Melendres v. Arpaio*, 695 F.3d 990, 999 (9th Cir. 2012). This review is "highly deferential to the district court." *Aircraft Service Int'l, Inc. v. Int'l Brotherhood of Teamsters*, 779 F.3d 1069, 1072 (9th Cir. 2015). The Court reviews conclusions of law de novo and findings of fact for clear error. *Alliance for the Wild Rockies v. Cottrell*, 632 F.3d 1127, 1131 (9th Cir. 2011). This Court "will not reverse the district court where it 'got the law right,' even if [the Court of Appeals] 'would have arrived at a different result,' so long as the district court did not clearly err in its factual determinations." *Id*. (citation omitted). The scope of a preliminary injunction is also reviewed for abuse of discretion. *California v. Azar*, 911 F.3d 558, 568 (9th Cir. 2018).

[3] If the stay order remains in effect when a merits panel hears this appeal and the merits panel deems itself bound by the stay order, *compare Innovation Law Lab v. McAleenan*, 924 F.3d 503, 518 (9th Cir. 2019) (Fletcher, J., concurring in result), *with Lair v. Bullock*, 798 F.3d 736, 747 (9th Cir. 2015), Plaintiffs respectfully submit that the merits panel should consider this brief as setting forth additional reasons why initial en banc review is appropriate. Plaintiffs today made a conditional request for initial en banc review by separate filing. Dkt. No. 42.

SUMMARY OF ARGUMENT

HHS fails to identify any abuse of discretion in the district court's ruling. The district court applied the correct preliminary injunction standard. It considered now-governing law and the 2018-19 HHS rulemaking record. It made findings of fact based on Plaintiffs' substantial showing of imminent irreparable harm if the Rule takes effect. It also made findings based on the lack of any evidence of countervailing harm to HHS from a preliminary injunction. Exercising its discretion, the court reasonably—and correctly—issued a preliminary injunction to preserve the longstanding status quo and the current functioning of the Title X program while the parties litigate the merits.

To vacate the preliminary injunction in this case would require a mistake of law or a clear factual error as to *every one* of the statutory violations and arbitrary-and-capricious claims that the district court deemed to have a likelihood of success. But, as the district court recognized, the Rule is in tension with an unequivocal mandate of Congress, passed every year since 1996, requiring that all pregnancy counseling in Title X must be nondirective. Similarly, the district court correctly applied five different provisions in the ACA's Section 1554, each of which the Rule violates. The district also properly found direct conflicts with the Title X statute itself.

Beyond those statutory violations, the district court also found Plaintiffs likely to succeed in showing that HHS has violated the APA's requirements for reasoned agency rulemaking. Applying the binding APA case law, the district court identified at least four different arbitrary and capricious claims that support

Plaintiffs' likely success on the merits, including at least two that would invalidate the Rule as a whole.

The district court's findings emphasized the substantial evidence of serious irreparable harms that the Rule threatens to Plaintiffs and to the entire Title X program, while finding that a preliminary injunction would only delay a desired change in policy by HHS that has no urgency. HHS can show no error in the district court's discretionary balancing of the equities and its action to protect the Plaintiffs and the public from disruption of the status quo while the merits of Plaintiffs' claims are decided. So, too, the scope of the injunction the district court issued is necessary to provide complete protection to Plaintiffs while this litigation proceeds, and to avoid any of the Rule's harms taking effect before the courts can resolve the many serious legal questions at issue.

ARGUMENT

I. The District Court Acted Well Within Its Discretion

A. The Court Applied the Governing Preliminary Injunction Standard

The district court applied the correct legal standard for assessing a motion for a preliminary injunction. It employed the governing, four-factor standard from *Disney Enters., Inc. v. VidAngel, Inc.*, 869 F.3d 848, 856 (9th Cir. 2017) and *Winter v. NRDC*, 555 U.S. 7, 20 (2008). ER115. The district court's decision accurately reflects this Circuit's "sliding scale" (or "serious question") approach to the likelihood-of-success factor, while also emphasizing that satisfying that factor is essential. ER115-16, 125; *see also Disney Enters.*, 869 F.3d at 856 (a

preliminary injunction may issue "if a movant raises 'serious questions going to the merits' and the 'balance of hardships ... tips sharply towards' it"). The district court assessed each claim based on whether Plaintiffs had presented facts and argument sufficient to show that the claim "has merit and a likely chance of success." ER125. It appropriately did not reach the question of whether Plaintiffs will "definitely prevail on the merits." ER125 (citing *California v. Azar*, 911 F.3d at 582). The court ultimately found Plaintiffs had shown "all four factors tip in their favor," ER125, and repeatedly reiterated Plaintiffs' likelihood of success, not only in granting the preliminary injunction but in denying a stay of that injunction, SER313.

Yet HHS argues that the district court used "an impermissibly relaxed standard." HHS Br. at 23. It questions the well-established Ninth Circuit standard and "preserves that issue for further review." *Id.* But *Alliance for the Wild Rockies v. Cottrell*, 632 F.3d 1127, 1131-35 (9th Cir. 2011) explained at length that the Ninth Circuit "serious question" approach to likelihood of success continues to apply after the Supreme Court's 2008 decision in *Winter*, and is not contrary to it as HHS suggests.

HHS also misleadingly claims that the district court failed to require at least a serious question on the merits, but instead "relied only on the bare assertion" of Plaintiffs' presenting "facts and argument" or a "colorable claim" to grant preliminary relief. HHS Br. at 1, 13, 23-24. An appellant cannot pluck a few words from a district court order while ignoring their context to establish an "error." *See American Whitewater v. Tidwell*, 770 F.3d 1108, 1122 (4th Cir. 2014)

("snippets of language in the district court opinion" should be "read in context"); *FMC Corp. v. Hennessy Indus., Inc.*, 836 F.2d 521, 524 (Fed. Cir. 1987) (a party "does injustice to the considered opinion of the district court" by "[s]eizing upon isolated words and phrases"). Here, the district court described exactly what it meant by a "colorable claim—a claim that has merit and a likely chance of success." ER125. It then went on to describe that Plaintiffs had "presented facts and argument" to meet that likelihood-of-success standard for each one of their claims. ER125-26, *see also* ER106-08. The district court treated likelihood of success as "the most important factor," ER116, and determined under the proper standard that Plaintiffs had met it. *See, e.g.*, ER125 ("Plaintiffs have presented reasonable arguments that indicate they are likely to succeed on the merits, thus meeting" the required inquiry). There was no flaw in the standard applied by the district court.

B. The Court Also Recognized That None of Plaintiffs' Claims Conflict with *Rust* or Involve an "Implied Repeal" of Section 1008

The district court also correctly based its decision on the current statutory requirements and legal precedent and examined HHS's 2018-19 rulemaking, rather than focusing on *Rust v. Sullivan* and the agency action taken in 1988. *See* ER121 n.4. Contrary to HHS's arguments, the "relevant statutory text" has not "remained unchanged" since *Rust*, HHS Br. at 13, 22. *See* ER59-60.

Moreover, even with regard to Section 1008 of Title X, which has been in place since Title X's inception, the Supreme Court in *Rust* explicitly held that it was "ambiguous" and found that the section "[did] not speak directly to issues of

counseling, referral, advocacy," or any other discussions about abortion. 500 U.S. at 184. The Court further found that as of 1991, Congress had not "enumerate[d] what types of medical and counseling services are entitled to [Title X] funding" and had made only "broad directives" about family planning. *Id.* As of that time and within that context, the Court determined simply that HHS had adopted one "permissible construction" of Section 1008. *Id.* ("we are unable to say that the Secretary's construction … is impermissible"); *see also* ER121 n.4.

But contrary to HHS's repeated assertions, the *Rust* decision never held that Title X contains "specific delegation of authority to the Secretary to adopt" restrictions on counseling about abortion. *Cf.* HHS Br. at 35; *id.* at 25, 28, 32, 36. There is no "statutory authorization" in Title X that would require "repeal" or "abrogation," *cf. id.* at 25, 35-36, and *Rust* decreed no definitive, settled construction of Section 1008.

Thus, there is no "implied repeal" or "implied amendment" issue in this case, because there are no "inconsistent commands" among Section 1008, the Nondirective Mandate, and Section 1554. *Cf.* HHS Br. at 32-33 (quoting *Nat'l Ass'n of Home Builders v. Defenders of Wildlife*, 551 U.S. 644, 664 n.8 (2007)). All statutes currently governing HHS rulemaking under Title X can and must be harmonized. *See Vance v. Hegstrom*, 793 F.2d 1018, 1024 (9th Cir. 1986) (in prescribing regulatory standards, "the Secretary may not read [one] subsection … independently of" others).[4]

[4] Soon after "a statute is enacted, it may have a range of plausible meanings. Over time, however, subsequent acts can shape or focus those meanings." *FDA v.*

C. The District Court Correctly Found Plaintiffs Likely to Succeed

1. Violation of the Nondirective Mandate

Every year from 1996 to the present, Congress has imposed an additional statutory requirement for Title X projects through its annual appropriations: that "all pregnancy counseling shall be nondirective." Pub. L. No. 115-245, 132 Stat. 2981, 3070-71 (for fiscal year 2019). Thus, Congress has made explicit that Title X clinical services include the counseling of pregnant patients and that such counseling must *always* be nondirective. HHS concedes in its 2019 rulemaking that it is bound by this requirement and that "[n]ondirective counseling is designed to assist the patient in making a free and informed decision" about a pregnancy. 84 Fed. Reg. at 7747; *see also id.* (describing "nondirective" as being unbiased and offering objective factual resources). But the Rule fails to comply with Congress's mandate in myriad ways.

Pregnant patients can make one of two decisions about the medical condition of pregnancy: continue the pregnancy or terminate it. (If patients continue the pregnancy, they also have a further decision about whether to parent or pursue adoption, but both options require carrying to term.[5]) But the Rule empowers

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Brown & Williamson Tobacco Corp., 529 U.S. 120, 143 (2000). The "implications of a statute may be altered by the implications of a later statute" and applying the collective result is a "classic judicial task"—not implied repeal. *United States v. Fausto*, 484 U.S. 439, 453 (1988).

[5] The subsequent nature of the adoption option helps explain why Congress, in a 2000 law involving training and resources for Title X and other providers, acted to ensure that "provision of adoption information and referrals to pregnant women [is] on an equal basis with all other courses of action included in

providers to foist directive counseling on patients by discussing only continuing the pregnancy and evading the possibility of abortion—even for a patient who solely seeks abortion information and does not want to hear any prenatal information. *See, e.g.*, Section 59.14(b) (allowing Title X providers to choose to offer only "[i]nformation about maintaining the health of the mother and unborn child"); 84 Fed. Reg. at 7748 (Title X projects are not required to offer "counseling or information on abortion"). Contrary to HHS's own definition of "nondirective," the Rule improperly allows for the "presentation of options" that "suggest[s] or advis[es] one option over another," 84 Fed. Reg. 7716, *i.e.*, carrying the pregnancy to term over abortion. This alone establishes that the district court correctly found Plaintiffs likely to succeed on their claim that the Rule violates Congress's Nondirective Mandate. ER125-16.

Additionally, Title X patients receive directive pregnancy counseling under the Rule because referral to prenatal care is mandatory and erroneously termed "medically necessary" for all, even those who have decided to have an abortion. Section 59.14(b); *but see* SER256 ("[Prenatal] care is *not* medically necessary for someone who wishes to terminate her pregnancy.").

And the Rule also violates the Nondirective Mandate because it prohibits referrals upon patient request for abortion care. As the 2000 Title X regulations reflect, appropriate referral of a pregnant Title X patient to further, out-of-program care depends upon the patient's own requests and plans. 42 C.F.R. § 59.5(a)(5);

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nondirective counseling to pregnant women." 42 U.S.C. § 254c-6(a)(1) (Infant Adoption Awareness Act) ("IAAA").

see also SER104 (QFP) (referral to "follow-up care should be made at the request of the client"). Truly nondirective pregnancy counseling always takes its cue from the patient, offering the availability of information about all pregnancy options, but proceeding with discussion about and/or with referral to any option only if the patient asks. *Id*. Contrary to HHS's assertions, HHS Br. at 25, this clinical context exposes the directive nature of refusing a requested referral to an abortion provider: The patient has asked for that information, wants to pursue abortion, but the Title X counselor must not provide it. Even without any accompanying referral to prenatal care (which the Rule mandates), the Title X counselor has adopted a directive rather than a neutral stance toward the patient's decision-making.

In multiple provisions of the new Rule, HHS tells Title X providers that they can choose to put "their thumb on the scale" and "unbalance what is supposed to be a balanced approach to health care," regardless of the wishes and requests of the patient. ER69. It violates the Nondirective Mandate with its invitations to providers to omit any facts and information about abortion and to focus on the health of the "unborn child," regardless of a particular patient's requests and plans. *See* Sections 59.2, 59.5(a)(5), (b)(1), (8), 59.13-59.18.

HHS's efforts to sow confusion through a misleading discussion of other laws and inapposite history, HHS Br. at 27-32, does not change the meaning of "nondirective" or "pregnancy counseling" in Congress's annual Nondirective Mandate. In particular, HHS claims that because Congress in one context elaborated that "nondirective" means that pregnancy options should be treated equally, Congress did not mandate counseling on abortion be treated equally here.

But Congress's description of "nondirective pregnancy counseling" in that instance supports Plaintiffs', not HHS's, reading of the Nondirective Mandate. As the California district court recognized, the IAAA and the Nondirective Mandate "appear to be the only instances in which Congress has used the term 'nondirective counseling.'" *See* 2019 WL 1877392 at *16. "Congress' use of the identical term 'nondirective counseling' should be read consistently across" the IAAA and appropriations rider "to include referrals as part of counseling." *Id.* (citing *Dir., OWCP v. Newport News Shipbldg. & Dry Dock Co.*, 514 U.S. 122, 130 (1995) (holding that, in interpreting an ambiguous statutory phrase, "[i]t is particularly illuminating to compare" two different statutes employing the "virtually identical" phrase)).

Likewise, examples that elaborate to describe counseling, referrals, information, and/or discussion within "pregnancy counseling" simply reflect that pregnancy counseling is the broadest category, which can be further described by referencing subparts. *See, e.g.* SER103-04 (QFP) (referring to "discussion," "information," "referral," and "counseling" within description of "pregnancy counseling"). As the district court remarked, the clear Nondirective Mandate from Congress for 22 straight years must be enforced as written and cannot be diminished through HHS's creative retelling of laws that never took effect or other history. ER60-64.[6]

[6] For example, HHS tries to make hay out of its contention that "HHS never concluded that [the Nondirective Mandate] language required suspension of the 1988 regulations." HHS Br. at 28. To do so would have been nonsensical and ahistorical: HHS had already suspended the 1988 regulations in 1993, when it also

Finally, as Plaintiffs explained in their briefing to the district court (which HHS ignores, Br. at 24), nondirective counseling, including referrals to abortion care upon request, "easily harmonizes with Section 1008." E.D. Wash. Dkt. No. 51 at 6. The nondirective counseling spelled out in the 2000 regulations, including requested referrals, has long been provided without Section 1008 conflict. ER108 (finding "no evidence presented by the Department to this court that Title X is being violated"). Enabling pregnant patients to dictate the nature of any referral for non-Title X care they wish to receive and referring patients who request abortion care to a provider operating *outside the Title X program*, plainly does not make abortion part of the Title X program. Nor does such nondirective counseling "promote" or "encourage" abortion, HHS Br. at 24. The essence of Title X's counseling is neutrality and any direction with regard to referrals, whether toward prenatal care or abortion, must come from the patient not the provider.

2. Violation of Section 1554's Limits on Rulemaking Authority

The Rule also violates the limits on HHS's rulemaking authority imposed by Congress in Section 1554 of the ACA. Section 1554 forbids HHS from promulgating "any regulation" that inflicts one or more of that section's six specified, impermissible effects on patients. 42 U.S.C. § 18114(1)-(6). HHS ignored Section 1554's explicit limits on its rulemaking authority, and as the district court found, likely violated five of its prohibitions. ER126. The Government's sole effort to respond substantively to these claims is to assert that

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reinstated the previous 1981 Title X guidelines. The Nondirective Mandate did not become law until 1996, three years later.

the Rule "does not create, impede, interfere with, restrict, or violate anything," HHS Br. at 35—an assertion completely at odds with the terms of the Rule and HHS's defenses of it. As HHS acknowledges elsewhere, the Rule intentionally creates new gaps in Title X pregnancy counseling (even when patients ask for information); restricts that counseling to prohibit any abortion referrals; impedes Title X providers' continued use of shared health care facilities, staff, and systems to serve their Title X patients; and interferes with Title X patients' access to communications, outreach, and timely access to care in numerous ways.

Contrary to HHS's arguments, Section 1554 does not give a pass to HHS regulations that define the operating terms of a federally funded program. Instead, it protects patients in all settings by ensuring that HHS never adopts "any regulation" that, *inter alia*, interferes with health care providers' "full disclosure of all relevant information to patients making health care decisions" or "create[s] unreasonable barriers" to individuals obtaining appropriate medical care. 42 U.S.C. § 18114. Here, the Rule as a whole and a number of its individual provisions violate Section 1554. For example, the Rule's counseling distortions and separation requirements interfere with disclosure of all relevant information and communication about the full range of treatment options, 42 U.S.C. § 18114(3)-(4). The Rule also creates "unreasonable barriers" and "impedes timely access" (*id.* § 18114(1)-(2)) to abortion care by, e.g., referring patients seeking an abortion referral to prenatal care instead and requiring separate personnel, and separate health care records from any activities that refer for, support, or "encourage, promote, or advocate for abortion." Sections 59.14-59.16.

And the Rule's counseling provisions "violate the principles of informed consent and the ethical standards of health care professionals," 42 U.S.C. § 18114(5).

HHS cannot avoid these statutory violations by pretending as if Plaintiffs were arguing affirmative constitutional claims or attempting to force the government to create the Title X grant program. HHS Br at 35. Congress created Title X. It has funded and continues to fund that program. And Congress has also explicitly limited HHS's rulemaking authority in any context—whether Title X or another—through Section 1554.[7] Thus, when HHS attempts to regulate the Title X program by rule, it must avoid imposing damaging restrictions on patient care that are prohibited by Section 1554. Here, HHS has failed to do so.

Moreover, Section 1554's rulemaking limits do not conflict with any part of the Title X statute. HHS once again argues as if Title X "authoriz[es]" the Rule, relying on *Rust*, HHS Br. at 35-36, when no such "authorization" exists. *See supra* at 24. HHS cannot sweep away Congress's explicit dictates in Section 1554 by nonsensically claiming no "abrogation" of an affirmative authorization that does not exist; nor can HHS claim that a statute's legal effect is determined by whether it was an "obscure" or dominant part of legislation. HHS Br. at 2, 33-36. Plaintiffs' challenge here seeks to enforce the terms of one part of the country's massive health care reforms enacted after *Rust* was decided.

[7] Likewise, HHS cannot avoid Section 1554 based on its "notwithstanding" clause. HHS BR at 36. This Court has rejected that very argument, holding that "notwithstanding subsection (a)(1)" does *not* limit what follows to (a)(1), because the ordinary meaning of "notwithstanding" is "in spite of." *See Hooks v. Kitsap Tenant Support Servs., Inc.*, 816 F.3d 550, 559-60 (9th Cir. 2016). The "notwithstanding" clause does not limit Section 1554's application to the ACA.

HHS suggests that Plaintiffs have waived any argument as to the Final Rule's conflict with Section 1554. As a threshold matter, the agency retains an independent obligation to examine the scope of its own authority to promulgate rules, even absent specific comments. *See Nat. Res. Def. Council v. EPA*, 755 F.3d 1010, 1022-23 (D.C. Cir. 2014); *Sierra Club v. Pruitt*, 293 F. Supp. 3d 1050, 1061 (N.D. Cal. 2018).

In addition, this record more than satisfies this Court's requirements for agency notice to avoid waiver of an APA claim. The Ninth Circuit's standard requires that an agency have "sufficient notice … to afford it the opportunity to rectify the violations that the plaintiffs alleged." *Nat'l Parks & Conservation Ass'n v. Bureau of Land Mgmt.*, 606 F.3d 1058, 1065 (9th Cir. 2010). Consistent with that "broad" theory, *id.*, commenters here put HHS on notice that the New Rule would create unreasonable barriers to care, impede timely access to services, interfere with patient-provider communications, and violate ethical standards, *see, e.g.*, NFPRHA Comments 1-37; *see also* No. 3:19-cv-1184 (N.D. Cal.), Dkt. No. 97 (compiling specific comments on each prong); No. 6:19-cv-317 (D. Or.), Dkt. No. 119 (same). Contrary to Defendants' suggestion, Plaintiffs and commenters need "not specifically cite" the relevant statute, *Idaho Sporting Cong., Inc. v. Rittenhouse*, 305 F.3d 957, 966 (9th Cir. 2002), or invoke an exact legal term of art drawn from a statute in order to "adequately raise" an issue to avoid waiver, *Nat'l Parks*, 606 F.3d at 1066. *See, e.g., Lands Council v. McNair*, 629 F.3d 1070, 1076 (9th Cir. 2010) (stating that "alerting the agency in general terms will be enough"); *Native Ecosystems Council v. Dombeck*, 304 F.3d 886, 899 (9th Cir. 2002) (same).

3. Violation of Title X

There are also two violations of the Title X statute on which Plaintiffs are likely to succeed. *See, e.g.*, ER24, 28-29, 201-02, 236-40, 244. First, Section 1007 of the statute, "Voluntary Participation," requires that "[t]he acceptance by any individual" of services or "information (including educational materials) provided … *shall be voluntary*." 42 U.S.C. § 300a-5 (emphasis added). HHS tries to erase that essential protection. It argues as if only a separate, second requirement exists in Section 1007, namely the provision that accepting Title X services not be a prerequisite for other programs. HHS Br. at 37. However, it completely ignores the basic voluntary participation requirement. The Rule violates that requirement by compelling all Title X projects to require pregnant patients' involuntary participation in counseling about continuing their pregnancy, even when the patient asks only for abortion information and explicitly does not wish to receive any information about or any referral for prenatal care. *See supra* at 26-28.

Second, the Rule as a whole sabotages "the central purpose of Title X, which is to equalize access to comprehensive, evidence-based, and voluntary family planning." ER126 (district court finding the Rule "likely violates" this central statutory purpose). As HHS's positions reflect, the Rule was adopted with a single-minded focus on just one part of the Title X law, Section 1008, as interpreted 30 years ago and with the aim of recruiting potential new Title X providers that *disagree* with core Title X services. HHS lost sight of the central purpose of keeping the overall Title X program functioning effectively nationwide to serve the program's mission of equalizing access to quality family planning care

for low-income patients. And it failed to take into account the harms the Rule would impose on Title X patients. HHS knew that if the Rule took effect it would force longstanding Title X providers serving more than 40% of the program's patients (roughly 2,000,000 patients) to immediately discontinue their Title X care. SER185. In Washington State, HHS knew that approximately 90% of the state's Title X patients would be left without providers. *See* ER23. HHS offered no evidence in its rulemaking of any new providers waiting to step in, much less providers that could offset such a vastly disrupted Title X network all across the country. It made bare assertions that new providers "may" emerge.[8] Nor did HHS consider what the resulting serious gaps in access to contraceptives, cancer screenings, and other vital Title X services would mean for patients. An "administrative construction[] of a statute that [is] inconsistent with the statutory mandate or that frustrate[s] the policy that Congress sought to implement" must be rejected. *S. Cal. Edison Co. v. FERC*, 770 F.2d 779, 782 (9th Cir. 1985); *see also Bresgal v. Brock*, 843 F.2d 1163, 1168 (9th Cir. 1987) (courts cannot "rubber-

[8] 84 Fed. Reg. 7780. HHS now calls its bare assumptions "predictive judgments." But HHS's decision-making in no way resembles *Trout Unlimited v. Lohn*, where an agency's predictions relied on "substantial" scientific data, not (as here) "mere speculation." 559 F.3d 946, 959 (9th Cir. 2009). Similarly, one commenter citing polling data about Christian medical providers' general attitudes creates no evidence of any such providers wanting to join Title X, whether under the Rule or otherwise. 84 Fed. Reg. 7780-81.

stamp … administrative decisions" that "frustrate the congressional policy underlying a statute").[9]

4. The Whole Rule and Its Parts Were Promulgated Through Arbitrary and Capricious HHS Decision-making

The district court also found Plaintiffs likely to succeed on their claims that the Rule, in whole and in parts, reflects arbitrary, unreasoned HHS decision-making. ER125-27. To assess Plaintiffs' arbitrary and capricious claims, the court applied the governing case law for those APA claims, relying on *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502 (2009), *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29 (1983), and *California v. Azar*, 911 F.3d at 581, among other cases. ER117-18, 125-27. It then found at least four grounds on which HHS violated the APA's rulemaking standards, including grounds applicable to the whole Rule and ones applicable to specific provisions. ER125-27.

i. The district court found Plaintiffs had presented facts and argument likely to succeed in establishing that the Rule as a whole "reverses long-standing positions of the Department without proper consideration of sound medical options and the economic and non-economic consequences." ER126. The district court relied on the legal principles described in *FCC v. Fox Television Stations*, 556 U.S.

[9] Contrary to HHS's assertions, neither of these two contrary-to-Title-X claims on which Plaintiffs are likely to succeed were made in *Rust*, nor were the challenged regulations and the prevailing facts the same then. *Cf.* HHS Br. at 37 (citing a passage of *Rust* that is discussing claims made then about the meaning of Section 1008, not any consideration of the voluntary participation requirement or contravention of Title X as a whole because a rule would decimate its functioning).

at 515, and *Encino Motorcars, LLC v. Navarro*, 136 S. Ct. 2117, 2126 (2016): when changing longstanding policy, an agency must provide good reasons and detailed justification for "disregarding facts and circumstances that underlay or were engendered by the prior policy." *FCC v. Fox*, 556 U.S. at 515. On appeal, HHS does not question, nor could it, the validity of those legal precedents. Thus, there is no legal error upon which to challenge the preliminary injunction.

HHS offers no rational reason or justification for abandoning the QFP. *See* HHS Br. at 37. The Rule departs from the QFP not only in the specifics of pregnancy counseling but also in prioritizing the personal preferences of individual Title X providers over patient preferences and values, and over the need for every patient to have access to a full range of FDA-approved contraceptive methods. SER92-94, SER97. HHS erroneously claims the authority to simply abandon national clinical standards without any reasoned explanation at all, HHS Br. at 37, contrary to governing case law. *See Encino Motorcars*; *Fox.*

Similarly, as the district court found, Plaintiffs will likely show that HHS's assessment of the overall economic and non-economic consequences of the Rule was woefully inadequate and resulted in unreasoned rulemaking. ER126-27. HHS failed to rationally consider the Rule's impact on the more than 1000 Title X administrator and provider organizations that have long relied on the previous set of Title X regulations to establish their Title X projects. *See, e.g.,* NFPRHA Comments 1-37; PPFA Comments 1-96; Federal AIDS Partnership Comments 1-16. And HHS failed to rationally consider the consequences of the diminished health care and resulting harms to public health the Rule would usher in. *See, e.g.,*

Guttmacher Comments 1-20; APHA Comments 1-5; ASTHO Comments 1-9. As the district court noted, facts and argument exposing these fundamental deficiencies were presented not only by Plaintiffs but joined by the *amici* ACOG and other medical societies and by the Institute for Policy Integrity, which explained HHS's arbitrary approach to cost-benefit analysis in detail. ER126.

Again, HHS does not even try to address these issues infecting the entire rulemaking. Its appeal points to no clear error in the district court's findings with regard to the factual record before it. Nor can HHS properly invite this Court on appeal to redo the district court's overall assessment. The district court did not abuse its discretion in finding Plaintiffs likely to succeed on their claim that the Rule reverses longstanding positions of the Department without proper, reasoned justification. Accordingly, the likelihood-of-success factor supporting the preliminary injunction stands firm on this ground alone.

ii. The district court identified another fundamental flaw in HHS's overall rulemaking on which Plaintiffs are likely to succeed. Because "the Department has relied on the record made 30 years ago, but not the record made in 2018-19," it violated multiple *State Farm* requirements. ER126-27. The district court found that Plaintiffs presented facts and argument showing that HHS "failed to consider important factors, acted counter to and in disregard of the evidence in the administrative record and offered no reasoned analysis based on the record." ER117-18, 126-27. HHS does not and cannot contend that *State Farm* is not good law. And HHS's arguments based on the 1988 rulemaking reinforce, rather than undermine, the district court's assessment that Plaintiffs are likely to succeed in

showing that the Rule is not properly grounded in the present-day administrative record.

iii. For example, HHS relies on the 1988 rulemaking record when it challenges the district court's conclusion that the Rule's ban on abortion referrals will likely be found arbitrary and capricious, ER126. HHS relies on "the limited nature of the program" as conceived of in 1988, when HHS viewed Title X as not providing any post-conception care—not even pregnancy counseling. HHS Br. at 39. On that premise, the Supreme Court accepted that Title X patients could not expect to receive counseling on abortion and would not be misled by silence. *Rust*, 500 U.S. at 200. HHS argues today that it is merely accomplishing "Congress's choice of what activities it will fund" by pointing back to the time of *Rust*. HHS Br. at 40.

But this wholly ignores that Congress itself subsequently made clear that pregnancy counseling *is* a funded part of Title X care and must be nondirective in all instances. HHS never mentions the Nondirective Mandate in asking this Court to revert to 1988-91 and to disagree with the district court's conclusion that Plaintiffs are likely to succeed in showing that the Final Rule's ban on abortion referrals would arbitrarily and unreasonably "be inconsistent with ethical, comprehensive, and evidence-based health care." ER126. By rooting itself in 1988-91, HHS ignores not only Congress's clarification of Title X's scope to include pregnancy counseling, but also HHS's own current evidence-based clinical standards in the QFP. And HHS ignores the overwhelming unanimity of comments from leading medical organizations in 2018-19 that a ban on abortion

referrals and the Rule's other counseling distortions contradict current health care standards and will confuse and shame patients during Title X counseling.

HHS fares no better in asserting that the Rule's unduly circumscribed pregnancy counseling is consistent with, rather than violates, medical ethics. Instead of discussing the numerous comments submitted by medical ethical authorities in the 2018-19 rulemaking—that show point by point how the Rule's counseling violates governing ethical standards[10]—HHS again invokes *Rust*, and argues that the Supreme Court's decision establishes the ethical parameters for today—even though that Court accepted in 1991 that patients could not look to Title X for pregnancy counseling because that service exceeded the program's scope. That no longer holds.

Nor do Congress's separate religious-refusal exemptions determine the parameters of pregnancy counseling within the Title X program or establish that the Rule complies with medical ethics. *Cf.* HHS Br. at 38. The "conscience statutes" describe certain circumstances in which a medical provider with religious objections cannot be forced to provide abortions or abortion referrals, or cannot be discriminated against for providing or not providing abortion care. Those statutes provide no exceptions to the generally applicable requirements of the Title X program once a provider voluntarily decides to participate in that program. Under the ethical and clinical standards governing today, including HHS's own, a clinician undertaking Title X pregnancy counseling must ensure that a pregnant

[10] *See*, *e.g.*, Am. Acad. Nursing Comments at 4, AMA Comments at 3, ACOG Comments at 6.

patient is offered accurate information about and given referral upon request to abortion. ER126 (crediting facts showing the Rule's counseling restrictions "inconsistent with ethical … and evidence-based health care").

Furthermore, the 2018-19 rulemaking record also contained substantial evidence that the ethical and clinical issues raised by the ban on abortion referrals were so grave that large numbers of provider organizations and individual clinicians would be forced to stop participating in Title X if that aspect of the Rule took effect. For example, the Planned Parenthood providers that currently serve more than 40% of Title X patients (almost two million patients annually) made clear in their comments that if the Rule's ban on referrals took effect, they would have to leave the program. PPFA Comments at 15. Such departures would make Title X care much less accessible and leave many patients without access to any of its services, including contraceptive care and screening for cancer and sexually transmitted infections. And yet, HHS decided to move ahead. It did so based on conjecture alone—that new providers (with "conscience objections") would emerge and that no "decrease in the overall number of" Title X providers would occur. *See* HHS Br. at 42. This is another ground on which HHS "acted counter to and in disregard of the evidence in the administrative record and offered no reasoned analysis based on the record." *See* ER126-27.[11]

[11] On appeal, HHS mentions a "new network of providers" named Obria, and Obria's efforts to use Title X funding, despite that organization's refusal to provide information about abortion in pregnancy counseling and its opposition to biomedical contraception. HHS Br. at 42. In the court action HHS cites, Obria alleged it hopes to serve 4000 patients in a first year of Title X funding and claimed connection to providers in five states. *See* Complaint at 3, *Obria Group*,

iv. HHS uses similar faulty reasoning based in 1988-91 to contest the district court's determination that HHS's separation requirements are likely arbitrary and capricious. The court recognized that they will "increase expenses unnecessarily and unreasonably," leading to reduced capacity for family planning care in the Title X network as well as to provider departures from the program. ER125-27. In downplaying its impact, HHS tries to sidestep the Rule's expanded physical separation factors and new infrastructure spending prohibition. HHS argues that it '"reaffirm[ed the] reasoned determination' it made in 1988," and that it acted to address the "risk and perception" of taxpayer funds being used to fund abortion. HHS Br. at 41. But the district court found that, based on the rulemaking record in 2018-19, the agency had not sufficiently explained the extreme duplication costs and new difficulty the Rule creates for providers to maintain the infrastructure of their Title X projects, holding that the separation requirements will likely be found arbitrary and capricious. ER125-26.

Invoking *Rust* and the record in 1988 is particularly insufficient because of the different factual backdrop three decades ago. In 1988, HHS stated that it was acting "in direct response to the observations in the GAO and OIG reports" that indicated a need in the 1980s for '"clear and operational guidance' to grantees about how to preserve the distinction between" their Title X activities and abortion. 500 U.S. at 187-88. The 1988 physical separation rule, however, never took effect,

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Inc. v. HHS, No. 19-905 (C.D. Cal.). This is not a network that could substitute for departing Title X providers that serve *millions* of patients annually. Nor did HHS refer to Obria in its rulemaking record, the basis on which it must defend the Rule.

because it was enjoined and then rescinded as unworkable and irrelevant for the Title X program, which is not defined by physical space. *See* 65 Fed. Reg. 41,276.

Instead, HHS issued clear and specific operational guidance in 2000 that has governed the program for almost two decades. 65 Fed. Reg. 41,281-82. The 2018-19 rulemaking record reveals no operational confusion or compliance issues today. *See* ER127 ("no evidence presented by the Department that Title X is being violated or ignored"); 84 Fed. Reg. 7725 (acknowledging that any HHS "examples of abuse" were from "other Federal programs" and that they do not "mean Title X grants are being abused"). Thus, "reaffirming" determinations made three decades ago is far from a sufficiently reasoned basis for imposing more sweeping physical separation rules and added infrastructure spending limits today.

Nor is there any factual support in the 2018-19 rulemaking record for the assertion that Title X funds impermissibly "subsidize abortion" when Title X projects operate in the same physical facilities as abortion care, as *amici* in support of HHS assert. *See also* HHS Br. at 10 (contending that "economies of scale" mean that Title X funds are "supporting abortion"). Title X grants must be for less than 100% of the Title X project's costs, *see* 42 C.F.R. § 59.7(c), and thus the operation of Title X activities alone consumes all of each project's federal funds (and more). Consistent with Section 1008, no Title X funds are used "in programs where abortion is a method of family planning." Co-location with abortion clinics or any other type of health care or tenant does not change that: Title X funds pay only for the Title X project's rent, staff, services, etc., and no federal funds are used to fund abortion care, abortion expenses, or any other non-Title X activities,

even when multiple types of care benefit from economies of scale in shared buildings.[12]

In considering Plaintiffs' numerous claims that HHS engaged in arbitrary and irrational rulemaking, the district court applied the correct legal standards, rested its determinations on the parties' respective arguments and submissions from the 2018-19 rulemaking record, made no clear errors of fact, and properly exercised its discretion to rule that Plaintiffs had a likelihood of success. HHS has established no ground for reversing the district court's conclusions, and cannot do so simply by asking this Court to make its own assessment anew. *See Alliance for the Wild Rockies*, 632 F.3d at 1131.

D. The Court Found Plaintiffs Faced Serious Irreparable Injury

In little more than one page, HHS tries to brush aside the "substantial evidence of harm" that supports the preliminary injunction—including fifteen lengthy declarations filled with specifics from public health experts, medical experts, and Title X grantees, subgrantees, and clinicians. ER128-29. As the district court found, each of the hundreds of Title X-funded NFPRHA members (including the Washington Department of Health), their staff clinicians, and their

[12] HHS attempts to create the impression of recent increased "risk" of co-location between Title X sites and those where abortions occur. It references increased percentages of abortions being performed in "nonspecialized" locations. But those increasing percentages result from diminishing numbers of specialized, standalone abortion clinics. As HHS concedes, "the number of nonspecialized clinics performing abortions *remained stable*," 84 Fed. Reg. at 7765 (emphasis added), and thus this data does not show any increased risk of Title X projects potentially operating within that same, stable number of nonspecialized abortion locations.

millions of Title X patients face many layers of irreparable injury if and when the Rule's implementation begins. ER127-29. HHS has identified neither erroneous law nor a clear error of fact in the district court's determinations. Thus, the court's conclusion of especially weighty irreparable harm to Plaintiffs must stand. *See* ER125.

HHS tries to skip over the most imminent and disruptive forms of harm that Plaintiffs face, and argues that Plaintiffs' harms depend upon an uncertain chain of future events—they do not. As the district court found, "upon its effective date" the Rule will force all Title X grantees, subrecipients and individual clinicians to either provide deficient care to pregnant patients or exit the program. ER128. In this Hobson's Choice, either result immediately damages Plaintiffs' health care missions and the patients *who are pregnant right then*, as well as harming Plaintiffs' reputations. ER128; *see Am. Trucking Ass'ns, Inc. v. City of L.A.*, 559 F.3d 1046, 1057 (9th Cir. 2009) (recognizing irreparable harm of similar Hobson's Choice). These injuries to Plaintiffs' health care services, along with the accompanying disruption to the Title X provider network, would occur instantly, mid-grant, to irreparably harm the Plaintiff providers and their patients whether or not HHS can eventually, months or years later, find and fund some replacements providers. SER47-63, SER235-248.

Similarly, the Rule's new infrastructure spending prohibition will, mid-grant, interfere with Title X providers' paying, for example, their project's electronic health record fees, rent, and staff salaries (though use of Title X funding to pay those expenses had earlier been approved by HHS, when the grants were

first made). The Rule's infrastructure and physical separation requirements do not merely impose financial costs, but directly and irreparably interfere with the Plaintiff organizations' continued functioning in service of "medically indigent" persons. *Id.*; *see also* SER217-24, SER273-287.

The Rule's multiple harms to Plaintiffs' health care missions, to those providers' relationships with their patients, and to the patients themselves—whose interests Plaintiffs properly protect in this case[13]—are serious and irreparable. *See, e.g.*, *Arc of Cal. v. Douglas*, 757 F.3d 975, 991 (9th Cir. 2014); *Valle del Sol, Inc. v. Whiting*, 732 F.3d 1006, 1029 (9th Cir. 2013); *League of Women Voters of U.S. v. Newby*, 838 F.3d 1, 9 (D.C. Cir. 2016). These types of harms bear no resemblance to those in the two cases invoked by HHS.[14]

The Rule would cause Plaintiffs to suffer concrete, well-recognized forms of irreparable harm if it ever takes effect, regardless of the Rule's lawfulness or unlawfulness. *Cf.* HHS Br. at 45 (erroneously arguing that Plaintiffs' irreparable injuries depend upon "their view of the legal merits"). Moreover, this Court has repeatedly found cognizable irreparable harms for preliminary injunction purposes

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[13] *See Singleton v. Wulff*, 428 U.S. 106, 111, 118 (1976); *Planned Parenthood of Idaho, Inc. v. Wasden*, 376 F.3d 908, 917 (9th Cir. 2004).

[14] *Cf. Freedom Holdings, Inc. v. Spitzer*, 408 F.3d 112, 115 (2d Cir. 2005) (holding a commercial entity's market share loss not irreparable, because it could be financially remedied, and any additional, mere financial cost of compliance with government regulation, without more, also was not sufficient to establish irreparable harm); *United States v. City of L.A.*, 595 F.2d 1386, 1391 & n.7 (9th Cir. 1979) (rejecting irreparable harm based on the "absence of" any "convincing showing" of negative effects from loss of funding).

in challenges to changed conditions for or threatened loss of government funding.[15] Contrary to HHS's efforts to erase Plaintiffs' harms, HHS Br. at 45, the courts do not ignore irreparable injuries simply because, on the merits, the government is attempting to defend the legality of funding changes.

E. The Court Appropriately Considered Harm to HHS and Balanced the Equities

In addition to finding strong evidence of irreparable harm to Plaintiffs, the district court considered whether the Government would suffer harm from an injunction and balanced the equities, consistent with the preliminary injunction standard. ER127-29. The sole harm that HHS argued to the district court was the asserted interference with "effectuating statutes enacted by representatives of the people," as it again raises here. HHS Br. at 45. But the statute that HHS invokes is Section 1008, enacted in 1970 and fully in force today, with the preliminary injunction in place. As Section 1008 requires, Title X funds have never been "used in programs where abortion is a method of family planning." 42 U.S.C. § 300a-6. All Title X funds are spent only on Title X projects', *inter alia*, rent, staff, and services; no federal funds are used to "subsidize abortion" even when multiple

[15] *See, e.g.*, *Arc of California*, 757 F.3d at 991 ("[W]e note that the harm alleged here related in part to the continued economic viability of service providers in the face of cuts in compensation."); *Indep. Living Center of S. Cal., Inc. v. Maxwell-Jolly*, 572 F.3d 644, 658 (9th Cir. 2009) (crediting irreparable harms from loss of Medi-Cal coverage where funding was centrally at issue on the merits); *Harris v. Bd. of Supervisors, Los Angeles Cty.*, 366 F.3d 754, 766 (9th Cir. 2004) (crediting health care harms in preliminarily enjoining proposed funding cuts); *see also Cty. of Santa Clara v. Trump*, 250 F. Supp. 3d 497, 537 (N.D. Cal. 2017) (crediting irreparable harm in challenge to changed conditions of federal funding).

types of health care providers share buildings. The district court found "no evidence . . . that Title X," including Section 1008, "is being violated or ignored," ER127, and there is no harm stemming from any misuse of taxpayer funds. HHS has not demonstrated any clear error in the district court's determinations.[16] *See Nat'l Wildlife Fed'n v. Nat'l Marine Fisheries*, 422 F.3d 782, 795 (2005).

The district court correctly found that the only harm that HHS will suffer is delay in implementing the new Rule—this Administration's new regulatory interpretation of Section 1008. The court also specifically found, on the record before it, that HHS had shown no cost to it from delay, that it had established no hurry to make the regulatory changes, and that the planned effective date was chosen arbitrarily. ER129. Each of those findings diminishes the weight of delay. *See also* ER64 (questioning why, contrary to any purported need for urgency, HHS did not propose these regulatory changes until July of 2018); *Miller v. Cal. Pac. Med. Ctr.*, 991 F.2d 536, 544 (9th Cir. 1993) (federal agency's protracted timeline "implies a lack of urgency and irreparable harm").

HHS erroneously argues that the district court should have weighed more harm to the Government because HHS might win on the merits and somehow

[16] HHS here offers purported "administrative burdens" and hypothesized rollout difficulties under a delayed Rule, HHS Br. at 45-46, that were not argued in the district court, *see* E.D. Wash. Dkt. No. 44 at 58-60, and thus are waived. *See Armstrong v. Brown*, 768 F.3d 975, 981 (9th Cir. 2014). Each of those claimed difficulties are within HHS's ability to control and prevent, regardless of whether the preliminary injunction stays in place. And those new suggestions of minor complications cannot possibly show an abuse of discretion, since the district court had no opportunity to consider them.

"thereby sustain" greater harm. HHS Br. at 46. But if that happens, the only harm that the Government has sustained is still just delay in accomplishing change, as the district court did weigh—not any permanent interference with its desired regulatory policy.

Thus, the district court appropriately weighed the limited, abstract injury of delay in implementing HHS's desired new Rule against Plaintiffs' many concrete irreparable harms. It also considered the "substantial equity and public interest in continuing the existing structure and network of health care providers" serving Title X patients. ER129. After a full and conscientious application of the governing preliminary injunction test, in which all four factors tipped in Plaintiffs' favor, the district court acted well within its discretion to preserve the status quo.[17]

II. The Preliminary Injunction Properly Maintains the Status Quo

The scope of the district court's injunction, forbidding all of the HHS defendants and their employees from implementing the Rule until resolution of this case, is also well-founded. HHS has not shown abuse of discretion there either.

[17] *See generally Indep. Living Ctr. of S. California*, 572 F.3d at 658 (the "abstract form of harm" that occurs whenever a government policy is enjoined cannot be dispositive; if it were, the preliminary injunction standard's balancing of competing harms would be eviscerated), *vacated and remanded on other grounds*, 565 U.S. 606 (2012); *cf. Maryland v. King*, 567 U.S. 1301, 1301 (2012) (Roberts, C.J., in chambers) (entering temporary stay based not only on abstract injury of enjoining state statute, but also on "an ongoing and concrete harm to Maryland's law enforcement and public safety interests").

A. The Injunction's Scope Is Necessary to Protect the Plaintiffs

The district court articulated and applied the correct legal standard for the terms of the injunction: "[I]njunctive relief should be no more burdensome to the defendant than necessary to provide complete relief to the plaintiffs[] before the Court," but there is also "no bar against nationwide relief … if such broad relief is necessary to give" Plaintiffs that complete relief. ER116-17 (citing, *inter alia*, *L.A. Haven Hospice, Inc. v. Sebelius*, 638 F.3d 644, 664 (9th Cir. 2011) and *Bresgal v. Brock*, 843 F.2d 1163, 1170-71 (9th Cir. 1987)).

Here, there were at least three reasons why the district court needed to enjoin HHS and its agents from enforcing the Rule anywhere in order to fully protect the Plaintiffs before the court. *See* ER96-98. First, Plaintiffs needed that relief because they include over 750 Title X-funded NFPRHA members, their clinicians, and their patients spread throughout all 50 states and the territories. SER4-5. Second, many of NFPRHA's Title X-funded members participate in Title X projects as a subrecipient under a *non*-NFPRHA member grantee or vice versa; without the injunction maintaining the status quo for those non-members too, the NFPRHA Plaintiffs would still be vulnerable to the Rule's harms. *See* SER15-16. (Grantees are affirmatively charged with monitoring and ensuring subrecipients' compliance. Section 59.1(a).) Third, the Rule changes the funding dispersal rules and competitive grant-making for Title X funds, both directly and by changing the operational requirements on which projects are judged. *See, e.g.*, Sections 59.7, 59.13, 59.18. A uniform set of requirements and criteria must apply to all Title X projects in order to prevent HHS from using its grant and funding-allocation

decisions to penalize any subset of Title X participants protected from the Rule against HHS's wishes (such as Plaintiffs), while others are not subject to a preliminary injunction and can be favored by HHS in dispensing funds (thereby harming Plaintiffs). *See Washington v. Reno*, 35 F.3d 1093, 1104 (6th Cir. 1994) (explaining that an injunction as to plaintiffs alone would not prevent the disputed pool of federal funds from being dispersed to third parties to plaintiffs' detriment). As HHS has stated, it is scheduled to begin another grant funding cycle later this year and could start one even earlier. ER101, *see also* HHS Br. at 45-46.

The Government has "fail[ed] to explain how the district court could have crafted a narrower injunction that would provide complete relief to the plaintiffs"—because no such arrangement exists. *Regents of Univ. of Cal. v. Dep't of Homeland Security*, 908 F.3d 476, 512 (9th Cir. 2018). HHS's specious suggestion that an injunction should reach only as far as the specific member(s) relied upon by an association to show standing, HHS Br. at 49, is fundamentally flawed. Associational standing may be established by "any one" member. *Hunt v. Washington State Apple Advert. Comm'n*, 432 U.S. 333, 343 (1977). It is black-letter law that such standing then confers on the association the ability to litigate on behalf of *all* relevant members and creates "an effective vehicle for vindicating interests that [those members] share." *Int'l Union United Auto., Aerospace & Agric. Implement Workers of Am. v. Brock*, 477 U.S. 274, 290 (1986). And here, NFPRHA has provided detailed evidence in the record establishing that all of its over 750 Title X-funded members are harmed by the Rule and need protection from it. SER47-63. NFPRHA's use of associational standing fully complies with

the requirement that Plaintiffs demonstrate standing "for each *form* of relief sought." *Cf.* HHS Br. at 49 (quoting *Town of Chester v. Laroe Estates, Inc.*, 137 S. Ct. 1645, 1650 (2017)) (emphasis added). Here, the single form of relief sought—a preliminary injunction—is necessary to protect each and every one of NFPRHA's Title X-funded members.

Finally, the injunction in this case does not interfere with the development of the law in multiple jurisdictions. There are numerous challenges to the Rule that continue to be litigated, including some that include different substantive claims than those raised here. *See, e.g.*, *Family Planning Ass'n of Maine v. HHS*, No. 19-100 (D. Me.). The preliminary injunction simply preserves the status quo to allow a meaningful opportunity for these Plaintiffs and others to litigate, and does not "deprive appellate courts of a wider range of perspectives." HHS Br. at 50.

B. The District Court Appropriately Enjoined the Whole Final Rule

HHS also asks for some unspecified severance of parts of the Rule from the injunction. HHS Br. at 51 (injunction of "lawful portions of the Rule" should be vacated). But as set forth above, Plaintiffs challenge the lawfulness of *the entire Rule*, including because the rulemaking as a whole conflicts with the central purpose of Title X and reflects an arbitrary, unreasoned rulemaking process. That process lost sight of Title X's operational needs, HHS's own principles of quality health care, and the needs of patients, and imposed unnecessary, extremely costly, and disruptive "compliance" steps throughout its nineteen sections in service of non-existent problems.

Moreover, the many changes in the Rule are interdependent and work together to help HHS redirect the Title X program. For example, as the Rule invites into the program providers with objections to nondirective pregnancy counseling and biomedical contraceptives, it also ratchets up the record-keeping required for encouraging family participation with (or otherwise screening) minor patients[18] and prioritizes serving women whose employers have a "conscience objection" to the employers' private health plan including contraceptive coverage. As it tries to bring in "nontraditional" Title X providers through grant-making, the Rule imposes new requirements for on-site or close-by primary care, which some highly effective current reproductive-focused providers cannot meet. And of course, the counseling distortions and separation / infrastructure requirements work together in service of HHS's current aims under Section 1008.

It would be harmful, confusing, and inappropriate at the preliminary injunction stage for an appellate court to attempt to pick apart this Rule—especially when HHS itself has not even attempted to do so—to exempt some portions from the injunction and allow them to go into effect prior to a full airing of the legal claims here, including those against the Rule as a whole.

[18] Title X providers are *already* bound by state and local laws regarding abuse reporting, *cf.* HHS Br. at 51; the Rule uses that fact as a jumping-off point to give HHS expansive record-keeping scrutiny powers under *all* sections of its Rule. Section 59.17(d).

CONCLUSION

The preliminary injunction order should be affirmed.

June 28, 2019

Respectfully submitted,

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STATEMENT OF RELATED CASES

The following known related cases are pending in this Court: *California v. Azar* & *Essential Health Access v. Azar*, Nos. 19-15974 & 19-15979; *State of Oregon v. Azar* & *American Medical Ass'n v. Azar*, No. 19-35386(L).

CERTIFICATE OF COMPLIANCE

I hereby certify that this brief complies with the type-volume limitation of Ninth Circuit Rules 32-1(c) because it contains 13,996 words, exclusive of the exempted portions of the brief. The brief has been prepared in a format, type face, and type style that comply with Fed. R. App. 32(a)(4)-(6). As permitted by Federal Rule of Appellate Procedure 32(a)(7)(C), the undersigned has relied upon the word-count feature of this word-processing system in preparing this certificate.

/s/ Fiona Kaye
FIONA KAYE

June 28, 2019

CERTIFICATE OF SERVICE

I hereby certify that on this 28th day of June 2019, I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Ninth Circuit using the appellate CM/ECF system. Counsel for all parties to the case are registered CM/ECF users and will be served by the appellate CM/ECF system.

/s/ Fiona Kaye
FIONA KAYE

SUPPLEMENTAL ADDENDUM

SUPPLEMENTAL ADDENDUM CONTENTS

Title X of the Public Health Service Act, Section 1007:

> Voluntary participation by individuals; participation not prerequisite for eligibility or receipt of other services and information
>
> 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 subchapter (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.