Case No. 19-15974 & 19-15979

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

STATE OF CALIFORNIA, BY AND THROUGH ATTORNEY GENERAL XAVIER BECERRA,
Plaintiff-Appellee,

v.

ALEX AZAR, IN HIS OFFICIAL CAPACITY AS SECRETARY OF THE U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES; U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES
Defendants-Appellants.

ESSENTIAL ACCESS HEALTH, INC.; and MELISSA MARSHALL, M.D.,
Plaintiffs-Appellees,

v.

ALEX M. AZAR II, in his official capacity as Secretary of the United States Department of Health and Human Services; and UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES,
Defendants-Appellants.

On Appeal from the United States District Court
for the Northern District of California
No. 3:19-cv-01195-EMC
Hon. Edward M. Chen

ANSWERING BRIEF OF APPELLEES ESSENTIAL ACCESS HEALTH, INC. and MELISSA MARSHALL, M.D.

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CORPORATE DISCLOSURE STATEMENT

Pursuant to Federal Rule of Appellate Procedure 26.1, Plaintiff Essential Access Health, Inc. discloses that it is a nongovernmental corporate entity. It does not have a parent corporation, nor is there a publicly held corporation that owns 10% or more of its stock.

s/Michelle S. Ybarra
MICHELLE S. YBARRA

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I. INTRODUCTION

In this appeal, the Department of Health and Human Services ("HHS") asserts that the district court abused its discretion by preliminarily enjoining in California the implementation of a new regulation (the "Final Rule") that would upend the federal Title X program and unravel the nation's public health safety net.

Title X has been hailed as one of the greatest public health achievements of the twentieth century, but the Final Rule imposes sweeping changes to the program that threaten to roll back its success. The Final Rule bars Title X-funded programs from counseling patients on abortion, referring them to abortion providers, or supporting abortion "as a method of family planning"; forces providers at Title X-funded clinics to give patients seeking abortion misleading information and to steer them into prenatal care; and requires organizations to duplicate their facilities, staff, and electronic systems to separate abortion-related care and activities from Title X-funded services.

The district court enjoined the Final Rule after finding it would decimate California's Title X network; drastically reduce patients' access to a wide range of vital services, including contraceptives,

screenings for sexually transmitted infections and reproductive cancers; and irreparably harm Plaintiffs-Appellees ("Plaintiffs"), individual patients, and the public health. As the district court found, Plaintiffs showed that the balance of harms and public interest "tip sharply" in their favor, while HHS made no harm showing whatsoever. Under this Court's "sliding-scale" approach to preliminary injunctions, that finding lowered the legal threshold that Plaintiffs had to clear to obtain injunctive relief: all Plaintiffs had to do was raise "serious questions" going to the merits of their Administrative Procedure Act ("APA") claims. That they surely did.

The district court determined that Plaintiffs had not only raised "serious questions going to the merits," but were likely to succeed on their claims. The district court concluded that the Final Rule likely contravenes the annual appropriations rider that Congress has passed each year since 1996, which mandates that Title X pregnancy counseling be "nondirective"—meaning that providers can't steer women who may want to terminate their pregnancies into prenatal care, as the Final Rule requires. And Section 1554 of the Patient Protection and Affordable Care Act ("ACA") broadly provides that the

Secretary "shall not promulgate any regulation that," *inter alia*, "interferes with communications regarding a full range of treatment options between the patient and the provider" or "restricts the ability of health care providers to provide full disclosure of all relevant information to patients making health care decisions." The Final Rule does precisely that. Finally, the district court also found that HHS's failure to offer any evidence to justify its costly rule likely renders it arbitrary and capricious.

When it comes to the merits of Plaintiffs' claims, HHS hangs its hat on *Rust v. Sullivan*, 500 U.S. 173. In 1991, *Rust* upheld a forerunner to the regulations at issue here; and HHS asserts that *Rust* should dispose of this case as well. But *Rust* cannot bear the immense weight that HHS would place on it. In the nearly thirty years since *Rust* was decided, Congress has repeatedly attached the appropriations riders to HHS funding, and passed Section 1554. HHS's complaint that neither statute is specific enough to abrogate *Rust* misses the mark. Congress may narrow the Secretary's authority without effectuating an implied repeal. And while *Rust* held that the regulations at issue in that

case were *one* permissible construction of Title X, it did not definitively interpret Title X or insulate all *future* regulations from judicial review.

The complexion of this appeal changed dramatically on June 20, 2019, when a motions panel of this Court issued a published 25-page order granting HHS's motion to stay the preliminary-injunction order pending appeal. Although most courts consider irreparable harm the linchpin of any preliminary-injunction analysis, the stay order devoted a scant page-and-a-half to that subject. Citing no evidence, the motions panel overrode the district court's factfinding and equitable judgment and held instead that the balance of harms favored HHS because the agency felt that policies embodied by the Final Rule were *important*. By that standard, of course, the government always wins. The motions panel also deferred to HHS's "expertise" on the balance of harms, crediting its speculation that the Final Rule would encourage *more* providers to enter the field over Plaintiffs' evidence that it would trigger an exodus.

Rather than maintain the *status quo*, the stay order allows into effect a regulation that reverses decades of agency practice and that will dramatically and irreversibly diminish the quality and quantity of

health care under Title X. The motions panel published its ruling without even hearing oral argument.

To the extent the stay order is precedential or the law of the case, only an en banc court can correct the motions panel's errors. Otherwise, the three judges empaneled to decide the *merits* of HHS's appeal may not be able to decide those merits at all, as they may be bound by the motions panel's published views. Such a result would subvert the Court's traditional review process. Plaintiffs, therefore, in a concurrently filed petition, seek initial hearing of this appeal en banc to ensure a full and fair consideration of the merits.

En banc review is also necessary "to . . . maintain uniformity of the court's decisions." Fed. R. App. P. 35(a)(1). The motions panel departed significantly from existing Circuit precedent in two ways. ***First***, it fashioned a new-for-this-case method of balancing the harms and, by doing so in a published opinion, created an intra-Circuit split. The settled rule in this Circuit is that the balance-of-harms inquiry must be fact-specific and grounded in the actual evidence of harm before the court. *Herb Reed Enters., LLC v. Fla. Entm't Mgmt., Inc.*, 736 F.3d 1239, 1250 (9th Cir. 2013). But here, the motions panel invented a

new rule in which the purported harm to the government trumps all competing concerns so long as its lawyers assert that the challenged regulation has important policy implications.

Second, the motions panel improperly deferred to agency "expertise" on the balance-of-harms inquiry. Circuit precedent is clear that the balance-of-harms determination falls squarely under the equitable power of the Court, and that deference to agency "expertise" regarding the requirements for an injunction is an abuse of discretion. *Sierra Forest Legacy v. Sherman*, 646 F.3d 1161, 1185 (9th Cir. 2011).

En banc consideration is also necessary because this case involves an issue of "exceptional importance," Fed. R. App. P. 35(a)(2). As the district court found after reviewing an extensive record, the Final Rule would decimate California's Title X program and drastically limit patients' access to vital care—factual findings the motions panel summarily dismissed instead of properly reviewing for clear error.

Once these issues are resolved, it should be easy to conclude that the district court properly exercised its discretion in ruling that the balance of harms and the public interest "tip sharply" in Plaintiffs favor, and that Plaintiffs raised at least "serious questions going to the

merits." That is all the Court need decide in order to affirm the preliminary injunction.

II. STATEMENT OF JURISDICTION

Plaintiffs agree with HHS's statement of jurisdiction. Appellants' Opening Brief ("AOB") at 3.[1]

III. ISSUES PRESENTED

1. Was the motions panel order granting a stay of the preliminary injunction incorrect in deciding (a) that a federal agency always wins the balance-of-the-harms inquiry if it can assert that a challenged rule embodies an important policy, and (b) that courts owe deference to agency "expertise" in carrying out their equitable role of balancing the harms, thereby creating an intra-Circuit split on these two issues?

2. Did the district court commit clear error in finding that Plaintiffs will suffer irreparable harm if the Final Rule were to take effect while this litigation is pending?

[1] Plaintiffs also invoked the district court's jurisdiction under, *inter alia*, 5 U.S.C. §§ 702-706 and 28 U.S.C. §§ 2201, *et seq*. *See* ER 91, 153.

3. Did the district court abuse its discretion by ruling that the balance of harms and the public interest "tip sharply" in Plaintiffs' favor, such that they need only establish a "serious question going to the merits" to be entitled to a preliminary injunction?

4. Did the district court abuse its discretion by ruling that Plaintiffs raised at least "serious questions going to the merits" of their claim that the Final Rule is contrary to Section 1554 of the Affordable Care Act, which, among other things, prohibits HHS from promulgating any regulation that impedes patients' timely access to necessary health care or that interferes with patient-provider communications?

5. Did the district court abuse its discretion by ruling that Plaintiffs raised at least "serious questions going to the merits" of their claim that the Final Rule is contrary to the HHS Appropriations Act, by which Congress mandates that all Title X pregnancy counseling "shall be nondirective"?

6. Did the district court abuse its discretion in ruling that Plaintiffs raised at least "serious questions going to the merits" that HHS acted arbitrarily and capriciously by promulgating the Final Rule without a reasoned justification?

7. Did the district court abuse its discretion in tailoring the injunction?[2]

IV. STATEMENT OF THE FACTS AND THE CASE

A. The Title X Program

The federal government's Title X program is a critical part of the nation's public health safety net, subsidizing high-quality family planning services for low-income individuals. C.SER 502-503.[3] Hailed by the Centers for Disease Control and Prevention as one of the greatest public health achievements of the twentieth century, Title X has successfully reduced rates of unintended pregnancy by facilitating contraceptive access and conducting pregnancy testing and counseling, including referrals. *Id.* 505-506. In addition to offering the most advanced contraceptive methods available, Title X-funded centers offer

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[2] Plaintiffs have not included pertinent statutes and rules, nor an addendum, because all applicable statutes, etc., are contained in Appellants' addendum, Dkt. 13.

[3] State of California's Supplemental Excerpts of Record ("C.SER") filed in Case No. 19-15974.

For the Court's convenience, Plaintiffs refer to documents filed in both consolidated cases as they appear in the State of California's (Case No. 19-15974) Supplemental Excerpts of Record ("C.SER"). Additional documents are submitted in Plaintiffs' Supplemental Excerpts of Record ("EA.SER").

infertility services; testing and treatment for sexually-transmitted infections ("STIs"); cervical and breast cancer screening; and screening for high blood pressure, diabetes, depression, and other pre-conception issues. *Id.* 499.

The ability of women to control family size and desired birth spacing has been revolutionary for women's health. EA.SER 3. Family-planning services allow women to prevent pregnancy-related health risks, reduce infant mortality, and enhance education, economic stability, and equality. *Id.* Contraception helps women avoid unintended pregnancy, which is associated with adverse prenatal and perinatal consequences, including delayed prenatal care, use of medications that are harmful during pregnancy, prematurity, and lack of breastfeeding. *Id.*

The Title X program currently serves over four million low-income, uninsured, and underserved individuals at 3,858 sites across the country. C.SER 150.[4] In 2017, 90 percent of Title X patients

[4] *See also* Office of Population Affairs, Family Planning Annual Report: 2017 National Summary A-33 (Aug. 2018) (hereafter, "2017 FPAR"), *available at* https://www.hhs.gov/opa/sites/default/files/title-x-fpar-2017-national-summary.pdf.

nationally—approximately 3.6 million people—had family incomes that qualified them for either subsidized or no-charge services. *Id.* 136. Sixty-seven percent of Title X patients nationally, or 2.7 million individuals, had family incomes at or below the federal poverty level, and 42 percent were uninsured. *Id.*

B. Plaintiffs Essential Access Health and Dr. Melissa Marshall

Plaintiff Essential Access Health ("Essential Access") has served as California's primary Title X grantee for nearly fifty years. C.SER 498. As grantee, Essential Access administers Title X funding to a diverse network of sub-recipient health-care organizations, including federally-qualified health centers, community health centers, city and county health departments, and hospitals. *Id.* Essential Access's network serves one million patients annually—more than 25 percent of Title X patients nationwide. *Id.* Plaintiff Melissa Marshall, M.D., is a practicing physician and CEO of CommuniCare Health Centers in Yolo County, California. C.SER 573. In 2017, CommuniCare served over 26,000 patients, nearly 80 percent of whom had income below the federal poverty level. *Id.*

C. Pregnancy and Abortion Counseling

Like any recipient of Title X funding, Plaintiffs must abide by the requirements of Title X and its implementing regulations. Title X projects must offer a "broad range of acceptable and effective family planning methods" and prioritize services for low-income individuals. 42 U.S.C. §§ 300, 300a-4, 300a-5. In addition, under the HHS Appropriations Act, "pregnancy counseling" offered by a Title X clinic must be "nondirective." Pub. L. No. 115–245, Div. B, Tit. II, 132 Stat. 2981, 3070–71 (2018). Consistent with these requirements, the prior 2000 regulations—like the regulations implemented in 1981—required Title X projects to offer pregnant patients "neutral, factual information and nondirective counseling" and a referral upon request for "(A) Prenatal care and delivery; (B) Infant care, foster care, or adoption; and (C) Pregnancy termination." 42 CFR § 59.5(5)(i) (2000).[5] They also

[5] For ease of reference, the provisions of the Final Rule are cited by their section number (e.g., "§ 59.5" or "§ 59.14"). The provisions of the regulations promulgated in 2000 (the "2000 regulations") are cited according to their section in the 2000 version of the Code of Federal Regulations (e.g., "42 C.F.R. § 59.5 (2000)"). The 2000 regulations were republished in the 2007 Code of Federal Regulations and are identical insofar as cited by Plaintiffs here.

required Title X projects to use "medically approved" family planning methods. *Id.* § 59.5(a)(1).

Under Section 1008 of Title X, "[n]one of the funds appropriated under [Title X] shall be used in programs where abortion is a method of family planning." 42 U.S.C. § 300a-6. Section 1008 is limited by its plain language to Title X ***programs***. It does not restrict Title X recipients from providing abortion care using *non*-Title X funds. Accordingly, while the 2000 regulations required entities that provide both Title X services and abortion care to ensure that the finances for each were completely separate, HHS allowed providers to use the same facilities for both Title X programs and abortion services, including shared waiting rooms, records systems, and staff. *See* Provision of Abortion-Related Services in Family Planning Service Projects, 65 Fed. Reg. 41281, 41282 (July 3, 2000).

D. The Final Rule

For the past three decades, Title X has been governed by a largely consistent set of regulations that leave the incredibly personal and sensitive issue of abortion counseling in the hands of patients and their

medical providers.[6] On March 4, 2019, however, HHS promulgated the Final Rule, with the purported goal of bringing the Title X program into compliance with Section 1008. But Title X regulations have *never* permitted Title X funds to be used to fund abortions, and have always required financial separation between Title X programs and abortion counseling or services. 65 Fed. Reg. at 41275–76. As President Trump made clear, the Final Rule aims (among other things) to ensure that entities that provide abortions using *non*-Title X funds are forced out of the program.[7] To that end, the Final Rule imposes sweeping changes.

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[6] In 1988, HHS promulgated regulations that prohibited Title X-funded projects from providing counseling or referrals for "the use of abortion as a method of family planning." 42 CFR § 59.8 (1988) (the "1988 regulations"). The 1988 regulations also required Title X-funded activities to be "physically and financially separate" from prohibited abortion activities. *Id.* § 59.9. The Supreme Court held that those 1988 regulations were a permissible interpretation of the Title X statute in *Rust*.

HHS argues that *Rust* precludes any challenge to the Final Rule today, but *Rust* allowed a different rule based on a very different administrative record and statutory landscape. The agency justifications that saved the *Rust* rule are absent here, and the laws that the Final Rule violates didn't exist at the time of *Rust*.

The government never fully implemented the 1988 regulations and suspended them in 1993. 58 Fed. Reg. 7455. From 1991 to 2019 the Title X program was governed by a consistent regulatory scheme.

[7] Remarks by President Trump at Susan B Anthony List 11th Annual Campaign for Life Gala, whitehouse.gov (May 22, 2018) ("My

Restriction on Abortion Counseling. The Final Rule substitutes the agency's political agenda in the place of a medical provider's clinical judgment by preventing medical providers from giving patients unbiased factual information about abortion services, while at the same time mandating referrals for prenatal care—even when such referral is not medically indicated or when the patient does not wish to continue the pregnancy. § 59.5(a)(5); § 59.14(b)(1). The provider may give "[n]ondirective pregnancy counseling," but only if the provider is a physician or "advanced practice provider" ("APP"), defined as someone who "receive[d] at least a graduate level degree in the relevant medical field and maintains a license to diagnose, treat, and counsel patients." §§ 59.2, 59.14(b)(i). The Final Rule does not explain how an APP can provide "nondirective pregnancy counseling" that discusses abortion without running afoul of § 59.14(a), which unequivocally states that "[a] Title X project may not perform, promote, refer for, or support abortion

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administration has proposed a rule to prohibit Title X funding from going to any clinic that performs abortions"), *available at* https://www.whitehouse.gov/briefings-statements/remarks-president-trump-susan-b-anthony-list-11th-annual-campaign-life-gala/.

as a method of family planning." § 59.14(a); *see also* §§ 59.5(a)(5), 59.16 (similar restrictions).

Ban on Abortion Referral. The Final Rule not only prohibits a Title X provider from referring a patient to a clinic where she can receive an abortion; it also prohibits a provider from referring a patient to an organization where she can receive *information* about that service. Instead, a provider may only offer "a list of . . . primary health care providers (including providers of prenatal care)," even in response to a patient's direct request for a referral to an abortion provider. § 59.14(b)(1)(ii), (c)(2). That list must not include ***only*** abortion providers, and need not include ***any***. § 59.14(c)(2). If abortion providers are included, they must also be "comprehensive primary health care providers," and cannot comprise more than half the list. *Id.* "Neither the list nor project staff may identify which providers on the list perform abortion," forcing patients and providers to engage in a farcical game of hide-the-ball. *Id.*[8]

[8] A Title X project must also provide assurance "satisfactory to the Secretary that the project does not provide abortion and does not include abortion as a method of family planning." § 59.13. The Final Rule does not explain what the Secretary considers "satisfactory."

The ban on abortion referral does not include an explicit exception for abortions that are medically necessary. Instead, "[i]n cases in which ***emergency*** care is required, the Title X project shall only be required to refer the client immediately to an appropriate provider of medical services needed to address the emergency." § 59.14(b)(2).

Physical and Financial Separation. The Final Rule attempts to regulate activities well outside the scope of the Title X program by mandating complete physical and financial separation between a Title X project and so-called "prohibited activities." § 59.15. "Prohibited activities" is broadly defined to include any activity that "encourage[s], promote[s] or advocate[s] abortion as a method of family planning." §§ 59.14, 59.16(a)(1). Even allowing brochures that discuss abortion to "sit[] on a table . . . within the same space where Title X services are provided" falls within the scope. *Id.* § 59.16(b)(1).[9] As a practical matter,

[9] The Secretary has virtually boundless discretion to determine whether a Title X project is physically and financially separate from an organization that engages in prohibited activity. The Final Rule identifies factors relevant to that determination, including the existence of separate accounting records; the degree of separation from "facilities" (e.g., office entrances and exits, phone numbers, email addresses) in which prohibited activity occurs; and the extent to which signs and material referencing or promoting abortion are absent from the Title X project, among others. § 59.15(a)-(d). The Final Rule does not specify

this requirement prohibits a provider who receives Title X funds from engaging in full, factual options counseling even outside of the scope of a Title X program.

Dilution of Quality of Care & Adolescent Reporting Requirements. The Final Rule eliminates the requirement that family planning methods provided through Title X projects be "medically approved." *Compare id.* § 59.5(a)(1) with 42 C.F.R. § 59.5(a)(1) (2000). This will allow Title X grants to fund methods of family planning that do not meet the FDA's or HHS's own standards for medical care. The Final Rule also deems adolescents ineligible for subsidized Title X services unless the provider has documented "specific actions taken by the provider to encourage the minor to involve her/his family (including her/his parents or guardian) in her/his decision to seek family planning services." § 59.2. A provider must give assurance "satisfactory to the Secretary" that the provider will "conduct a preliminary screening of any minor who presents with a sexually transmitted disease (STD)" or "pregnancy" in order to "rule out victimization of a minor," regardless of

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what weight each factor carries, nor does it prohibit the Secretary from considering other, unidentified factors.

whether there is any indication of abuse. § 59.17(b)(1)(iv). Providers who specialize in the treatment of adolescents overwhelmingly believe that these new requirements will inhibit access to care for adolescents and dissuade teen patients from seeking care. C.SER 542-43, 569, 571.

E. The Preliminary Injunction

Plaintiffs filed their Complaint challenging the Final Rule on March 4, 2019, and moved for a preliminary injunction shortly thereafter. On April 26, 2019, following a two-hour hearing on Plaintiffs' motion, the district court issued an exhaustively reasoned 78-page order preliminarily enjoining the Final Rule in California. The district court held that the Final Rule was likely arbitrary and capricious and contrary to two laws: (1) the annual appropriations rider that Congress has passed each year since 1996, requiring that "all pregnancy counseling" in the Title X program "shall be nondirective,"[10] and (2) Section 1554 of the ACA, which prohibits HHS from promulgating "any regulation" that creates unreasonable barriers to individuals seeking appropriate medical care.[11] ER 34-54.

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[10] Pub. L. No. 115-245, 132 Stat. 2981, 3070-3071 (2018) (the "Nondirective Mandate").

[11] 42 U.S.C. § 18114 ("Section 1554").

Based on the sworn written testimony of more than a dozen program administrators, experts, and healthcare providers, the district court also found the following:

- The Final Rule threatens to decimate the network of Title X providers in California by driving large numbers of providers out of the program because compliance with the physical separation requirement will be cost-prohibitive; and compliance with the restrictions on abortion counseling will compromise quality of care and violate providers' ethical obligations. ER 23-24.
- Decimation of California's Title X network will drastically restrict patients' access to a wide range of vital services. Thousands of low-income Californians will suffer from reduced availability of care and diminished quality of care, while many others will lose access to important medical services altogether, resulting in worse health outcomes for patients and the public as a whole. ER 24-26.
- The exodus of providers from the Title X program will likely increase the number of unintended pregnancies, increase abortion rates, and increase instances of STIs and other conditions that would otherwise have been diagnosed with Title-X funded testing.

ER 26.

- The decimation of Essential Access's network will frustrate Essential Access's organizational mission to promote access to quality sexual and reproductive care and irreparably harm Plaintiffs, patients, and the public health. ER 26.
- The Final Rule's physical separation requirement will cause Essential Access irreparable economic harm by requiring it to expend "exorbitant sums" to construct a "mirror" office, diverting resources it would otherwise devote to its core operations and mission. ER 27-28.
- HHS failed to identify any real harm it would suffer were the preliminary injunction to issue. ER 33.

Recognizing that "there is generally no public interest in the perpetuation of unlawful agency action," ER 33 (citing *League of Women Voters of United States v. Newby*, 838 F.3d 1, 12 (D.C. Cir. 2016) (citation omitted)), the district court ruled that the balance of hardships and public interest "tip sharply" in Plaintiffs' favor. *Id*. The district court determined that Plaintiffs not only raised "serious questions" on the merits of their claims that the Final Rule is contrary to law and

arbitrary and capricious, but that Plaintiffs were likely to succeed on the merits of many of their claims. *Id.* Ultimately, the district court denied Plaintiffs' request for a nationwide injunction, but enjoined the Final Rule in California, excluding sections 59.3 and 59.5(a)(13) from the injunction's scope. ER 86; ER 4. District courts in Oregon and Washington also issued preliminary injunctions temporarily blocking enforcement of the Rule under similar rationales. *See Washington v. Azar*, 376 F. Supp. 3d 1119 (2019); *Oregon v. Azar*, No. 6:19-CV-00317-MC, 2019 WL 1897475 (D. Or. Apr. 29, 2019).

On May 6, 2019, HHS asked the district court to stay the injunction pending appeal. The district court denied the stay but narrowed the scope of its injunction. ER 1-4.

F. Appellate Proceedings

On May 10, 2019, HHS filed in this Court a motion to stay the preliminary injunction pending appeal. Motion for Stay Pending Appeal, No. 19-15979, Dkt. 8. On June 20—after HHS had filed its opening merits brief challenging the preliminary injunction, but before Plaintiffs' July 1 deadline to respond—a motions panel stayed all three preliminary injunctions pending resolution of the appeals. *California v.*

Azar, — F.3d —, 2019 WL 2529259 (9th Cir. 2019) (per curiam) ("Stay Ord."). The motions panel issued a published opinion without hearing any argument. The stay opinion does more than rule on HHS's request to stay the preliminary injunction; the opinion comments extensively on the legal and factual questions at issue in the appeal.

The motions panel found that the balance of harms favors HHS, but cited no actual evidence of any harm to HHS or the public—for there was none—stating only that the public would be hurt by the continuation of policies that have governed Title X for thirty years. *See id* *8. The motions panel reasoned that if the preliminary injunction remained in place, "HHS [would] be forced to allow taxpayer dollars to be spent in a manner that it has concluded violates the law, as well as the Government's important policy interest." *Id.* The motions panel further decried the "administrative costs" and "uncertainty" that would result from a "lengthy appeals process." *Id.*

On the other side of the ledger, the motions panel declared the harms to Plaintiffs "comparatively minor," sweeping aside the district court's extensive factual findings that the Final Rule will irreparably harm Plaintiffs, patients, and public health by driving providers out of

the Title X program and decreasing access to and quality of critical reproductive care. *Id.* Instead, the motions panel relied on HHS's speculation, unsupported by evidence, that implementation of the Final Rule would ***increase*** the number of providers participating in Title X. *Id.* The motions panel devoted the rest of its opinion to its conclusions that Plaintiffs had not established that they were "likely to succeed" on the merits[12] and that a stay was appropriate. *Id.* at *3–8. As the motions panel published its opinion, Plaintiffs expect HHS to argue that the stay opinion requires resolution of the entire appeal in its favor.

V. SUMMARY OF ARGUMENT

1. The Court should not follow the reasoning of the stay order because it is incorrect and conflicts with Circuit precedent in two ways. *First*, instead of weighing the actual evidence of harm to each party as Circuit precedent demands, the motions panel fashioned a new rule under which the government always wins the balance-of-harms inquiry so long as it "concludes" that its new regulation embodies an important policy. *Second*, the motions panel deferred to HHS's "expertise" on the

[12] Because its finding for HHS on the balance-of-harms avoided use of the "serious questions" standard, the motions panel made no findings under that standard.

balance-of-harms, improperly committing that equitable determination to federal agencies instead of the courts. Both of these newly-announced rules improperly weight the scales in favor of HHS.

2. The district court did not abuse its discretion by preliminarily enjoining the Final Rule in light of its factual findings regarding the harms, the equities, and the public interest. The district court's factual findings that implementation of the Final Rule will irreparably harm Plaintiffs were not clearly erroneous. Plaintiffs submitted overwhelming record evidence in support of their motion for a preliminary injunction corroborating the district court's well-reasoned factual findings. By contrast, HHS failed to identify any irreparable harm to itself or the public should the *status quo* under the prior regulations remain in place. The district court thus properly found that the balance of equities and public interest "tip sharply" in Plaintiffs' favor.

3. The district court did not abuse its discretion in holding that because the balance of hardships and public-interest factors "tip sharply" in Plaintiffs' favor, Plaintiffs need only raise "serious questions

going to the merits" of their claims to warrant injunctive relief. *All. for the Wild Rockies v. Cottrell*, 632 F.3d 1127, 1135 (9th Cir. 2011).

4. The district court correctly found that Plaintiffs raised at least "serious questions going to the merits" of their claim that the Final Rule is contrary to law because (a) it violates Section 1554's prohibition on "any regulation" that interferes with patient-provider communications, violates principles of medical ethics, or impedes patients' access to medical care and information; and (b) because it violates Congress's mandate that all Title X pregnancy counseling "shall be nondirective" by requiring providers to steer pregnant patients away from abortion and into prenatal care. *Rust* does not foreclose Plaintiffs' claim; nor does it compel the conclusion that Section 1554 or the appropriations rider impliedly repealed Section 1008.

5. The district court correctly found that Plaintiffs raised at least "serious questions going to the merits" of their claim that the Final Rule is arbitrary and capricious because HHS ignored substantial evidence that the Final Rule would have a significant adverse impact on the Title X network and patient health, and failed to offer any justification for its reversal of long-standing agency policies. *Rust*

upheld prior regulations on different justifications than HHS now provides and does not control here.

6. The district court did not abuse its discretion in tailoring the injunction. The district court specifically considered which provisions of the Final Rule to invalidate; narrowly tailored the injunction to exclude the provisions it determined were unchallenged; and limited the injunction's scope to California.

VI. STANDARD OF REVIEW

This Court reviews a district court's grant of a preliminary injunction for abuse of discretion, and that review is "limited and deferential." *Sw. Voter Registration Educ. Project v. Shelley*, 344 F.3d 914, 918 (9th Cir. 2003) (en banc).[13] The reviewing court's task is not to resolve disputes of fact between the parties; "as long as findings are plausible in light of the record viewed in its entirety, a reviewing court

[13] A district court may abuse its discretion granting a preliminary injunction in three ways: (1) by resting its decision to grant a preliminary injunction on a clearly erroneous finding of fact; (2) by applying incorrect substantive law or an incorrect preliminary injunction standard; or (3) by applying an acceptable preliminary injunction standard in a manner that results in abuse of discretion. *Zepeda v. U.S. I.N.S.*, 753 F.2d 719. 724 (9th Cir. 1983). None of those circumstances is present here.

may not reverse even if convinced it would have reached a different result." *Nat'l Wildlife Fed'n v. Nat'l Marine Fisheries Serv.*, 422 F.3d 782, 795 (9th Cir. 2005) (citations omitted).[14]

A district court properly grants a preliminary injunction if the movant establishes that four factors, balanced together, weigh in its favor: that (1) it "is likely to succeed on the merits," (2) it "is likely to suffer irreparable harm in the absence of preliminary relief," (3) "the balance of equities tips in [its] favor," and (4) "an injunction is in the public interest." *Winter v. Nat. Res. Def. Council, Inc.,* 555 U.S. 20, 26 (2008). When the government is a party, "the last two factors [of the test] merge." *California v. Azar*, 911 F.3d 558, 575 (9th Cir. 2018).

Courts in this Circuit evaluate these factors on a "sliding scale," whereby "a stronger showing of one element may offset a weaker showing of another." *Cottrell*, 632 F.3d at 1131. A plaintiff who

[14] This standard applies equally in an APA case. Although some of this Court's opinions state that it does not accord deference to a district court's decision in an APA case, those statements concern review of decisions on the *merits*, and are inapposite. *See, e.g., Asarco, Inc. v. U.S. Envt'l Prot. Agency*, 616 F.2d 1153, 1155 (9th Cir. 1980) (reviewing de novo district court's final determination, after four-day hearing, that agency's order was arbitrary and capricious)); *Nevitt v. United States*, 828 F.2d 1405, 1406 (9th Cir. 1987) (reviewing de novo district court's order granting summary judgment for agency).

demonstrates that the balance of hardships tips "sharply" in her favor need only raise "serious questions going to the merits"—a less rigorous showing than likelihood of success on the merits. *Id.* at 1131-35.

Plaintiffs' showing satisfied both standards. *All* of the evidence on irreparable harm, the balance of hardships, and the public interest favors Plaintiffs. *See* Sections VII.B. and VII.C., below. HHS cannot demonstrate that the district court abused its discretion in concluding that the balance of hardships and public interest "tip sharply" in Plaintiffs' favor, particularly where HHS failed to make any evidentiary showing at all. Nor can there be any rational doubt that Plaintiffs raised, at the very least, "serious questions" on the merits of their claims. *See* Sections VII.D. and VII.E., below. The Court should affirm the preliminary injunction.

VII. ARGUMENT

The motions panel's stay order was incorrectly decided. The motions panel applied a balance-of-harms analysis that contravenes established precedent of this Court on the standard of review for a preliminary-injunction order. And it disregarded the district court's well-reasoned factual findings, which can only be overturned for clear

error. Nonetheless, HHS will certainly argue that the stay order is binding on any subsequent merits panel under *Lair v. Bullock*, 798 F.3d 736 (9th Cir. 2015) ("*Lair II*").[15] Far from promoting the "orderly course of justice," *Lockyer v. Mirant Corp.*, 398 F.3d 1098, 1110 (9th Cir. 2005),

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[15] Plaintiffs seek en banc review given the possibility that the Stay Order is binding on the merits panel, but *Lair II* does not compel that result. There, a motions panel applied pre-existing Circuit precedent in holding that a Supreme Court's plurality opinion was persuasive, but not binding, authority. *Lair v. Bullock*, 697 F.3d 1200, 1205-06 (9th Cir. 2012) ("*Lair I*"). The merits panel in *Lair II* followed that same, pre-existing precedent. 798 F.3d at 747 (stating that "the *Lair I* panel was not the first one to hold that" the Supreme Court opinion in question was not binding because "no opinion . . . carried a majority."). Where, as here, the motions panel sets new Circuit precedent, *Lair II* does not conclusively bind the merits panel to its determinations. *See United States v. Houser*, 804 F.2d 565, 568 (9th Cir. 1986) ("[W]hile a merits panel does not lightly overturn a decision made by a motions panel during the course of the same appeal," it is not bound to follow it.").

Indeed, to allow the motions panel to dictate the merits of an appeal flies in the face of its intended role in considering a stay: to predict whether HHS has "made a strong showing that [it] is *likely* to succeed" in its challenge to the district court's preliminary injunction. *Nken v. Holder*, 556 U.S. 418, 427 (2009) (emphasis added). A merits panel considering an appeal with the benefit of full briefing and oral argument should not be bound by a motions panel's hastier prediction regarding the ultimate outcome. *See Innovation Law Lab v. McAleenan*, 924 F.3d 503, 518 (9th Cir. 2019) (W. Fletcher, J., concurring in the judgment) (inviting the merits panel "with the benefit of full briefing and regularly scheduled argument" to reach a different conclusion than the motions panel); *Wild Rockies*, 632 F.3d at 1139 (Mosman, D.J., concurring) (where "the whole question of the merits comes before the court on an accelerated schedule," it "can seem almost inimical to good judging to hazard a prediction about which side is likely to succeed.").

then, the stay order would render the merits appeal pointless and disrupt the decision-making process in other appeals. The en banc court may need to intervene to correct the stay decision's errors; accordingly, Plaintiffs have sought initial hearing en banc of this appeal and the Court should not follow the stay order.

1. The stay order creates a conflict in Circuit precedent regarding the balance-of-harms inquiry

In effect, the stay order creates a *per se* rule that harm to the government from delaying implementation of a regulation always outweighs the potential harm to litigants challenging that regulation. The motions panel concluded that HHS would be irreparably harmed if the Final Rule were not implemented pending appeal because during that time it couldn't implement its preferred policy choices. But both the Supreme Court and this Court require careful balancing of the interests of the respective parties, based on actual evidence of the harm that each party will suffer. *Friends of the Earth, Inc. v. Coleman*, 518 F.2d 323, 330 (9th Cir. 1975), *abrogated on other grounds by Cottonwood Envtl. Law Center v. U.S. Forest Serv.*, 789 F.3d 1075 (9th Cir. 2015); *see also*, *Winter,* 555 U.S. at 26 (disapproving of the district court's "cursory," one-sentence consideration of this factor, "[d]espite the importance of

assessing the balance of equities"); *Herb Reed Enters.,* 736 F.3d at 1250 (district court's irreparable-harm analysis must be "grounded in . . . evidence," and should not be "cursory and conclusory"). The motions panel's circular logic—that the government is irreparably harmed every time it cannot immediately implement a challenged regulation—does away with that balancing altogether.

Applying its new rule, the motions panel concluded that HHS would suffer irreparable harm if the regulations which have governed Title X for decades remained in place pending this expedited appeal, because HHS will be forced to allow taxpayer dollars to be spent in a manner that "***it has concluded*** violates the law." Stay Ord. at *8 (emphasis added). But no court has ever concluded that the Title X regulations in place for the past thirty years violated any law; HHS's conclusion is simply that prior regulations didn't do enough to ensure that Title X funds did not "indirectly" facilitate abortion.

The motions panel's irreparable-harm analysis is especially remarkable given that the current administration did not itself view the harm from the prior regulatory scheme as imminent or irreparable, and waited *years* to implement these new changes to the Title X program.

Despite this delay, the motions panel came to the erroneous conclusion that a stay was necessary to ensure that the decades-long *status quo* did not suddenly cause HHS supposedly imminent and irreparable harm. The motions panel furnishes no authority supporting this new rule.[16] Nor can it. Circuit precedent is clear that the government is not irreparably harmed merely because it is prevented from carrying out its desired policy. *See, e.g.*, *Regents of the Univ. of Cal. v. U.S. Dep't of Homeland Sec.,* 908 F.3d 476, 500 (9th Cir. 2018) (affirming injunction against termination of DACA program despite agency's "belief that DACA was unlawful"); *Rodriguez v. Robbins*, 715 F.3d 1127, 1145 (9th Cir. 2013) (balance of hardships favored plaintiffs where "[t]he government provide[d] almost no evidence that it would be harmed . . .

[16] HHS's reliance on *Maryland v. King*, 567 U.S. 1301 (2012), for this proposition is unavailing. Relying on *Maryland*, HHS has contended that it will suffer irreparable injury if "'enjoined . . . from effectuating statutes enacted by representatives of its people.'" ER 33 (citing HHS's Opposition to Preliminary Injunction). But the district court enjoined an agency *rule*—not a statute, as in *Maryland*. *See id*. Moreover, the *Maryland* court found that "Maryland's law enforcement and public safety interests" would suffer "concrete harm" if the statute at issue were suspended. *Maryland*, 567 U.S. at *3. HHS has not identified any analogous interest here.

other than its assertion that the order enjoins 'presumptively lawful' government activity").

2. The stay order creates a conflict in Circuit precedent regarding the deference owed to the government's "predictive judgment" on harm

Under Circuit precedent, reviewing courts defer to "agency decision-making" "[w]here scientific and technical expertise is necessarily involved." *Trout Unlimited v. Lohn*, 559 F.3d 946, 958 (9th Cir. 2009); Stay Ord. at 23. Here, however, the motions panel impermissibly extended *Trout Unlimited* deference to subsume the balance-of-harms inquiry, holding that "HHS's predictions" regarding the "minor" harm Plaintiffs would suffer "[are] entitled to more deference than Plaintiffs' contrary predictions." Stay Ord. at *8. In other words, the motions panel credited HHS's unsupported assessment of the harm to *Plaintiffs*, rather than the district court's factual findings and the sworn evidence.

There is no precedent for such a sweeping abnegation of the Court's equitable responsibility to itself balance the harms based on evidence, not conclusions. "Where plaintiff and defendant present competing claims of injury, the traditional function of [the court at]

equity has been to arrive at a nice adjustment and reconciliation between the competing claims" by "balanc[ing] the conveniences of the parties and possible injuries to them according as they may be affected by the granting or withholding of the injunction." *Weinberger v. Romero-Barcelo*, 456 U.S. 305, 312 (1982) (citations omitted). Indeed, "the comprehensiveness of this equitable jurisdiction is not to be denied or limited in the absence of a clear and valid legislative command." *Id.* at 313 (citation omitted).

With those principles in mind, this Circuit has already categorically rejected the new rule of deference that the motions panel announced. In *Sierra Forest Legacy v. Rey*, 670 F. Supp. 2d 1106 (E.D. Cal. 2009), the district court deferred to the Forest Service experts' "predictive judgment," among other things, that "the risk of stand-replacing wildfire is more significant to the survival of species like the California spotted owl tha[n] the risk that some habitat . . . will be lost in attempting to ameliorate the fire risk." *Id.* at 1111. The Court reversed, holding that the district court had improperly "deferred to [agency] experts in its own equitable analysis." *Sierra Forest Legacy v. Sherman*, 646 F.3d at 1185. As the *Sierra* Court explained, "If the

federal government's experts were always entitled to deference concerning the equities of an injunction, substantive relief against federal government policies would be nearly unattainable" because "government experts will likely [always] attest that the public interest favors the federal government's preferred policy." *Id.* at 1186.

Blanket deference to "agency expertise" on the issue of relative harm makes no sense for a second reason—it improperly extends the government's "predictive judgment" into areas where the agency has no unique proficiency. Indeed, in many instances, the plaintiff may have at least as much, if not more, "expertise" as the agency in assessing the harm it will incur if the *status quo* is not preserved.

As noted by *Sierra*, "*Winter* is illustrative" on this point. *Id.*at 1185-86. In *Winter,* the Supreme Court held that "lower courts failed properly to defer to senior Navy officers' specific, predictive judgments about how the preliminary injunction would reduce the effectiveness of the Navy's . . . training exercises." *Winter*, 555 U.S. at 27. Deference to ***that*** judgment was appropriate given the government's unique expertise on issues of national security and military functioning. However, "*Winter* applied no such deference concerning the possibility

that sonar testing would irreparably harm whales," because "ecology is not a field within the unique expertise of the federal government." *Sierra*, 646 F.3d at 1185-86. Establishing, as the motions panel has, a rule of deference to the government's balance-of-harms determinations invites pronouncements on subjects far afield of the agency's expertise. And here, the motions panel did not even bother to assess whether the harm that Plaintiffs would suffer as a result of the Final Rule was within HHS's expertise. The motions panel's decision completely distorts the balance-of-harms inquiry, gutting the court's equitable discretion in violation of *Sierra* and *Winter*, and virtually guaranteeing that the government will always prevail. Accordingly, the Court should not follow the motions panel's reasoning or be bound by its order.[17]

B. The district court's findings of irreparable harm are not clearly erroneous

Appellate review of factfinding is restricted to the limited record available to the district court when it decided the motion. *Hunt v. Nat'l*

[17] As discussed in Plaintiffs' concurrently filed petition for initial hearing en banc and section VII.B, the harms Plaintiffs stand to suffer present an issue of "exceptional importance." Fed. R. App. P. 35(a)(2). The Court should not allow this case to rest on the decision of a motions panel order decided without even a hearing.

Broad. Co. Inc., 872 F.2d 289, 292 (9th Cir. 1989). A finding of fact is clearly erroneous only if it is "implausible in light of the record viewed in its entirety, or if the record contains no evidence to support it." *Nat'l Wildlife Fed'n*, 422 F.3d at 794 (citations omitted). Here, the extensive, uncontroverted record evidence undergirding the district court's findings demonstrate they were far more than "plausible," and by no means clearly erroneous.

First, this Court has recognized that "ongoing harms to a [plaintiff's] organizational missions" may establish a likelihood of irreparable harm. *See, e.g., Valle del Sol Inc. v. Whiting*, 732 F.3d 1006, 1029 (9th Cir. 2013). Here, the district court found that the Final Rule is likely to irreparably harm Essential Access "both . . . qualitatively and quantitatively" by thwarting its mission to "promote access to high-quality healthcare." ER 22-23.

Citing the unrebutted sworn testimony of Essential Access, its sub-recipients, and record survey evidence, the district court found that "a significant number of Title X projects" would likely discontinue participation in Title X if the Final Rule took effect. ER 23-24. "[Providers] representing 233 clinic cites serving over 774,000 patients

would leave or consider leaving Title X if they are prohibited from referring patients for abortions," and "[providers] representing 194 clinic cites serving over 682,00 patients [would] leave or consider leaving if required by the Final Rule to encourage family involvement when an adolescent patient seeks confidential services." ER 24. The district court found that the loss of Title X funds would result in provider lay-offs; reduced clinic hours; diminished access to quality contraceptives; curtailed outreach and education efforts; and the loss of programming aimed at youth and low-income individuals. ER 24. This, in turn, would result in "a significant reduction in the availability of important medical services," and the loss of patient access to a wide range of vital health services, "many of which have nothing to do with abortion." ER 24-25.

For providers that remain in the program, the district court found the Final Rule will "compromise [Title X] providers' ability to deliver effective care and force them to obstruct and delay patients with pressing medical needs." ER 23. Record evidence confirms the district court's determination that the Final Rule's restrictions on abortion counseling and mandatory prenatal referral "erect[] barrier after

barrier between patients trying to make an informed decision about their pregnancies and their clinicians," and the referral list restrictions will "harm and confuse" patients and "threaten their health and well-being." ER 23. The requirement that pregnancy counseling be provided only by physicians and APPs would "compound an already severe crisis in physician and nurse practitioner availability" and force patients to wait longer to receive time-sensitive counseling, or forego it altogether. ER 25. Based on the overwhelming evidence before it, the district court concluded that the Final Rule will result in "worse health outcomes for patients and the public as a whole," including increases in unintended pregnancies, abortion rates, and rates of STIs, and will irreparably harm Essential Access's mission and public health. ER 26.

Second, the district court found that the Final Rule would inflict irreparable economic harm on Essential Access by forcing it to spend enormous resources on compliance and divert resources that it would otherwise devote to its core operations and interests. ER 27. This Court has held that such harm is irreparable. *See California v. Azar*, 911 F.3d 558, 581 (9th Cir. 2018) (citing 5 U.S.C. § 702); *Valle del Sol*, 732 F. 3d at 1029. The district court also found that the physical separation

requirement would force Essential Access to construct a costly "mirror" office at the cost of $325,000 in the first year and $212,500 every year thereafter. ER 27.

Rather than make a serious run at showing any particular factual finding was clearly erroneous, HHS denigrates Plaintiffs' injuries as "overstated," "unfounded," and "speculative." AOB at 43. Far from it. This Court has repeatedly held that Plaintiffs' harms are legally cognizable. *See, e.g.*, *Azar*, 911 F.3d at 581*; Valle del Sol*, 732 F. 3d at 1029. And the district court's irreparable harm findings are amply supported by an evidentiary record that includes more than a dozen uncontroverted declarations of distinguished health care professionals, physicians, and public health experts submitted in support of Plaintiffs' preliminary injunction. C.SER 36-601; EA.SER 1-24. HHS cannot credibly maintain that the district court's findings—soundly rooted in that evidence—are clearly erroneous. *Nat'l Wildlife Fed'n*, 422 F.3d at 794.

HHS complains that the district court failed to credit its "expert prediction" that the "Rule may expand the pool of potential Title X providers to 'fill [any] gaps.'" AOB at 43 (citing 84 Fed. Reg. at 7756).

HHS's claim "is not backed by any discernible evidence or analysis," but rather based on a notion the government asserts is "just intuitive." ER 29-30. Intuition is not an expert prediction, and it certainly isn't proof of any fact. To the contrary, the evidence (all presented by Plaintiffs) showed that the Final Rule would diminish access to family planning services, in rural counties in particular, leaving individuals without access to high-quality affordable family planning care at all. ER 25, 30. In effect, HHS argues that it is entitled to deference as to its estimation of the respective harms the government and Plaintiffs will suffer. But HHS is not entitled to blind deference to its "intuition" regarding ***Plaintiffs'*** harm—to the contrary, it would be an abuse of discretion for the district court to defer to the agency "in its own equitable analysis." *Sierra*, 646 F.3d at 1185. Because HHS's claim is "implausible in light of the record" and unsupported by evidence, the district court correctly discounted it. *Nat'l Wildlife Fed'n*, 422 F.3d at 794.

C. The district court correctly found that the balance of harms and public interest tip sharply in Plaintiffs' favor

Where the government is party to a case in which a preliminary injunction is sought, the balance of the equities and public interest factors merge. *Drakes Bay Oyster Co. v. Jewell*, 747 F.3d 1073, 1092

(9th Cir. 2014). Here, the district court correctly found that the balance of hardships and the public interest tip sharply in favor of Plaintiffs. ER 32-33. As the district court found, the evidence showed that the Final Rule "threatens to impair the health and welfare of women who benefit from Title X-funded services and Plaintiffs' mission to provide quality healthcare." ER 32. Absent an injunction, the district court determined Plaintiffs would face "potentially dire" public health consequences, including an increased number of unintended pregnancies, leading to premature births, low-birth-weight infants and congenital defects; increased rates of abortion, STIs, and HIV; and higher instances of ectopic pregnancies, infertility cases, and reproductive cancers. ER 26, 32. These public health problems will adversely impact the general public, which the district court properly considered. *See Golden Gate Rest. Ass'n v. City & Cty. Of San Francisco*, 512 F.3d 112, 1126 (9th Cir. 2008) ("In considering the public interest, we may consider the hardship to all individuals covered by the [challenged law], not limited to parties . . .); *see also Stormans, Inc. v. Selecky,* 586 F.3d 1109, 1139 (9th Cir. 2009)("The general public has an interest in the health of state residents") (citations omitted).

Conversely, the only harm HHS asserted was its inability to "effectuat[e] statutes enacted by representatives of its people." ER 33; *see also* AOB at 45.[18] But the Final Rule is an agency regulation, not a statute. "There is generally no public interest in the perpetuation of an unlawful agency action." ER 33 (citing *League of Women Voters of United States v. Newby*, 838 F.3d 1, 12 (D.C. Cir. 2016)).

Essentially, HHS's position boils down to a claim that its harm trumps that of other litigants whenever it is prevented from carrying out its desired policy. Of course, as set forth above, Circuit precedent says otherwise. *See, e.g., Regents*, 908 F.3d at 500 (affirming injunction against termination of DACA program despite agency's "belief that DACA was unlawful"); *Rodriguez*, 715 F.3d at 1145 (balance of

[18] Though not raised in its opposition to Plaintiffs' motion for preliminary injunction, HHS now argues that the injunction imposes "significant administrative burdens" and "uncertainty" for the agency, precluding it from providing guidance to grantees about applicable program requirements. AOB at 45. That argument is waived because it was not raised below. *Whittaker Corp. v. Execuair Corp.*, 953 F. 2d 510, 515 (9th Cir. 1992). In any event, by this logic, the government would *always* suffer irreparable harm from a preliminary injunction blocking a change in agency policy. Further, HHS has issued guidance to grantees clarifying that Title X will continue to operate under the current regulations until all of the preliminary injunctions are lifted and HHS issues new guidance. EA.SER 26-30.

hardships favored plaintiffs where "[t]he government provide[d] almost no evidence that it would be harmed . . . other than its assertion that the order enjoins 'presumptively lawful' government activity"). Indeed, if HHS's position were adopted, "substantive relief against federal government policies would be nearly unattainable" because "government experts will likely [always] attest that the public interest favors the federal government's preferred policy." *Sierra*, 646 F.3d at 1186.

In any event, HHS offered no ***evidence*** of any hardship it would suffer if the injunction issued. ER 33. Where irreparable injury is weighed against zero evidence of hardship, the balance of hardships tips decidedly in Plaintiffs' favor. *Republic of the Philippines v. Marcos*, 862 F.2d 1355, 1362 (9th Cir. 1988). The district court did not abuse its discretion in so finding.

D. Plaintiffs raised serious questions as to whether the Final Rule is contrary to law

Where the balance of hardships and the public interest "tip sharply" in Plaintiffs' favor, injunctive relief is warranted if Plaintiffs show there are "serious questions going to the merits." *Alliance for the Wild Rockies v. Pena,* 865 F.3d 1211, 1216 (9th Cir. 2017) (quotations

omitted). Unlike the "likelihood of success on the merits" standard, "[s]erious questions need not promise a certainty of success, nor even present a probability of success, but must *involve* a fair chance of success on the merits." *Marcos*, 862 F.2d at 1362 (emphasis added) (quotations and citations omitted). The district court properly concluded that Plaintiffs *at least* raised serious questions on their claim that the Final Rule violates Section 1554 of the Affordable Care Act and the HHS Appropriations Act. ER 33.

1. The Final Rule violates the ACA

Section 1554 provides that the Secretary "shall not promulgate any regulation that creates "unreasonable barriers" or "impedes timely access" to care; "interferes with communications regarding a full range of treatment options between the patient and the provider"; "violates principles of informed consent"; or "limits the availability of" treatment. 42 U.S.C. § 18114.[19] The district court correctly found that the Final Rule likely violates each of these requirements. ER at 54.

[19] A federal district court judge in Texas recently held that the Affordable Care Act is unconstitutional. *Texas v. United States*, 340 F. Supp. 3d 579 (N.D. Tex. 2018). However, because that decision has been stayed pending appeal, *Texas v. United States*, 352 F. Supp. 3d 665, 690 (N.D. Tex. 2018), the ACA remains in effect and the Secretary must

The Final Rule's restrictions on abortion counseling and referral "interferes with communications regarding a full range of treatment options" for pregnant patients and "restricts the ability of health care providers to provide full disclosure of all relevant information to patients making health care decisions." 42 U.S.C. § 18114(3), (4). As the district court noted, the Final Rule would

> (1) permit a Title X project to give a patient who *specifically requests* a referral for abortion a referral list that contains *no* abortion providers; (2) require the project to compile a list of providers, a majority of whom are *not* responsive to the patient's request; (3) prevent[] the project from identifying which providers on the list *are* responsive to the patient's needs; and (4) *does not require the project to even alert the patient that the list is incomplete and nonresponsive*.

ER 50-51. By forcing providers to obfuscate the identity of available abortion providers, the Final Rule will require patients to investigate and identify such providers themselves, impeding "timely access to healthcare services" that the ACA seeks to protect. *See* C.SER 62-63, 152-53, 156-59, 170, 511-12, 579-82; EA.SER 15;.

The Final Rule's counseling and referral restrictions "are also squarely at odds with established ethical standards and therefore

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follow the requirements of Section 1554 in promulgating regulations under Title X.

Section 1554(5)." ER 52. They contradict HHS's own Quality Family Planning ("QFP") Guidelines, which provide that once a patient receives a positive pregnancy test, referral to appropriate providers "should be made at the request of the client" with "every effort" to "expedite" them. ER 52 (citing QFP Guidelines at 14). The American College of Obstetricians and Gynecologists confirms that physicians have an ethical obligation to give patients *all* information relevant to their treatment options. ER 52. This includes information regarding referrals. *See* C.SER 577-79; EA.SER 14-15. The "family participation" requirement likewise violates ethical standards. While Title X itself only asks grantees to encourage family participation "to the extent practical," 42 U.S.C. § 3000(a), the Final Rule goes farther in directing providers to document "specific actions" taken—even where doing so would force the provider to breach their ethical obligation and "drive some minors away from returning for critical health services." ER 54.

* * *

HHS does not seriously contend that the Final Rule is consistent with Section 1554, and rightly so. Instead, HHS advances a number of arguments that Section 1554 does not apply to the Final Rule. All fail.

First, HHS argues that Section 1554 cannot abrogate HHS's "pre-existing authority to adopt regulations that are materially indistinguishable from . . . the ones upheld in *Rust*." AOB at 32. But *Rust* didn't set all law governing HHS in stone. *Rust* held only that *as of 1991*, the Secretary's interpretation of Section 1008 was one "permissible construction" and did not "otherwise conflict with Congress' expressed intent." *Id.* at 184-85. In the 28 years since, Congress enacted Section 1554, which expressly limits the Secretary's authority. Congress may narrow the Secretary's authority—even if *Rust* earlier held that it could be read more broadly. *See FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 129, 143 (2000) ("Over time, . . . subsequent acts can shape or focus [the plausible] meanings" of a statute).

Second, HHS argues that because *Rust* effectively blesses the Final Rule, Section 1554 must evince Congress's "clear and manifest" intent to "erase the Secretary's pre-existing authority to adopt . . . materially indistinguishable" regulations. AOB 32. In other words, HHS argues that Congress needed to do more if it intended to "repeal" a once-permissible interpretation of the statute. That argument is inapposite

because the Title X statute and Section 1554 do not conflict. Questions of "implied repeal" are only triggered when "two statutes are in irreconcilable conflict or where the latter [a]ct covers the whole subject of the earlier one and is clearly intended as a substitute." *Branch v. Smith*, 538 U.S. 254, 273 (2003) (quotations and citations omitted. The district court correctly found the "implied repeal" analysis inapplicable here because there is no "irreconcilable conflict" between Section 1008 and Section 1554. ER 35. "The former forbids the use of Title X funds 'in programs where abortion is a method of family planning," whereas "the latter limits HHS's authority to promulgate any regulation which violates the principles of informed consent and ethical standards of medical professionals." ER 49. "Repeal is to be regarded as implied only if necessary to make the (later enacted law) work, and even then only to the minimum extent necessary. This is the guiding principle to reconciliation of the two statutory schemes." *See Radzanower v. Touche Ross & Co.*, 426 U.S. 148, 155 (1976). Here, the two statutes may be read in harmony.[20] The only possible tension between the two is that

[20] *National Association of Home Builders v. Defenders of Wildlife*, 551 U.S. 644, 664 (2007), on which HHS relies, is inapposite. AOB at 31. *Home Builders* involved two statutes that the Ninth Circuit interpreted

Section 1554 cabins discretion that the Secretary might have once had without it. But the Supreme Court has rejected the notion that a subsequent enactment narrowing the range of permissible constructions of an earlier statute is necessarily an implied repeal. *See United States v. Fausto*, 484 U.S. 439, 453 (1988) ("Th[e] classic judicial task of reconciling many laws enacted over time, and getting them to 'make sense' in combination, necessarily assumes that the implications of a statute may be altered by the implications of a later statute."). The Court should reject HHS's invitation to manufacture a conflict that does not exist.

Third, HHS argues that the Final Rule does not violate Section 1554 because "the Secretary's decision to fund childbirth but not abortion" leaves a woman seeking to terminate her pregnancy "'in no different position than she would have been if the Government had not enacted Title X.'" AOB 34 (citing *Rust*, 500 U.S. at 201-02). HHS's reliance on *Rust*'s disposition of *constitutional* claims is misplaced. *Rust* held that "Congress refusal to fund abortion counseling and advocacy"

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as irreconcilable. Here, HHS concedes the statutes at issue do not conflict.

did not impermissibly burden a woman's Fifth Amendment right to choose (*Rust*, 500 U.S. at 202); its constitutional analysis is inapposite here, where Plaintiffs claim the Final Rule violates Section 1554's far more specific statutory mandate. ER 50. Moreover, the district court found that "as a factual matter, the Final Rule's referral list restrictions go far beyond anything in the 1988 regulations"; "[u]nlike in *Rust*, the . . . Rule may well make patients *worse* off than if they had not sought help from a Title X project to begin with." *Id.* ER 50-51.[21] The Final Rule's affirmative misdirection of patients seeking care plainly violates Section 1554.

Finally, HHS argues that Plaintiffs waived any challenge to the Final Rule under Section 1554 because commenters did not specifically cite Section 1554 during rulemaking. Not so.[22] Comments that the Rule

[21] For this reason, among others, HHS is incorrect when it argues that the district court found "the challenged provisions of the Rule . . . materially indistinguishable from the 1988 regulations." AOB 22.

[22] "[T]he waiver rule does not apply to preclude argument where the scope of the agency's power to act is concerned." *Sierra Club v. Pruitt*, 293 F. Supp. 3d 1050,1061 (N.D. Cal. 2018). HHS does not contend it was unaware of Section 1554—nor could it, having addressed it in separate rulemaking contemporaneous with the Final Rule's notice-and-comment period. *See*, *e.g.*, Fed. Reg. 57536, 57552 (Nov. 15, 2018).

violates the ACA, creates "unreasonable barriers" and "impedes timely access" to care satisfied the exhaustion requirement. *See Nat'l Parks & Conservation Ass'n v. Bureau of Land Mgmt.*, 606 F.3d 1058, 1065 (9th Cir. 2010)(holding that exhaustion requirement is satisfied so long as the agency has sufficient notice of the issue raised, even if the plaintiffs do not state their claims in precise legal terms). The district court correctly found that these comments provided HHS "sufficient notice . . . to afford it the opportunity to rectify the [Section 1554] violations that the plaintiffs alleged." ER 44 [PI Order at 36]; *Native Ecosystems Counsel v. Dombeck*, 304 F.3d 886, 899 (9th Cir. 2002). At a minimum, Plaintiffs raised "at least a serious question" as to whether their claim has been adequately exhausted. ER 44-45.

2. The Final Rule violates the Health and Human Services Appropriations Act

The Final Rule also violates the HHS Appropriations Act, which requires that "all pregnancy counseling" in Title X projects "shall be nondirective." "Nondirective pregnancy counseling is the meaningful presentation of options where the [medical professional] is not suggesting one option over another." 84 Fed. Reg. at 7716. The district court correctly ruled that the Final Rule likely violates the non-directive

counseling mandate in three ways: (1) the prenatal referral requirement requires a Title X provider to refer a pregnant patient for prenatal care in all circumstances—regardless of the wishes of the patient or the medical judgment of her doctor (§ 59.14(b)(1));[23] (2) the categorical prohibition on abortion referral "prevents Title X projects from presenting abortion on an equal basis with other pregnancy options"; (ER 41-42); and (3) the referral list restrictions "cause confusion and delay" for a patient seeking care, and "does not place abortion on an equal basis" with other options. ER 42. HHS's arguments to the contrary are meritless.

First, HHS argues without support that the prohibition on abortion referral "does not *direct* the patient to do anything." AOB 24. But the mandatory prenatal-care-referral requirement certainly does. Moreover, HHS's myopic focus on the verb "direct" ignores that the agency's own definition of nondirective counseling requires the

[23] The Final Rule's reference to prenatal health care as "medically necessary" does not make it so. 84 Fed. Reg. 7714, 7761-62. Prenatal services are not medically necessary if a patient is terminating her pregnancy. C.SER 79-80. Requiring a patient who wishes to terminate her pregnancy to seek prenatal care only delays the treatment she seeks. *Id.*

meaningful presentation of options and not the suggestion of one option over another. Excluding all discussion of one option is the suggestion of one option over another. As the district court correctly held, "The categorical prohibition on [abortion] referrals . . . is ***not*** nondirective because it prevents Title X projects from presenting abortion on an equal basis with other pregnancy options." ER 41-42 (emphasis added). HHS itself states that if abortion were "the only option presented," the presentation would run afoul of the nondirective counseling mandate. 84 Fed. Reg. at 7747. That logic applies with equal force here.

Second, HHS insists that "nondirective provision is limited to 'pregnancy counseling,'" a "distinct" term that "does not apply to referrals." AOB 25. But Congress itself has "expressed its understanding" to the contrary. In the Public Health Service Act ("PHSA"), Congress directs HHS to make grants "providing adoption information *and referrals* to pregnant women on an equal basis with all other courses of action *included in nondirective counseling* to pregnant women" 42 U.S.C. § 254c-6(a)(1) (emphases added).[24]

[24] As the district court noted, the PHSA and the Appropriations Act seem to be the *only* instances in which Congress has used the term "nondirective counseling" – rendering the PHSA a crucial source for

HHS's response—pointing to other instances where Congress referred to "counseling" and/or referral" (conjunctively or disjunctively)—is unavailing. AOB at 25. Congress's occasional mention of counseling *and/or* referral does not excise referral from counseling's scope. Additionally, the statutes HHS cites—including an unrelated *criminal* code (AOB at 25 (citing 18 U.S.C. § 248(e)(5))—are far less relevant than the PHSA language on which the district court relied, which specifically discusses "nondirective counseling." Congress's *express* statement that "nondirective counseling" "includes" referrals controls. 42 U.S.C. § 254c-6(a)(1).[25]

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understanding the statutory meaning of the Appropriations Act term. *See, e.g.*, *Erlenbaugh v. United States*, 409 U.S. 239, 243 (1972) ("[A] legislative body generally uses a particular word with a consistent meaning in a given context.").

[25] HHS distorts this language, arguing that the term "included" modifies only the "other courses of action" and not "referrals." AOB 27. But that reading contradicts the statute's plain language, which requires HHS grantees to provide "adoption *information and referrals* . . . on an equal basis with *all other courses of action included in nondirective counseling*." 42 U.S.C. § 254c-6(a)(1)(emphasis added). As HHS concedes, "nondirective counseling," is about "neutral presentation of information." AOB at 9. Plainly, the "courses of actions included in nondirective counseling" encompass the provision of information *and* referrals.

Moreover, as the district court found, HHS itself characterizes referral as part of counseling. ER 37 (noting HHS incorporated "the [PHSA's] definition of 'nondirective counseling'" in interpreting Title X). The Final Rule clearly states that "Congress has expressed its intent that . . . adoption *information and referrals be included as part of any nondirective counseling* in Title X projects when it passed [§ 254c-6(a)(1)]." 84 Fed. Reg. at 7733 (emphasis added). HHS describes referrals as part of counseling throughout the Final Rule. *See id.* at 7730 ("[N]ondirective pregnancy counseling can *include* counseling on adoption, and corresponding *referrals* to adoption agencies.") (emphases added); 7733–34 ("Title X providers may provide adoption counseling, information, *and referral* . . . as part of nondirective postconception counseling . . . .") (emphasis added). These descriptions were not anomalies. "As early as 1981, HHS has defined counseling in its Title X Guidelines to include referral." ER 37-38. (citation omitted). That use is consistent with "the accepted usage within the medical field," and supports Plaintiffs' interpretation here. ER 38-39; *see also Louisiana Pub. Serv. Comm'n v. F.C.C.*, 476 U.S. 355, 357 (1986) ("[T]echnical terms of art should be interpreted by reference to the trade or industry

to which they apply") (citations omitted). Though HHS ignores this last point altogether, every relevant industry source—including HHS's own Title X guidelines—agree referral is part of counseling. ER 38-39.

Third, HHS's "implied repeal" argument is inapposite, because the Appropriations Act and Section 1008 can be read in harmony. *See* Section VII.D.1., above. HHS conceded this point below. ER 35 ("There is no conflict – much less an irreconcilable one – between Title X . . . and the nondirective provision").

* * *

The Final Rule violates the ACA and the Appropriations Act and mandates conduct that those laws were designed to thwart. The district court did not abuse its discretion in ruling that Plaintiffs are likely to succeed on the merits of their contrary to law claim, or at least raised "serious questions" going to the merits.

E. Plaintiffs raised serious questions as to whether the Final Rule is arbitrary and capricious

The district court correctly found that Plaintiffs not only raised a "serious question" as to whether the Final Rule is arbitrary and capricious, but that Plaintiffs are likely to succeed on their claim. ER 64

(*citing Encino Motorcars, LLC v. Navarro*, 136 S. Ct. 2117, 2126-27) (2016)). None of HHS's arguments withstands scrutiny.

1. Physical Separation

HHS contends that the district court erred in finding the physical separation requirement arbitrary and capricious given *Rust*'s blessing of similar requirements. AOB at 38. But *Rust* upheld the 1988 Regulations based on different justifications than those HHS now provides—specifically, the "critical reports of the General Accounting Office (GAO) and the Office of the Inspector General (OIG), that prior policy failed to implement properly the statute." 500 U.S. at 187; ER 55-56.[26] No similar reports supported the Final Rule, nor did HHS even cite in its rulemaking the 1980's reports provided in *Rust*. An agency "stands on shaky legal ground relying on significantly outdated data [to justify its actions]." *Sierra Club v. U.S. E.P.A.*, 671 F.3d 955, 966 (9th Cir. 2012). The district court correctly held that "[t]he justifications

[26] In this respect, HHS misstates *Rust*'s holding and misconstrues its import. *Rust* did not, as HHS now claims, "h[o]ld that HHS's predictive judgment about how best to comply with § 1008 was a reasonable basis for the [physical separation] requirement." AOB (citing *Rust*, 500 U.S. at 187). *Rust* says nothing about predictive judgments; it held that HHS "justified [its] change of interpretation with a 'reasoned analysis'" given these critical reports and other evidence. 500 U.S. at 187.

supporting the 1988 regulations upheld in *Rust* cannot insulate the Final Rule from review now, almost three decades later." ER 57. Instead, HHS must "examine the relevant data and articulate a satisfactory explanation for its action" in light of the current landscape. *See Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983).

It failed to do so. Instead, HHS relied on "speculative fears of theoretical abuse of Title X funds" to justify the separation requirement. ER 57. The district court found no "evidence in the record of *actual* co-mingling or misuse of Title X funds," ER 58, and HHS has not challenged that finding. Where there is "no evidence of a real problem," an agency action is arbitrary and capricious. *Nat'l Fuel Gas Supply Corp. v. F.E.R.C.*, 468 F.3d 831, 839-41 (D.C. Cir. 2006).

Moreover, HHS failed to even acknowledge its own findings in 2000 that physical separation requirements were unnecessary, "costly" and "medically unwise" (ER 62 (citing 65 Fed. Reg. at 41275-6))—much less provide the "detailed justification" required when an agency decision relies upon factual findings that contradict those underlying its

prior policy.[27] *F.C.C. v. Fox Television Stations Inc.*, 556 U.S. 502, 515 (2009). HHS contends that its "predictive judgment" is all the justification necessary. AOB at 38. But an agency's "predictive judgment" is entitled to deference only "[w]here scientific and technical expertise is necessarily involved." *Trout Unlimited*, 559 F.3d at 958; *see also Sorenson Commc'ns Inc. v. FCC*, 755 F.3d 702, 708 (D.C. Cir. 2014) (predictive judgments must "be based on some logic and evidence, not sheer speculation."). In *Trout Unlimited*, upon which HHS relies, the Court deferred to agency expertise because it was "convinced" the agency's decisions were "based upon the best scientific evidence available," including criteria identified by experts. 559 F.3d at 958. No such record exists here.[28] Although HHS cites the Final Rule's

[27] HHS cites *International Rehabilitative Sciences Inc. v. Sebelius* to argue that its radical policy changes are permissible. AOB 39 (citing 688 F.3d 994, 1001 (9th Cir. 2012)). But there, the agency explained the inconsistency in detail, noting specific deficiencies in studies on which it had previously relied. HHS provided no such explanation here.

[28] HHS's reliance on *BNSF Railway Company* is similarly misplaced. AOB 41. Unlike here, the agency in *BNSF* provided a *well-reasoned* prediction on a "hyper-technical" question about a hypothetical railroad. *BNSF Ry. Co. v. Surface Transp. Bd.*, 526 F.3d 770, 781 (D.C. Cir. 2008)).

"prediction" that "more clients [will be] served" under it, AOB 39, HHS offers only "intuition"—and no *evidence*—in support of that "prediction."

To the contrary, the district court found that HHS failed to engage with "substantial evidence" that physical separation "would create significant (and in many cases prohibitive) compliance costs, drastically reduce access to Title X services, and lead to serious disruptions in care." ER 65. HHS "ignored [the] consequential costs of compliance" (ER 67) and gave "no consideration to the disruption" physical separation would cause. ER 69. Exacerbating that disruption, the district court found that HHS's prior policy engendered "serious reliance interests" by Title X recipients, including Plaintiffs. ER 63-64. Citing ample record evidence, the district court details multi-year investments by Essential Access and its sub-recipients in physical infrastructure, programming, and records systems in reliance on HHS "consistently interpreting Section 1008 to require only financial separation for over a quarter a century." ER 63-65. The district court properly rejected HHS's justification that "physical collocation" of Title X projects and clinics that provide abortion care necessarily "impermissibly subsidize[s] abortion." AOB at 38. That logic ignores *Rust's* express distinction

between Title X *projects* and Title X *grantees*, *Rust*, 500 U.S. at 196, and "goes far beyond any rationale for physical separation approved in *Rust*." ER 60.

2. Counseling and Referral Restrictions

The district court also correctly found that Final Rule's restrictions on abortion counseling and referral are arbitrary and capricious because HHS's purported justification—that prior regulations conflict with federal conscience laws—is without merit. ER 70. As the district court ruled, other HHS regulations ensure Title X's implementation comports with the conscience laws, and in any event the conscience laws "do not provide a basis for HHS to bar *all* Title X grantees from providing abortion referrals." ER 70-71.

HHS's argument on appeal fares no better. It complains that the district court "completely ignored" the agency's real reason for the restrictions: "that the best reading of § 1008 is that a program that refers patients for abortion as a method of family planning . . . *is* a program 'where abortion is a method of family planning.'" AOB 37-38 (emphasis added). That *ipse dixit* fails to address HHS's 2000 justification for rescission of similar 1988 regulations on the grounds

that they "endanger women's lives and health," "interfere with the doctor-patient relationship" and "seem[ed] . . . inconsistent with the concerns underlying the nondirective counseling requirement." ER 71 (citing 65 Fed. Reg. at 41270-75). Nor has HHS provided the "more detailed justification" required under *Fox Television* when an agency significantly alters a longstanding prior regulatory scheme. *Id.*

3. "APP" and "Medically Approved" Requirements

The district court correctly found that Final Rule's requirement that nondirective pregnancy counseling be provided only by physicians or APPs, and elimination of the requirement that Title X-funded family planning methods be "medically approved" are arbitrary and capricious. Far from simply "substitut[ing] its views for the agency's," as HHS contends (AOB 42), the district court properly examined the record and found HHS failed to offer rational, record-based explanation for its policy reversals. *See Motor Vehicle Mfrs. Ass'n,* 463 U.S. at 42-43 (where the agency acts counter to record evidence or offers no "reasoned analysis" for its action, the rulemaking is invalid).

On the "advanced practice provider" requirement, the district court found that HHS "cannot point to any part of the Final Rule where

HHS explains *why* [APPs] are necessary to qualify someone to provide pregnancy counseling." ER 72. In fact, the record reveals that HHS failed to address "voluminous evidence that non-APP personnel" have long been capably provided such counseling." *Id*. An agency's failure to "articulate a satisfactory explanation for its action" renders the action arbitrary and capricious. *Id*. (citing *State Farm*, 463 U.S. at 43). Here, HHS failed to articulate any explanation at all.

HHS's elimination of the requirement that Title X-funded family planning methods be "medically approved" meets a similar fate. HHS's lone justification for removing the language was that it "risked creating confusion" about what kind of "approval" satisfied the requirement. ER 73. But the district court found that HHS "[could not] identify a single instance in the eighteen years" the regulation was in effect where an entity expressed such confusion, and numerous commenters confirmed the term is well-understood. *Id*. The district court thus properly found that HHS's purported explanation "runs counter to the evidence before [it]." *Motor Vehicles Mfrs. Ass'n,* 463 U.S. at 43.

* * *

The district court correctly concluded that HHS repeatedly failed to provide evidence of an actual problem or any reasoned justification for the Final Rule's onerous requirements and reversals of long-standing policies. The district court did not abuse its discretion in ruling that Plaintiffs are likely to succeed on the merits of their arbitrary and capricious claim, or at least raised "serious questions" going to the merits.

F. The injunction is not overbroad

Finally, HHS argues that the preliminary injunction is overbroad because the Final Rule is severable but the district court nonetheless enjoined most provisions. AOB 46. But the district court specifically considered which provisions of the Final Rule to invalidate; narrowly tailored the injunction to exclude the provisions it determined were unchallenged; and limited the scope of the injunction to California. ER 3-4, 84-86. Save for one provision (which HHS failed to raise below), HHS fails to identify which provisions were erroneously enjoined. This Court should not engage in an analysis of each provision of the Final Rule in the first instance. HHS's request to vacate the injunction as to unidentified portions of the Final Rule should be denied.

VIII. CONCLUSION

For the foregoing reasons, the Court should affirm the district court's preliminary-injunction order.

Dated: July 1, 2019

Respectfully submitted,

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STATEMENT OF RELATED CASES

Counsel for Plaintiffs are aware of 3 related cases pending in the Ninth Circuit:

- *State of California v. Alex Azar II & Dep't v. Health & Human Serv.*, Case No. 19-15974 (consolidated with this case)
- *State of Oregon, et al. v. Alex Azar II, et al. & Am. Med. Ass'n, et al. v. Alex Azar II, et al.*, Case No. 19-35386
- *State of Washington, et al. v. Alex Azar II, et al.*, Case No. 19-35394

These cases are related to this action because they raise the same or closely related issues and involve the same unlawful events.

Dated: July 1, 2019

s/Michelle S. Ybarra
MICHELLE S. YBARRA

CERTIFICATE OF COMPLIANCE

I certify that this brief contains 11,436 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(f). The brief's type size and typeface comply with Fed. R. App. P. 32(a)(5) and (6). I certify that this brief complies with the word limit of Cir. R. 32-1.

Dated: July 1, 2019

s/Michelle S. Ybarra
MICHELLE S. YBARRA

CERTIFICATE OF SERVICE

I hereby certify that on July 1, 2019, I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Ninth Circuit by using the appellate CM/ECF system.

I certify that all participants in the case are registered CM/ECF users and that service will be accomplished by the appellate CM/ECF system.

s/Michelle S. Ybarra
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