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IN THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

STATE OF CALIFORNIA, by and through ATTORNEY GENERAL XAVIER BECERRA, Plaintiff, **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.	3:19-cv-01184-EMC **CALIFORNIA'S REPLY IN SUPPORT OF MOTION FOR PRELIMINARY INJUNCTION** Administrative Procedure Act Case Date: April 18, 2019 Time: 12:30 p.m. Dept: Courtroom 5, 17th Floor Judge: The Honorable Edward M. Chen Trial Date: Not set Action Filed: March 4, 2019

TABLE OF CONTENTS

Page

INTRODUCTION 1

ARGUMENT 1

I. California is Likely to Succeed on the Merits 1

A. California's Lawsuit is Not Foreclosed by *Rust v. Sullivan*. 1

B. HHS' Interpretation of the Non-Directive Mandate Is Unreasonable. 4

C. Section 1554 Applies to the Final Rule. 5

1. California Has Not Waived its ACA Claim 5

2. Defendants' Attempts to Evade Section 1554 are Unavailing. 6

D. *Rust* Does Not Speak to the Final Rule's Additional Provisions that are in Excess of Statutory Jurisdiction 9

E. California's Arbitrary and Capricious Claim Is Not Foreclosed By *Rust* 10

II. California Has Shown Serious, Unrebutted Evidence of Likely, Imminent Harm Caused by the Final Rule 12

III. Issuing an Injunction to Preserve the Status Quo Would Properly Balance the Equities and Serve the Public Interest. 14

IV. A Nationwide Injunction is Necessary to Redress the Likely Injury Shown. 14

CONCLUSION 15

TABLE OF AUTHORITIES

Page

CASES

Abbott Laboratories v. Gardner
387 U.S. 136 (1967) 14, 15

All. for the Wild Rockies v. Cottrell
632 F.3d 1127 (9th Cir. 2011) 12

Ass'n of Am. R.R. v. S. Coast Air Quality Mgmt. Dist.
622 F.3d 1094 (9th Cir. 2010) 2, 8

California v. Azar
911 F.3d 558 (9th Cir. 2018) 13, 14, 15

California v. Health and Human Servs.
351 F.Supp.3d 1267 (N.D. Cal. 2019) 13

Citizens to Preserve Overton Park, Inc., v. Volpe
401 U.S. 402 (1971) 8

Comm'r v. Engle
464 U.S. 206 (1984) 4

Douglas v. Indep. Living Ctr.
565 U.S. 606 (2012) 14

Earth Island Inst. v. Ruthenbeck.
490 F.3d 687 (9th Cir. 2007) 14

Encino Motorcars, LLC v. Navarro
136 S. Ct. 2117 (2016) 11

F.C.C. v. Fox Television Stations, Inc.
556 U.S. 502 (2009) 11

F.C.C. v. NextWave Personal Commc'ns, Inc.
537 U.S. 293 (2003) 8, 11

Great Basin Mine Watch v. Hankins
456 F.3d 955 (9th Cir. 2006) 5

Hecht Co. v. Bowles
321 U.S. 321 (1944) 14

Indep. Living Ctr. of S. Cal. v. Maxwell-Jolly
572 F.3d 644 (9th Cir. 2009) 14

TABLE OF AUTHORITIES
(continued)

Page

Jicarilla Apache Nation v. U.S. Dep't. of Interior
613 F.3d 1112 (D.C. Cir. 2010) 11

Klamath-Siskiyou Wildlands Cir. v. Nat'l Oceanic and Atmospheric Admin.
109 F.Supp.3d 1238 (N.D. Cal. 2015) 14

Lands Council v. McNair
629 F.3d 1070 (9th Cir. 2010) 6

Morton v. Mancari
417 U.S. 535 (1974) 2, 3

Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto Ins. Co.
463 U.S. 29 (1983) 1, 12

Nat'l Ass'n of Home Builders v. Defs. of Wildlife
551 U.S. 644 (2007) 7

Nat'l Fuel Gas Supply Corp. v. FERC
468 F.3d 831 (D.C. Cir. 2006) 11

Nat'l Mining Ass'n v. U.S. Army Corps of Eng'rs,
145 F.3d 1399 (D.C. Cir. 1998) 14

Nat'l Parks & Conservation Ass'n v. Bureau of Land Mgt.
606 F.3d 1058 (9th Cir. 2010) 5

NW Enviro. Defense Ctr. v. Bonneville Power Admin.
477 F.3d 668 (9th Cir. 2007) 15

RadLAX Gateway Hotel, LLC v. Amalgamated Bank
566 U.S. 639 (2012) 7

Rust v. Sullivan
500 U.S. 173 (1991) ..... *passim*

Sierra Club v. Pruitt
293 F.Supp.3d 1050 (N.D. Cal. 2018) 6

U.S. v. Novak
476 F.3d 1041 (9th Cir. 2007) 3

Universal Health Servs. v. Thompson
363 F.3d 1013 (9th Cir. 2004) 6

TABLE OF AUTHORITIES
(continued)

Page

Vimar Seguros y Reaseguros, S.A. v. M/V Sky Reefer
515 U.S. 528 (1995) 3

STATUTES

5 U.S.C. § 706(2) 15

42 U.S.C.
§ 254c-6(a)(1) 4
§ 300(a) 10
§ 300a-6 ..... *passim*
§18114 ..... *passim*
§ 18115 8
§ 18116 8

Administrative Procedure Act ..... *passim*

Affordable Care Act ..... *passim*

Pub. L. No. 91-572 § 2, 84 Stat. 1504 (1970) 10

Public Health Services Act 8

OTHER AUTHORITIES

42 C.F.R. § 59.18(a) 10

83 Fed. Reg. at 57,552 6

84 Fed. Reg. at 7,778 15

84 Fed. Reg. at 7,730 4

84 Fed. Reg. at 7,745 3

84 Fed. Reg. at 7,774 11

Black's Law Dictionary 4

INTRODUCTION

Defendants have issued a Final Rule that will cause serious harm to the State of California and have devastating impacts on the lives of its residents in need of high-quality preventive healthcare, reproductive and sexual care. The "benefits to individual and public health achieved by the Title X program over decades will be undone," and the Final Rule will "gravely harm low-income women and families who are already medically underserved, and exacerbate existing public health challenges and health disparities." Brindis Decl. ¶¶ 93, 94. Nothing in Defendants' opposition rebuts Plaintiff's extensive evidence documenting the harm the Final Rule will cause.

Instead, Defendants ground their opposition on the Supreme Court's decision in *Rust v. Sullivan*, 500 U.S. 173 (1991), which upheld similar (though not identical) regulations issued in 1988. But the laws, and the facts, have evolved since that decision. Defendants do not make a serious attempt—either in their rulemaking or in their opposition—to grapple with these changes. As a result, Defendants are in violation of the Administrative Procedure Act (APA), which requires, *inter alia*, that an agency "examine the relevant data and articulate a satisfactory explanation for its action." *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto Ins. Co*., 463 U.S. 29, 43 (1983). Because Plaintiff is likely to succeed on its APA claims, because of the imminent, irreparable harm that will occur if the Final Rule takes effect, and because the public interest tips sharply in Plaintiff's favor, the Court should grant Plaintiff's motion for a preliminary injunction.

ARGUMENT

I. CALIFORNIA IS LIKELY TO SUCCEED ON THE MERITS

A. California's lawsuit is not foreclosed by *Rust v. Sullivan*.

Throughout their opposition, Defendants rely heavily on *Rust v. Sullivan*, an approach that is fundamentally misguided because it overgeneralizes the Supreme Court's holding in *Rust*, mischaracterizes Plaintiff's legal claims (which do not require the Court to act contrary *Rust* or to repeal Section 1008), and fails to acknowledge that later Congressional acts have affected the scope of Title X and HHS's rulemaking authority.

To begin, Plaintiff acknowledges that *Rust* never held that the 1988 regulations were a necessary or mandatory interpretation of Section 1008; if it had, HHS's subsequent rulemaking, undoing the 1988 regulations and replacing them with the regulatory scheme in place for the last two decades, would have been contrary to law. The Supreme Court held only that the language of Section 1008, which provides that "none of the funds appropriated under this subchapter shall be used in programs where abortion is a method of family planning," is ambiguous, and thus Defendants' interpretation must be upheld if it is "a plausible construction of the plain language of the statute and does not otherwise conflict with Congress' expressed intent." 500 U.S. at 184. The Court concluded (contrary to Defendants' suggestion, ECF 61 at 4), that the legislative history "fails to shed light on relevant congressional intent," because "at no time did Congress directly address the issues of abortion counseling, referral, or advocacy." 500 U.S. at 185. With respect to the *Rust* plaintiffs' APA claims, the Supreme Court concluded only, "*we are unable to say that the Secretary's construction* of the prohibition in § 1008 to require a ban on counseling, referral, and advocacy within the Title X project *is impermissible*," and that the separation requirements were "not inconsistent with congressional intent." *Id.* at 184, 189 (emphasis added).

Defendants repeatedly refer to Plaintiff's argument as that of "implied repeal," but this is a misnomer designed to shift the legal burden away from Defendants. Plaintiff is *not* arguing that either Congress' nondirective counseling mandate or Section 1554 of the Affordable Care Act (ACA)'s ban on regulations that create barriers to care have repealed Section 1008. Instead, Plaintiff argues that subsequent laws have foreclosed one interpretation of Section 1008 that HHS adopted for a short period of time, which the Supreme Court found was a permissible (but not a necessary) interpretation of that law.

When confronted with two acts of Congress touching on the same topic, courts are not at "liberty to pick and choose among congressional enactments" and must instead strive "'to give effect to both.'" *Morton v. Mancari*, 417 U.S. 535, 551 (1974); *see also Ass'n of Am. R.R. v. S. Coast Air Quality Mgmt. Dist.*, 622 F.3d 1094, 1097 (9th Cir. 2010) (when two federal laws purportedly conflict, courts must strive to harmonize the two laws). A party seeking to determine that two statutes cannot be harmonized, and that one displaces the other, bears the heavy burden

of showing "'a clearly expressed congressional intention'" that such a result should follow. *Vimar Seguros y Reaseguros, S.A. v. M/V Sky Reefer*, 515 U.S. 528, 533 (1995). The intention must be "'clear and manifest.'" *Morton*, 417 U.S. at 551.

Here, it is Plaintiff's claims that present the Court with an opportunity to harmonize Title X's original provision with later Congressional enactments, and Defendants' Final Rule that (unnecessarily) creates conflict. After *Rust*, Congress clarified an ambiguity that the Supreme Court had identified: whether Section 1008's prohibition on funding of abortion services (which are not, and never have been, covered by Title X) encompass services that may present or refer for abortion in the course of providing counseling (which has almost always been covered by Title X, notwithstanding HHS's attempt to disallow it in the short-lived 1988 regulations). *Rust* upheld an interpretation that Section 1008 prohibited not just provision of abortion services, but also counseling regarding abortion, including neutral presentation of potential care options and referrals for abortion. Defendants make no showing or convincing argument that if either the non-directive mandate or Section 1554 had been in place at the time *Rust* was decided, the Supreme Court would have reached the same decision.

Defendants' arguments that the nondirective mandate or Section 1554 should not be interpreted to "smuggle […] a major change on a highly controversial topic," ECF No. 61 at 2, would be much more compelling if either of these provisions *had* wrought a major change in Title X practice. But by the time Congress enacted these laws, HHS had already fully repealed the 1988 regulations. Instead, these measures confirmed and preserved a status quo that for many decades has embodied federal lawmakers' compromise with respect to women's health, forbidding federal funding for abortion while simultaneously allowing low-income women to be connected to such services according to strict medical ethics principles of neutrality and informed consent. Defendants elsewhere acknowledge, as they must, that a return to the 1988 Rule is impossible because the nondirective mandate *has* changed the law.[1] *See* 84 Fed. Reg. at 7745

[1] The fact that the nondirective mandate is a stripped-down alternative to earlier legislation vetoed in 1992 by then-President George Bush does not mean that Congress' subsequent repeated, successful attempts to mandate nondirective counseling is a significantly different enactment. Neither piece of legislation was attempting to repeal Section 1008, and so *U.S. v. Novak*, 476 F.3d 1041, 1071 (9th Cir. 2007) is inapposite.

(noting that "[s]ince that time [1988], […] Congress has contemplated that nondirective pregnancy counseling may be offered in Title X projects"). It is the Final Rule that constitutes a "major change on a highly controversial topic."

B. HHS' interpretation of the non-directive mandate is unreasonable.

Additional questions about whether the Final Rule is contrary to law should be interpreted according to normal canons of judicial interpretation. Statutory terms must not be interpreted in isolation, but rather must be interpreted in the context of the whole statute in the manner "most harmonious with its scheme and with the general purposes that Congress manifested." *Comm'r v. Engle*, 464 U.S. 206, 217 (1984).

In this case, Congress has already indicated that it considers both provision of information and referrals to be part of the act of "nondirective counseling." *See, e.g.*, 42 U.S.C. § 254c-6(a)(1) (providing that "adoption information and referrals" should be included "with all other courses of action included in nondirective counseling"). At many points throughout the Final Rule, Defendants confirmed their own understanding that referrals are part of counseling. *See, e.g.*, 84 Fed. Reg. at 7730 ("nondirective pregnancy counseling can include counseling on adoption, and corresponding referrals"), 7733-34 ("Title X providers may provide adoption counseling, information, and referral […] as part of nondirective postconception counseling"). And as Plaintiff explained in its motion for a preliminary injunction, previous HHS rules and guidance incorporated a well-accepted definition of non-directive counseling. In conjunction with the Centers for Disease Control and Prevention (CDC), HHS issued the evidence-based Quality Family Planning guidelines, considered "the standard of care for all family planning practitioners." Brindis Decl. ¶¶ 16-17. These guidelines delineate clinically appropriate practices that fall within the definition of "nondirective counseling," including prompt referrals that respect patients' wishes. *Id.* Ex. C, p. 14; Kost Decl. ¶ 25. Defendants now resort to Black's Law Dictionary as an authority for the proposition that "counseling" does not include a referral. ECF No. 61 at 17. Comments show that this interpretation is untethered to actual medical practice. *See, e.g.*, Rich Decl. Ex. G (ACOG Letter) p. 3, 5; Ex. I (AMA Letter), p. 3, Ex. J.

(ACNM Letter), p. 2. Defendants' reliance on this source undercuts any claim to expertise that the agency might otherwise make.

Defendant complains that Plaintiff "does not explain why" the Final Rule inhibits "respectful, client-centered counseling." ECF at 29. In fact, Plaintiff addressed this point at length, explaining that the Final Rule has undone the CDC recommendations for providing high-quality patient care options by, for example, requiring Title X providers to direct patients toward prenatal services, regardless of the patient's choices; doubling down and refusing to provide a patient's requested abortion referral; mandating inaccurate and/or misleading post-conception referral lists; offering non-medically approved contraceptive methods; etc. *See* Pl.'s Mot. for Prelim. Inj., at 6-7, 8-9, 11-12. Defendants' characterization of mandatory referrals for all pregnant patients for prenatal care—even patients who have clearly expressed their choice to obtain an abortion—as the provision of "information or medically necessary services," see ECF No. 61 at 10, illustrates Defendants' willful misunderstanding of what respectful, client-centered counseling entails. Prenatal care is not "medically necessary" for patients who have clearly expressed their choice to obtain an abortion. No reasonable interpretation of the nondirective counseling mandate can encompass Defendants' construction.

C. Section 1554 applies to the Final Rule.

1. California has not waived its ACA claim

Rather than addressing the provision on its merits, Defendants rely on two out-of-circuit cases for the proposition that Plaintiff has waived this claim. But the Ninth Circuit cautions that this prudential requirement "should be interpreted broadly;" plaintiffs "need not state their claims in precise legal terms, and need only raise an issue 'with sufficient clarity to allow the decision maker to understand and rule on the issue raised.'" *Nat'l Parks & Conservation Ass'n v. Bureau of Land Mgmt.*, 606 F.3d 1058, 1065 (9th Cir. 2010) (quoting in part *Great Basin Mine Watch v. Hankins*, 456 F.3d 955, 968 (9th Cir. 2006).

Plaintiff and many other commentators put Defendants fully on notice during the comment process that the Final Rule would violate elements of Section 1554 by creating unreasonable barriers to care, impeding timely access to services, interfering with communications between

provider and patient, violating principles of informed consent and ethical standards, and limiting the availability of healthcare treatment. Numerous commenters stated that the Final Rule violated the Affordable Care Act, although as far as Plaintiff can determine, none cited Section 1554 specifically. The fact that Plaintiff's argument is "more fully developed" during litigation does not mean that Plaintiff waived its claim, as long as Defendants were on notice of the issues. *Lands Council v. McNair*, 629 F.3d 1070, 1076 (9th Cir. 2010). Defendants do not claim actual surprise in their waiver argument; indeed, they cannot, as HHS analyzed Section 1554 in its recent rulemaking regarding the contraceptive coverage mandate. *See* 83 Fed. Reg. 57552 (Nov. 15, 2018). In disregarding this statutory provision, Defendants failed in their basic obligation to examine their legal authority to act. *See Sierra Club v. Pruitt*, 293 F.Supp.3d 1050, 1061 (N.D. Cal. 2018) (rejecting agency's waiver argument where agency was presented with sufficient challenges to its behavior and still failed to fulfill its "obligation to examine its own authority").

To the extent Defendant believes that Plaintiff and other commenters' extensive comments were not specific enough to put Defendants on notice, this disadvantage was self-inflicted. Attorney General Xavier Becerra informed Defendants via letter that the 30-day comment period was inadequate for Plaintiff and others to conduct a sufficiently thorough review of the proposed rule; Defendants effectively denied this request. Complaint ¶ 80. If the Court finds that Plaintiff has waived its right to bring a claim based on Section 1554 of the Affordable Care Act, Plaintiff respectfully suggests that this is a case involving "exceptional circumstances" in which the interests of the plaintiffs to find redress outweigh "the agency's interests in applying its expertise, correcting its own errors, making a proper record, […] and maintaining an administrative process free from deliberate flouting." *Universal Health Servs. v. Thompson*, 363 F.3d 1013, 1021 (9th Cir. 2004). Defendants show no interest in correcting the Final Rule so as to avoid violation of Section 1554, suggesting that any comments raising it would have been futile.

2. Defendants' attempts to evade Section 1554 are unavailing.

Defendants' additional attempts to evade Section 1554 are similarly unavailing. Congress was very clear in its directive: the Secretary "*shall not promulgate any regulation*" that creates unreasonable barriers, impedes timely access, interferes with communications regarding a full

range of treatment options between the patient and provider, and so forth. 42 U.S.C. § 18114 (emphasis added). Defendants do not claim that Section 1554 is unclear; Defendants largely ignore the language of this statutory provision. Instead, Defendants claim, with no direct evidence, that Congress implicitly excluded Title X from Section 1554. Yet Section 1554 is consistent with HHS regulations interpreting Title X at the time the ACA was passed (and for a long time prior); it follows Congress' successful and repeated clarification of Title X through the nondirective mandate. The lack of enlightening legislative history merely places it in the same category as Section 1008.

HHS does not attempt to make a statutory construction argument. Instead, it merely says that the more general language of Section 1554 must give way to the more specific language in Section 1008. But what is missing from this analysis is an acknowledgement that Section 1008 is not Congress' last word on the scope of Title X; the non-directive mandate is. Plaintiff agrees that Sections 1554 and 1008 are not in "irreconcilable conflict," and that it neither "covers the whole subject" of Section 1008 nor "is clearly intended as a substitute." *Nat'l Ass'n of Home Builders v. Defs. of Wildlife*, 551 U.S. 644, 663 (2007). Defendants note that the "specific governs the general," but this statutory canon is only relevant where a general permission is contradicted by a specific prohibition or permission, or where one statute renders another superfluous. *See RadLAX Gateway Hotel, LLC v. Amalgamated Bank*, 566 U.S. 639, 645 (2012) (noting that the general/specific canon is most frequently applied to contradictory statutes, but also applies to situations where the general would render the specific superfluous). Sections 1008 and 1554 are neither. Section 1554 does not disrupt the basic rule that Section 1008 does not cover abortion, but it does put new limitations on HHS's rulemaking ability, in terms that place the Final Rule outside of Defendants' legal authority. The Final Rule violates that directive by expressly denying Title X patients access to abortion information and referrals by making the former optional, and the latter forbidden, and by steering patients toward prenatal care, regardless of their choice. Congress had already signaled its departure from the *Rust*-era regulations when it enacted the nondirective mandate, and Section 1554's objectives (while not specific to Title X) are even more explicit and specific. To the extent that two federal laws purportedly conflict,

agencies and courts should strive to harmonize the two laws. *Ass'n of Am. R.R. v. S. Coast Air Quality Mgmt. Dist.*, 622 F.3d 1094, 1097 (9th Cir. 2010). In this case, a demonstration of harmony already exists, in the form of the Title X regulations that Defendants enacted in 2000.

Section 1554 was enacted as part of the ACA, not the Public Health Services Act, but this does not necessarily limit its scope. Section 1554 falls within a subchapter that contains a number of miscellaneous provisions that apply to various federally funded health programs. *See, e.g.*, 42 U.S.C. § 18116 (prohibiting discrimination in "any health program or activity, any part of which is receiving Federal financial assistance"). In another adjacent provision, guaranteeing the freedom "not to participate in Federal health insurance programs," Congress specified that the provision was limited to "health insurance program created under this Act (or amendments made by this Act)." 42 U.S.C. § 18115. Such explicit targeting of otherwise generally-worded ACA provisions indicate that a comparable, implicit targeting should not be inferred. *See, e.g.*, *F.C.C. v. NextWave Personal Commc'ns, Inc.*, 537 U.S. 293, 302 (2003) (exception not inferred when Congress had clearly and expressly created other exceptions). That Section 1554 applies "notwithstanding any other provision of this Act [the ACA]" is not relevant; the plain language simply suggests that Defendants should not engage in this type of rulemaking even if another provision of the ACA could be interpreted as permitting them. Defendants offer no other affirmative support for their interpretation that Section 1554 should apply narrowly.

Defendants do claim that Section 1554 is so broadly drawn that it is unreviewable; in other words, that it is one of "those rare instances where 'statutes are drawn in such broad terms that in a given case there is no law to apply." *Citizens to Preserve Overton Park, Inc., v. Volpe*, 401 U.S. 402, 410 (1971). To the contrary, the conditions set forth in 1554 are clear and specific, and Defendants fail to identify any relevant caselaw in which a court found a comparable statute to be unreviewable. Defendants were obliged to take this law into account when engaging in rulemaking affecting access to healthcare services, but they did not.[2]

[2] The lack of legislative history means that the Court must limit its inquiry to the statutory text and the reasonableness of Defendants' interpretation. It is not reasonable because Defendants have acknowledged that Title X is a crucial part of how women access contraceptive services—indeed, in other litigation, Defendants are relying upon the existence of Title X in order to evade liability for violation of Section 1554. Cantwell Decl. ¶ 31.

Defendants import language from *Rust* to justify their position that the Final Rule "denies nothing" because it places no restrictions on individuals or providers outside of Title X programs. ECF No. 61, at 21. But that portion of *Rust* pertained to the question of whether the 1988 regulations impermissibly burdened constitutional rights, not whether Defendants had issued regulations in line with the statue. Focusing on the latter question, and reading Section 1008 and Section 1554 together—as Defendants should have done, and as the Court must do— reveals that Congress no longer intended to allow regulations that deliberately interfere with the patient-provider relationship, as the gag rule does, or that create new barriers that impede access to care, as the separation requirements do. Furthermore, many aspects of the Final Rule, most egregiously the new separation requirements, are simply about Defendants' attempt to promote an appearance of separation, rather than what Title X will or won't fund. As the administrative record makes clear, the gag and separation requirements, which the Supreme Court never found to be mandatory, will have a substantial impact on timely access to reproductive healthcare services, by pushing out convenient and highly-qualified Title X providers. *See, e.g.*, Brindis Decl. Ex. B, p. 2-3. This is clearly contrary to Section 1554.

Ultimately, Defendants never offer a construction of Section 1554 that can be reconciled with the Final Rule, effectively conceding that if Section 1554 applies to their current rulemaking effort, then the Final Rule is invalid.

D. *Rust* does not speak to the Final Rule's additional provisions that are in excess of statutory jurisdiction

California's complaints regarding some of the novel aspects of the Final Rule—specifically, the removal of the requirement that Title X programs offer "medically approved" methods of contraception, the prohibition on so-called "infrastructure building," and the new restrictions on communications with adolescent patients—are also not foreclosed by *Rust*.

In addition to the problems with the gag and separation provisions, discussed above, Plaintiff identified a number of other aspects of the Final Rule that remove or weaken Title X's requirement that programs provide "a broad range of acceptable and effective family planning methods and services," 42 U.S.C. § 300(a), that services be comprehensive, and that they be

voluntary. Plaintiff agrees that these core statutory requirements predate *Rust*, but, as described in Section I(B-C) above, Congress has since clarified the scope of Defendants' authority to interpret Title X. Moreover, the Final Rule introduces numerous new provisions that the Supreme Court has never considered, including the ban on so-called building "infrastructure," 42 C.F.R. § 59.18(a), that requires, for example, that the majority of grant funds must be spent on "direct services," ignoring and in some cases disparaging the many uses of funds that help connect patients to family planning services, or that increase the provider's expertise and capacity to provide those services. This provision is not authorized by Section 1008, and therefore *Rust* is irrelevant. The ban on clinicians without graduate degrees, and the elimination of the requirement that contraceptive services be "medically approved," are likewise divorced from text and express purpose of Title X, in which Congress demonstrated its commitment to quality and evidence-based care. *See* Pub. L. No. 91-572 § 2, 84 Stat. 1504 (1970).

E. California's arbitrary and capricious claim is not foreclosed by Rust

Defendants again rely heavily on *Rust* to negate Plaintiff's strong showing of a likelihood of success on the merits of their arbitrary and capricious claim. Dkt. No. 61 at 24-26. But Defendants make no attempt to address the differences between the administrative record before the Supreme Court in *Rust* and the record before this Court today. The Supreme Court's rejection of the *Rust* plaintiffs' arbitrary and capricious claim rested in crucial part on a finding that the Secretary had "amply justified his change of interpretation" "in the wake of 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. No comparable evidence exists in the record today; indeed, the record shows that the safeguards enacted in the 2000 regulations, as well as the diligent efforts of Title X grantees (described in Rabinovitz Decl. ¶¶ 16-20), have resulted in no misuse or improper commingling of Title X funds.

Instead, Defendants' justification relies primarily on incorrect public perceptions of how Title X funds are used in order to support their claims that the long-standing Title X regulations have created uncertainty and confusion, and failed to effectuate policy faithfully, perceptions

actively created by opponents of women's healthcare.[3] The alleged "environment of ambiguity" has been fostered by Defendants' own errors, such as its conclusion that organizations that engage in activities like condom distribution equate to "support for the abortion business"—without citing evidence that those organizations even provide abortions. 84 Fed. Reg. at 7774. *See Nat'l Fuel Gas Supply Corp. v. FERC*, 468 F.3d 831, 841 (D.C. Cir. 2006) (holding agency rule arbitrary and capricious where alleged record of abuse indicates "no evidence of a real problem").

Defendants contend that the Final Rule's discussion of their abrupt change of course is adequate. Dkt. No. 61 at 27-34. But the Final Rule contains no meaningful discussion that would discredit their prior evidence-based policy, including the CDC Quality Family Planning guidelines, or for their creation of the Final Rule. Defendants accuse California of simply not liking Defendants' conclusion, but in fact Defendants fail to realize the serious reliance interests at stake. Those interests require Defendants to provide a more "detailed justification" of their change of policy. *F.C.C. v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009); *Jicarilla Apache Nation v. U.S. Dep't. of Interior*, 613 F.3d 1112, 1119 (D.C. Cir. 2010) (holding that an agency that neglects to explain its departure from established precedent acts arbitrarily and capriciously). A detailed justification is also required here because the new policy "rests upon factual findings that contradict those which underlay its prior policy." *F.C.C.* at 515. *F.C.C.* requires that Defendants not only explain their current position, but also *why* they have changed from their prior position. Simplistic recitation of what some "commenters believe" is insufficient.

In any event, Plaintiff's arbitrary and capricious claim goes far beyond a mere lack of empirical evidence to support Defendants' conclusion (although Defendants identify none), but to the disregard for empirical evidence that the Final Rule will have perverse consequences. The Final Rule demonstrates an awareness of Defendants' change in policy yet fails to recognize the consequences of that reversal of course or to provide a sufficiently reasoned explanation for "why [they] deemed it necessary to overrule [their] previous position." *Encino Motorcars, LLC v.*

[3] *See, e.g.*, ECF No. 76, Am. Br. of Susan B. Anthony Center at 5 (claiming that "there has been widespread violation of Section 1008" without identifying a single instance of alleged misuse of Title X funds).

Navarro, 136 S. Ct. 2117, 2126 (2016). As a result, the Rules are arbitrary, capricious, and "cannot carry the force of law." *Id*. at 2127.

Defendants complain that "no reasonable reader" would interpret an ectopic pregnancy as the exclusive example of a medical emergency warranting an abortion, but in fact, the mainstream medical opinion about when an abortion is "medically necessary" appears very different than that described in the Final Rule. Rich Decl. Ex. M (PPFA Letter), p. 22. Given that Defendants have chosen not to align the Final Rule with accepted medical practice, it is quite reasonable for practitioners to conclude that they may place federal funding at risk when engaging in referrals that they deem medically necessary, but Defendants do not. Marshall Decl. ¶ 21-22.

II. CALIFORNIA HAS SHOWN SERIOUS, UNREBUTTED EVIDENCE OF LIKELY, IMMINENT HARM CAUSED BY THE FINAL RULE

Defendants neither rebut nor address the well-supported harm showing that California has made, merely dismissing it as "harm to third parties."[4] But harm to Title X patients and providers is directly relevant to Plaintiff's own showing of irreparable harm to its interests.

Plaintiff will face increased costs as Title X patients face increased difficulty getting access to reproductive care, which in turn causes an increase in unintended pregnancies, causing harm to public health and the state fisc. Pl.'s Mot. Prelim. Inj. at 19-23; Cantwell Decl. ¶¶ 24, 27-32; Rabinovitz Decl. ¶¶ 39, 46-47; Brindis Decl. ¶¶ 51-57; Kost Decl. ¶¶ 35, 44, 123. And Plaintiff's ability to establish and enforce standards for high quality family planning services will be impeded. Pl.'s Mot. Prelim. Inj. at 23; Cantwell Decl. ¶¶25-26; Morris Decl. ¶¶ 6-9; Brindis Decl. ¶¶78, 93. Just as in *Motor Vehicle Mfrs. Ass'n*, where automobile insurance companies were indirectly affected by the National Highway and Transportation Association's arbitrary and capricious rescission of a rule requiring passive restraints in cars, so too is the State of California indirectly affected by Defendants' unlawful Title X Final Rule, which will undermine the quality and accessibility of critical healthcare services, resulting in costs ultimately born by Medi-Cal,

[4] In light of Defendants' failure to rebut the bulk of Plaintiff's harm allegation, this case is one where the balance of hardships "tips sharply towards the plaintiff," and thus a preliminary injunction is warranted even if Plaintiff were to show only "serious questions going to the merits" of its claims. *All. for the Wild Rockies v. Cottrell*, 632 F.3d 1127, 1135 (9th Cir. 2011).

which insures 64% of unintended births in the state. Cantwell Decl. ¶¶ 27-30; Tosh Decl. ¶ 23-28, 44.

Defendants assert that Plaintiff lacks standing because it has not shown requisite injury to its own interests, and because *parens patriae* standing is unavailable in this case. ECF No. 61 at 42. Yet Plaintiff never relied upon *parens patriae* for standing in this case. In a directly analogous case, the Ninth Circuit concluded that recent HHS regulations would "lead to women losing employer-sponsored contraceptive coverage, which will then result in economic harm to the states." *California v. Azar*, 911 F.3d 558, 571 (9th Cir. 2018). "Just because a causal chain links the harm to the state[] does not foreclose standing." *Id*. Further, a state "need not have already suffered economic harm," and there is "no requirement that the economic harm be of a certain magnitude." *Id*. at 572. Plaintiff faces the same type of likely harm as a result of the Title X Final Rule as it did from Defendants' changes to contraceptive coverage regulations. *See California v. Health and Human Servs*., 351 F.Supp.3d 1267, 1297-98 (N.D. Cal. 2019) (finding that fiscal harm will flow to the state as a result of women's loss of access to contraceptives).

Defendants complain that Plaintiff has "no basis to challenge a rule" allowing some grantees to refuse to provide nondirective options counseling, since other grantees are "allowed" to provide non-directive options counseling (albeit subject to an interpretation of that term that flies in the face of common medical understanding). ECF No. 61 at 10. Defendants misunderstand Plaintiff's position in the lawsuit. California is not a Title X grantee, and does not engage in Title X options counseling. But Plaintiff has made a thorough showing that the actions of Title X-funded providers within the state have a direct impact on the State's finances and public health efforts. Pl.'s Mot. at 19-24. And Plaintiff has shown that the Final Rule will interfere with its ability to set clinical standards for family planning providers, and to discipline licensees who violate state law in the course of following the Final Rule, impeding regulation of medical practice. Cantwell Decl. ¶ 25-26; Morris Decl. ¶¶ 8-9.

Plaintiff's harms are qualitatively different than the harms faced directly by Title X patients. But they are serious, and more than sufficient for California to obtain a preliminary injunction, much less meet the minimum criteria for Article III standing.

III. ISSUING AN INJUNCTION TO PRESERVE THE STATUS QUO WOULD PROPERLY BALANCE THE EQUITIES AND SERVE THE PUBLIC INTEREST.

The "potentially dire public health and fiscal consequences" from curtailing access to contraceptive care warrants injunctive relief. *California v. Azar*, 911 F.3d at 582. Moreover, "there is a robust public interest in safeguarding access to health care for those [eligible for Medicaid], whom Congress has recognized as 'the most needy in the country.'" *Indep. Living Ctr. of S. Cal. v. Maxwell-Jolly*, 572 F.3d 644, 659 (9th Cir. 2009) (quoting *Schweiker v. Hogan*, 457 U.S. 569, 590 (1982)) (vacated on other grounds, *Douglas v. Indep. Living Ctr.*, 565 U.S. 606 (2012). This includes the large majority of Plaintiff's Title X patients.

In the face of judicial recognition of the important public interests at stake and widespread harm that would result from this extraordinary Final Rule, Defendants fail to demonstrate that the public interest will be harmed by enjoining their effort to undo the carefully and deliberately crafted regulations governing standards for Title X services that are currently in place. Defendants have offered nothing to cast doubt on the urgent need for a preliminary injunction.

IV. A NATIONWIDE INJUNCTION IS NECESSARY TO REDRESS THE LIKELY INJURY SHOWN.

Vacatur is the standard remedy for agency actions found to be in violation of the APA. *Nat'l Mining Ass'n v. U.S. Army Corps of Eng'rs*, 145 F.3d 1399, 1409 (D.C. Cir. 1998); *Klamath-Siskiyou Wildlands Cir. v. Nat'l Oceanic and Atmospheric Admin*., 109 F.Supp.3d 1238, 1241 (N.D. Cal. 2015). Further, the Ninth Circuit has held that a "nationwide injunction . . . is compelled by the text of the [APA], which provides [that] [t]he reviewing court *shall . . . hold unlawful and set aside agency action*" that violates any provision of § 706. *Earth Island Inst. v. Ruthenbeck*, 490 F.3d 687, 699 (9th Cir. 2007), *aff'd in part, rev'd in part on other grounds sub nom. Summers v. Earth Island Inst*., 555 U.S. 488 (2009). The cases that Defendants rely on to the contrary are inapposite. *Hecht Co. v. Bowles* concerned a statute that explicitly gave the court the option of whether "a permanent or temporary injunction, restraining order, or other order shall be granted." 321 U.S. 321, 322 (1944). Defendants also rely on the Supreme Court's decision in *Abbott Laboratories v. Gardner*, 387 U.S. 136 (1967), and argue for the proposition that all injunctive relief is necessarily discretionary. *Abbott Labs.* addressed injunctive relief and

observed that "injunctive and declaratory judgment remedies" are "equitable in nature." *Id.* at 148, 155. But the Court discussed these in evaluating a ripeness issue, not the scope of available relief under § 706. Likewise, §§ 703 and 702 of the APA are inapposite because they concern not the scope of relief, but whether actions are reviewable.

A nationwide injunction is not foreclosed where there is a "showing of nationwide impact or sufficient similarity to the plaintiff states." *California*, 911 F.3d at 584; *see also NW Enviro. Defense Ctr. v. Bonneville Power Admin.*, 477 F.3d 668, 680-81 (9th Cir. 2007) (noting that courts retain "broad equitable powers" to grant necessary relief under § 706(2) of the APA). Plaintiff has provided ample evidence of nationwide harm—not controverted or given meaningful consideration in Defendants' opposition. The record includes evidence that the Final Rule will have significant public health and fiscal consequences that will be felt nationwide. Kost Decl. ¶ 78; Brindis Decl. ¶¶ 80-93; Cantwell Decl. ¶ 32. *See California*, 911 F.3d at 584 (nationwide injunctive relief appropriate where evidence shows "nationwide impact"). Reductions in access to Title X services outside the state will likely impact California as patients cross state lines in search of reproductive healthcare, and California's existing Title X network will be affected by grant-making decisions at a national level. Tosh Decl. ¶ 52.

Absent a nationwide injunction, California will not receive complete relief. Unrebutted evidence shows that a California-only injunction would not fully alleviate Plaintiff's harm. *See* Dkt. No. 26 at 25. There are more than 226,000 Title X patients in states surrounding California. Tosh Decl. ¶ 52. Unlike other states, California's laws protect a patient's rights to comprehensive and medically informed services, and the Final Rule will increase visits from out-of-state patients who are not afforded the same protections. *Id.* A nationwide injunction is required to redress demonstrated nationwide harm and to provide complete relief to California.

CONCLUSION

California respectfully requests that the Court grant its motion for a preliminary injunction and enjoin implementation of the Final Rule.

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