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UNITED STATES DISTRICT COURT
DISTRICT OF OREGON

STATE OF OREGON et al.,

Plaintiffs,

v.

ALEX M. AZAR II et al.,

Defendants.

AND

AMERICAN MEDICAL ASSOCIATION et al.,

Plaintiffs,

v.

ALEX M. AZAR II et al.,

Defendants.

Consolidated Civil Action Nos.
6:19-cv-00317-MC (Lead Case)
6:19-cv-00318-MC

DEFENDANTS' OPPOSITION TO PLAINTIFFS' MOTIONS FOR PRELIMINARY INJUNCTION

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INTRODUCTION

Distilled to its essence, this lawsuit seeks to overrule the Supreme Court's decision in *Rust v. Sullivan*, 500 U.S. 173 (1991). Then, as now, section 1008 of the Public Health Service Act (PHSA) provided that "[n]one of the funds appropriated under [the Title X program] shall be used in programs where abortion is a method of family planning." 42 U.S.C. § 300a-6. In 1988, the Department of Health and Human Services (HHS) promulgated regulations extremely similar to the Rule challenged here. Those regulations "require[d] a ban on . . . referral. . . and advocacy [of abortion] within the Title X project" and "mandate[d] that Title X programs be organized so that they are physically and financially separate from [abortion-related] activities." *Rust*, 500 U.S. at 184, 188. The Supreme Court upheld those regulations in *Rust*, concluding that they were a lawful construction of the Title X statute, were not arbitrary and capricious, and did not violate the First or Fifth Amendments. *Id.* at 184, 192-203.

Plaintiffs nevertheless seek to preliminarily enjoin a March 4, 2019 HHS Final Rule, the major components of which are materially indistinguishable from the requirements the Supreme Court upheld in *Rust*. *See* Compliance with Statutory Program Integrity Requirements, 84 Fed. Reg. 7714 (Mar. 4, 2019) (Final Rule or Rule). Plaintiffs make no serious effort to distinguish the Rule from the regulations upheld in *Rust*, and Congress has not amended the statute *Rust* authoritatively interpreted. To the contrary, Congress *attempted* to enact legislation that would have partially overruled *Rust* by permitting abortion referrals within the Title X program, but its efforts were vetoed. *Rust* thus squarely controls.

In light of *Rust*, neither group of Plaintiffs seriously contends that the Rule reflects an impermissible interpretation of section 1008—nor could they, as *Rust* squarely held otherwise, and Congress has not changed the statutory language since. Nor do Plaintiffs seriously challenge the

Rule on constitutional grounds. One group of Plaintiffs—Oregon, 19 other States, and the District of Columbia (collectively, States)—do not assert any constitutional claims in their motion. And although the other group—the American Medical Association and several other organizations (collectively, AMA)—contends that one of the Rule's requirements violates the First Amendment, even it admits that *Rust* rejected a First Amendment challenge to a prior, stricter version of the same requirement. Although AMA asserts that the Supreme Court should revisit *Rust*, it concedes that *Rust* binds this Court. In short, as to both the Constitution and the statute interpreted in *Rust*, Plaintiffs all but admit that the claims on which they seek preliminary relief are legally foreclosed.

Plaintiffs nonetheless try to sidestep *Rust* in a number of ways, none of them persuasive. They principally argue that Congress silently superseded section 1008 as interpreted in *Rust* in two provisions—(1) a one-line rider Congress began adding to appropriations bills in 1996 providing that "all pregnancy counseling shall be nondirective" (the nondirective provision); and (2) a section of the Affordable Care Act (ACA), codified at 42 U.S.C. § 18114 (section 1554), that says nothing specific about abortion or abortion-related services. This argument—an implied repeal on steroids—is implausible. Neither the nondirective provision nor section 1554 even mentions abortion, section 1008, or *Rust*, much less creates a statutory conflict. And Plaintiffs cite no legislative history suggesting that Congress sought to smuggle such a major change on a highly controversial subject into these subsequent provisions.

The problems with Plaintiffs' statutory arguments do not end there. If anything, the nondirective provision supports the Rule, which allows pregnancy counseling, including about abortion, if it is nondirective. In addition, the presumption against implied repeals "applies with even *greater* force when the claimed repeal rests solely on an Appropriations Act," *TVA v. Hill*, 437 U.S. 153, 190 (1978), and there is a "very strong presumption that [appropriations bills] do

not" substantively change existing law, *Calloway v. District of Columbia*, 216 F.3d 1, 9 (D.C. Cir. 2000). Plaintiffs come nowhere close to rebutting that "very strong presumption"—the nondirective provision nowhere mentions abortion, *Rust*, or (unlike the legislation that Congress unsuccessfully tried to enact following *Rust*) referrals.

Plaintiffs have also waived any challenge based on section 1554 because they never allege that they (or anyone else) raised this provision during the notice-and-comment process. That omission is understandable. Section 1554 concerns the *denial* of information and services. As the Supreme Court held in *Rust*, restrictions such as those in the Rule *deny* nothing; they are merely limitations on what the Government chooses to fund. And even if section 1554 and section 1008 did somehow conflict, section 1554 only supersedes contrary requirements in the ACA—not preexisting requirements elsewhere in the U.S. Code, such as section 1008. *See* 42 U.S.C. § 18114 (applies only "[n]otwithstanding any provision of [the Affordable Care] Act").

Plaintiffs' remaining challenges to the Rule likewise fail:

(1) Contrary to AMA's cursory claim that the Rule is an unreasonable interpretation of the Title X statute, the Rule follows directly from section 1008 and includes requirements *Rust* expressly affirmed.

(2) There is no merit to Plaintiffs' claims that the Rule is arbitrary and capricious. The agency thoroughly explained its reasoning and articulated a rational justification for the choices it made—choices the Supreme Court has already upheld in substantial part.

(3) Plaintiffs fare no better in arguing that HHS provided inadequate notice of an ancillary provision of the Rule requiring that nondirective medical counseling within the Title X program be provided by medical professionals who are licensed with a relevant graduate degree. The Notice of Proposed Rulemaking would have allowed *only physicians* to provide nondirective

counseling. In response to comments, HHS simply adopted a *less* restrictive approach on this subject, rendering this provision a logical outgrowth of the proposed rule.

(4) The States also contend that HHS failed to disclose sufficient information in its regulatory impact analysis, but such analyses are neither subject to judicial review nor create a cause of action under the APA.

(5) AMA's argument that the Rule's counseling and referral provisions violate the First Amendment is a non-starter. AMA acknowledges that *Rust* rejected a First Amendment challenge to materially indistinguishable provisions—provisions that, if anything, were *more restrictive* than those here—but contends that *Rust* was incorrectly decided and inconsistent with intervening Supreme Court precedent. But the two recent opinions AMA cites have nothing to do with the principles announced in *Rust*, and the Supreme Court reaffirmed *Rust* six years ago. In any event, none of this matters now: as AMA admits, only the Supreme Court can reconsider *Rust*. Thus, no one contends that this Court can rule in Plaintiffs' favor on their lone constitutional claim.

Given Plaintiffs' failure to establish a likelihood of success on the merits, they cannot obtain the extraordinary relief they seek. But even setting the merits aside, Plaintiffs also fail to meet the equitable criteria for a preliminary injunction. Plaintiffs' speculative predictions of injury fail to establish that they will suffer any irreparable harm in the absence of preliminary relief. The remaining two factors favor the government, which suffers irreparable injury whenever its laws are set aside by a court and which has a compelling interest in following longstanding federal law prohibiting the use of Title X funds for programs where abortion is a method of family planning.

Finally, even if the Court grants relief, that relief should be limited in at least two respects. First, any relief should be confined to Plaintiffs and not extended nationwide. Indeed, in the lead-up to *Rust*, every court that enjoined the 1988 regulations limited that relief to the parties before

it, and Plaintiffs provide no good reason for a broader remedy here. In addition, a nationwide injunction would render the proceedings in three other district courts academic and effectively allow Plaintiffs' views to govern the entire country. Second, any relief should be limited to particular provisions found unlawful. The Rule contains a severability statement and, as a practical matter, the Rule's major components can operate independently. Even if the Court agrees with Plaintiffs' attacks on some parts of the Rule, there is no basis for enjoining it in its entirety.

LEGAL AND FACTUAL BACKGROUND

Congress enacted Title X of the PHSA in 1970 to provide federal subsidies for certain types of family planning services. *See* Pub. L. No. 91-572. Nothing material in the statutory language of Title X has changed since the 1970s, or, for that matter, since the Supreme Court decided *Rust* in 1991. Section 1001(a) authorizes the Secretary of HHS to make grants and enter into contracts with public or private nonprofit entities "to assist in the establishment and operation of voluntary family planning projects which shall offer a broad range of acceptable and effective family planning methods and services (including natural family planning methods, infertility services, and services for adolescents)." 42 U.S.C. § 300(a). Section 1006(a) in turn provides that "[g]rants and contracts made under this subchapter shall be made in accordance with such regulations as the Secretary may promulgate." *Id.* § 300a-4(a). And section 1008 requires that "[n]one of the funds appropriated under this subchapter shall be used in programs where abortion is a method of family planning." *Id.* § 300a-6. As a sponsor explained, "the committee members clearly intend that abortion is not to be encouraged or promoted in any way through this legislation." 116 Cong. Rec. 37,375 (1970) (Rep. Dingell).

I. PRIOR REGULATORY INTERPRETATIONS AND *RUST V. SULLIVAN*

HHS's initial regulations for the Title X program required only that a grantee's application

state that the Title X "project will not provide abortions as a method of family planning." 36 Fed. Reg. 18,465, 18,466 (Sept. 15 1971); 42 C.F.R. § 59.5(a)(9) (1971). Between the time of those regulations and 1988, however, HHS interpreted Title X both to prohibit projects from engaging in activities that "in any way promot[e] or encourag[e] abortion as a method of family planning," and to "requir[e] that the Title X program 'be separate and distinct from any abortion activities of a grantee.'" 53 Fed. Reg. 2922, 2923 (Feb. 2, 1988). In 1981, HHS issued guidelines that required Title X projects to offer "nondirective" counseling about pregnancy termination, followed by referral for abortions if requested. *Id.* At the time, HHS "took the view that activity which did not have the principal purpose or effect of promoting abortion was permitted." *Id.*

The agency in some respects modified its approach in 1988. The Secretary adopted final regulations to address uncertainty and confusion concerning the use of Title X funds and to effectuate more faithfully the underlying policy embodied in section 1008 against the use of Title X funds in any way to encourage or promote abortion. *See* 53 Fed. Reg. at 2923-25; Proposed Rules, 52 Fed. Reg. 33,210, 33,211-22 (Sept. 1, 1987). Those 1988 regulations bear a striking resemblance to the ones Plaintiffs challenge here. The 1988 regulations:

- Prohibited Title X projects from engaging in abortion counseling and referrals, even upon specific request. *See* 53 Fed. Reg. at 2945 (section 59.8(a)(1)).
- Required referrals "for appropriate prenatal and/or social services by furnishing a list of available providers that promote the welfare of mother and unborn child" to every patient client. *Id.* (section 59.8(2)).
- Prohibited Title X projects from "encourag[ing], promot[ing] or advocat[ing] abortion as a method of family planning." *Id.* (section 59.10).
- Prohibited providers from using a list of prenatal and/or social services to indirectly encourage or promote abortion. *Id.* (section 59.8(a)(3)).

- Prohibited providers from "including on the list of referral providers health care providers whose principal business is the provision of abortions." *Id.* (section 59.8(a)(3)).

- Required all abortion services to be separate and distinct from a Title X funded project, including by requiring Title X grantees to structure their Title X project "so that it is physically and financially separate" from other parts of a grantee's organization that might provide abortion services. *Id.* (section 59.9).

These requirements were challenged as unauthorized by Title X, arbitrary and capricious, and impermissible under the First and Fifth Amendments. In *Rust*, the Supreme Court upheld the regulations against these attacks, concluding that they were based on a permissible interpretation of the statute and were not arbitrary and capricious. 500 U.S. at 183-91. The Court accepted as reasonable the Secretary's explanation that the "prior policy failed to implement properly the statute and that it was necessary to provide clear and operational guidance to grantees about how to preserve the distinction between Title X programs and abortion as a method of family planning," as well as that "the new regulations [were] more in keeping with the original intent of the statute, [were] justified by client experience under the prior policy, and [were] supported by a shift in attitude against the elimination of unborn children by abortion." *Id.* at 187 (internal quotation marks omitted). The Court also rejected Plaintiffs' constitutional challenges. *Id.* at 192-203.

In February 1993, the President suspended the 1988 regulations and directed HHS to propose new regulations. *See* The Title X "Gag Rule," Memorandum, 58 Fed. Reg. 7455 (Jan. 22, 1993). HHS then issued a proposed rule, *see* 58 Fed. Reg. 7464 (Feb. 5, 1993), which HHS finalized on July 3, 2000, *see* 65 Fed. Reg. 41,270 (July 3, 2000). The 2000 regulations removed the provisions of the 1988 regulations that (1) prohibited Title X projects from counseling or referring project clients for abortion, (2) required grantees to separate their Title X project physically from any abortion activities, and (3) implemented compliance standards for Title X projects designed to eliminate the promotion or encouragement of abortion as a method of family

planning. *See id.* at 41,280. The regulations also affirmatively required grantees to provide counseling concerning and referrals for abortion in certain situations. *Id.* at 41,279.

II. THE FINAL RULE

On June 1, 2018, HHS published a proposed rule soliciting comments on proposed changes to the 2000 regulations. *See* Proposed Rules, 83 Fed. Reg. 25,502 (June 1, 2018) (NPRM). HHS explained that its proposed changes were based on what HHS considers the best interpretation of Title X, and, in particular, section 1008. *Id.* at 25,505. HHS further explained that the intent of the changes was to "refocus the Title X program on its statutory mission—the provision of voluntary, preventive family planning services specifically designed to enable individuals to determine the number and spacing of their children." *Id.*

On March 4, 2019, after considering public comments, HHS published in the Federal Register the Final Rule at issue. *See* 84 Fed. Reg. 7714. The Rule adopted the proposals from the proposed rule with only modest changes. As discussed in detail below, the Rule for all intents and purposes restores the 1988 regulations that the Supreme Court upheld in *Rust*. *See infra* Part I.A. HHS explained that the Rule provides much needed clarity regarding the Title X program's role as a family planning program that is statutorily forbidden from paying for abortion and from funding programs/projects where abortion is a method of family planning. *See* 84 Fed. Reg. at 7721. HHS further explained that the Rule is necessary because the 2000 regulations "fostered an environment of ambiguity surrounding appropriate Title X activities"—an assessment confirmed by many of the comments submitted in response to the proposed rule. *Id.* at 7721-22. HHS explained that the Final Rule rectifies this ambiguity by making a clear delineation between Title X and non-Title X activities and provides grantees with clear direction on how to ensure that no Title X funds are expended where abortion is a method of family planning. *Id.* at 7722.

One portion of the Rule—to be codified at 42 C.F.R. § 59.14(b) & (e)(5)—explains that if a pregnant woman "requests information on abortion and asks the Title X project to refer her for an abortion," a provider may "offer[] her nondirective pregnancy counseling, which may discuss abortion, but [may] neither refer[] for, nor encourage[] abortion." 84 Fed. Reg. at 7789. In this respect, the Rule is actually more permissive than the 1988 regulations sustained in *Rust* in that it allows (but does not require) nondirective counseling discussing abortion.

The Final Rule will become effective on May 3, 2019, although funding recipients have until July 2, 2019, to comply with the financial separation requirement, and until March 4, 2020, to comply with the physical separation requirement. 84 Fed. Reg. at 7714.

III. THIS LITIGATION

On March 5, 2019, the States filed a complaint contending, *inter alia*, that the Rule violates the nondirective provision and section 1554 of the ACA; is arbitrary and capricious; and was promulgated without observance of procedure required by law. *See* Compl., No. 6:19-cv-00317-MC, ECF No. 1. AMA filed suit the same day asserting similar claims. *See* Compl., No. 6:19-cv-00318-AA, ECF No. 1. On March 21, Plaintiffs in both cases moved for a preliminary injunction to block implementation of the Rule. *See* No. 6:19-cv-00317-MC, ECF No. 35 (States Mem.); No. 6:19-cv-00318-MC, ECF No. 42 (AMA Mem.). The next day, the Court granted an unopposed motion to consolidate the two cases for pre-trial proceedings. No. 6:19-cv-00317-MC, ECF No 70. Defendants now file this consolidated opposition.[1]

[1] At the March 14 telephonic status conference, the Court orally granted Defendants' request to file one consolidated opposition brief of no more than 65 pages.

ARGUMENT

A preliminary injunction is "an extraordinary and drastic remedy" that should not be granted "unless the movant, *by a clear showing*, carries the burden of persuasion." *Lopez v. Brewer*, 680 F.3d 1068, 1072 (9th Cir. 2012). "A plaintiff seeking a preliminary injunction must establish that he is likely to succeed on the merits, that he is likely to suffer irreparable harm in the absence of preliminary relief, that the balance of equities tips in his favor, and that an injunction is in the public interest." *Winter v. NRDC*, 555 U.S. 7, 20 (2008). Plaintiffs fail to satisfy any of these requirements.

I. PLAINTIFFS ARE UNLIKELY TO SUCCEED ON THE MERITS

Plaintiffs challenge a Rule that is materially indistinguishable from one the Supreme Court has already upheld. Most of Plaintiffs' arguments bear a striking resemblance to those the Supreme Court rejected in *Rust*, and their remaining claims are without merit. Because Plaintiffs have no realistic likelihood of prevailing on the merits, their motions should be denied for that reason alone.

A. *Rust* Rejected Arguments Indistinguishable From Those Plaintiffs Advance

Plaintiffs' challenge to the Rule fails in significant part for a simple reason: The Supreme Court has already upheld HHS's materially indistinguishable—indeed, stricter—1988 regulations against both statutory and constitutional challenges. Section 1008 of the PHSA provides that "[n]one of the funds appropriated under [the Title X program] shall be used in programs where abortion is a method of family planning." 42 U.S.C. § 300a-6. In *Rust*, the Court held that this text authorized regulations that (1) barred counseling concerning the use of abortion and abortion referrals as a method of family planning within the Title X program, (2) broadly prohibited a Title X project from advocating abortion as a method of family planning, and (3) mandated financial and physical separation between Title X projects and prohibited abortion activities. 500 U.S. at 183-91. The Court rejected multiple constitutional challenges as well. *Id.* at 192-203.

The text of Title X and section 1008 has not changed since *Rust*. The regulatory provisions Plaintiffs principally challenge—which prohibit abortion referrals as a method of family planning and mandate the physical separation of Title X projects from abortion activities—are materially indistinguishable from those upheld in *Rust*. Indeed, Plaintiffs make no serious effort to distinguish the Rule from the 1988 regulations, and their objections to the Rule are for the most part indistinguishable from those that *Rust* rejected.

The counseling, referral, and advocacy restrictions: The Final Rule prohibits referrals for abortion as a method of family planning but allows nondirective pregnancy counseling, including counseling concerning abortion, so long as "[a] Title X project [does] not perform, promote, refer for, or support abortion as a method of family planning, nor take any other affirmative action to assist a patient to secure such an abortion." 84 Fed. Reg. at 7788-89 (to be codified at 42 C.F.R. § 59.14(a)). The 1988 regulations likewise prohibited "referral for abortion as a method of family planning" in a Title X project, 53 Fed. Reg. at 2945, and the Supreme Court held that this interpretation was "plainly allow[ed]" under "the broad directives provided by Congress in Title X in general and § 1008 in particular," *Rust*, 500 U.S. at 184. The Rule's more modest approach—prohibiting referrals but permitting nondirective counseling—is thus even more defensible.

Plaintiffs do not explain what features of the restrictions on abortion counseling, referral, and advocacy here distinguish this case from *Rust* in a way that favors them. Indeed, the aspects of the Rule that Plaintiffs attack here were all features of the 1988 regulations *Rust* upheld:

a. Plaintiffs complain that the Rule generally bars abortion referrals within the Title X program. *E.g.*, States Mem. at 7. So did the 1988 regulations. *See* *Rust*, 500 U.S. at 184.

b. Plaintiffs object that the Rule mandates referrals for prenatal care. States Mem. at 7; AMA Mem. at 11. Again, so did the 1988 regulations. *See* *Rust*, 500 U.S. at 179 (noting that

the regulations "clarif[ied] that pregnant women must be referred to appropriate prenatal care services" (quoting 53 Fed. Reg. at 2925)); *compare* 42 C.F.R. § 59.14(b)(1) (effective May 3, 2019) (providing that "once a client served by a Title X project is medically verified as pregnant, she shall be referred to a health care provider for medically necessary prenatal health care"), *with* 53 Fed. Reg. at 2945 (providing that "once a client served by a Title X project is diagnosed as pregnant, she must be referred for appropriate prenatal and/or social services by furnishing a list of available providers that promote the welfare of mother and unborn child").

c. Plaintiffs protest that, under the Rule, providers may refuse to provide information about abortion even if a Title X patient directly requests abortion-related information, and providers must furnish information about alternatives to abortion even if the provider believes that the patient does not want this information. States Mem. at 6; AMA Mem. at 12. But the 1988 regulations, like the Rule, "expressly prohibited [a Title X project] from referring a pregnant woman to an abortion provider, even upon specific request." *Rust*, 500 U.S. at 180. And they were even more stringent on counseling. The Rule allows providers to furnish "nondirective pregnancy counseling, which may discuss abortion," 42 C.F.R. § 59.14(e)(5) (effective May 3, 2019), whereas the 1988 regulations prohibited *any* "counseling concerning the use of abortion as a method of family planning." *Rust*, 500 U.S. at 179 (quoting 42 C.F.R. § 59.8(a)(1) (1989)).

d. The Rule permits a provider to furnish a pregnant patient with a "list of licensed, qualified, comprehensive primary health care providers (including providers of prenatal care) some, but not the majority, of which also provide abortion as part of their comprehensive health care services." 42 C.F.R. § 59.14(c)(2) (effective May 3, 2019). Plaintiffs object that the Rule requires including providers who do not provide abortion on the list, even if the patient indicates she would like to seek an abortion. AMA Mem. at 11. But the same was true of the 1988

regulations. *See* *Rust*, 500 U.S. at 180 (list could not "exclud[e] available providers who do not provide abortions"). Plaintiffs also attack the no-majority specification but, again, the regulations upheld in *Rust* prohibited providers from "weighing the list of referrals in favor of health care providers which perform abortions." *Id*. at 179; *see also* 53 Fed. Reg. at 2945. And while Plaintiffs note that the Rule bars including abortion providers who do not also provide comprehensive primary health care, AMA Mem. at 11, 15, the 1988 regulations likewise prohibited "including on the list of referral providers health care providers whose principal business is the provision of abortions." *Rust*, 500 U.S. at 180; *see also* 53 Fed. Reg. at 2945.

e. Plaintiffs repeatedly—but incorrectly—assert that the Rule requires them to conceal information from patients in a manner that violates ethical principles. States Mem. at 2-3, 12, 15; AMA Mem. at 11, 18-19. Plaintiffs omit the fact that, unlike the regulations sustained in *Rust*, the Rule permits providers to offer "nondirective pregnancy counseling, *which may discuss abortion*, [provided that] the counselor neither refers for, nor encourages, abortion." 42 C.F.R. § 59.14(e)(5) (effective May 3, 2019) (emphasis added). Plaintiffs largely ignore this component of the Rule. Virtually all of Plaintiffs' "concealment" allegations concern the aspect of the Rule that prohibits providers supplying patients with a list from identifying which providers on that list perform abortions. But the 1988 rule did that and more, prohibiting counseling discussing abortion, and also allowing a list of care providers but similarly prohibiting using such a list to "steer[] clients to providers who offer abortion as a method of family planning." *See* 53 Fed. Reg. at 2945. Nor is the provision of such a list at all "misleading." States Mem. at 15; AMA Mem. at 17. If a patient requests a list of abortion providers, the Title X provider may simply inform the patient that "the project does not consider abortion a method of family planning and, therefore, does not refer for abortion." 42 C.F.R. § 59.14(e)(5) (effective May 3, 2019). Informing a patient

about limitations required by law is not "misleading." And again, the regulation upheld in *Rust* permitted a virtually identical response. *See* *Rust*, 500 U.S. at 180 (noting that a "permissible response" to a patient's request for an abortion referral "is that 'the project does not consider abortion an appropriate method of family planning and therefore does not counsel or refer for abortion'").

f. AMA objects that the Rule "provides only a limited exception" for emergencies. AMA Mem. at 11. The Rule states, however, that "[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," 42 C.F.R. § 59.14(b)(2), and gives an example of an emergency warranting an abortion referral (an ectopic pregnancy), *id.* § 59.14(e)(2). The 1988 regulations took the same approach. *See* *Rust*, 500 U.S. at 195 (noting that the regulations "provide a specific exemption for emergency care and require Title X recipients 'to refer the client immediately to an appropriate provider of emergency medical services'") (quoting 42 C.F.R. § 59.8(a)(2) (1989)); 42 C.F.R. § 59.8(b)(2) (1989) (offering the ectopic pregnancy example). HHS was even clearer here, specifying that "[r]eferrals for abortion for emergency care purposes are not prohibited." 84 Fed. Reg. at 7747. And because the language prohibiting referrals for abortion encompasses only "abortion *as a method of family planning*," 42 C.F.R. § 59.14(a) (emphasis added), as *Rust* explained, "it does not seem that a medically necessitated abortion in [the circumstance of a medical emergency] would be the equivalent of its use as a 'method of family planning.'" 500 U.S. at 195; *see also* 53 Fed. Reg. at 2945.

More fundamentally, any attempt to distinguish the counseling, referral, and advocacy restrictions here from those in *Rust* cannot be reconciled with *Rust*'s categorical reasoning. *Rust* broadly held that section 1008 "plainly allows" a "ban on [abortion] counseling, referral, and

advocacy" within the Title X program. 500 U.S. at 184. Here, where only referral and advocacy are banned, the Rule is permissible under *Rust*. Even if Plaintiffs could identify some differences in their favor between the prohibitions here and those considered in *Rust*—and they hardly try to—*Rust* obviously encompasses these restrictions.

The program integrity requirements: The States characterize the Rule's program integrity requirements as "represent[ing] a radical departure from the Department's established policy." States Mem. at 7. But although these requirements are an acknowledged and justified change from the 2000 regulations, *see infra* Part I.D, they are materially indistinguishable from the 1988 regulations—which themselves were a departure from HHS's previous approach—upheld in *Rust*. The Court held that the program integrity requirements—"mandating separate facilities, personnel, and records"—were "not inconsistent with the plain language of Title X" and "[c]ertainly . . . cannot be judged unreasonable." *Rust*, 500 U.S. at 187-88, 190. The Court thus accepted HHS's view that "meeting the requirement of section 1008 mandates that Title X programs be organized so that they are physically and financially separate from other activities which are prohibited from inclusion in a Title X program" and that "[h]aving a program that is separate from such activities is a necessary predicate to any determination that abortion is not being included as a method of family planning in the Title X program." *Id.* at 188 (quoting 53 Fed. Reg. at 2940).

Plaintiffs do not—and cannot—identify any material differences between these requirements and those upheld in *Rust*:

a. Both mandate that "[a] Title X project must be organized so that it is physically and financially separate . . . from activities which are prohibited under section 1008";

b. Both provide that a "project must have an objective integrity and independence from prohibited activities";

c. Both direct that "[m]ere bookkeeping separation of Title X funds from other monies is not sufficient";

d. Both set forth a list of four basically identical factors that the Secretary will use to determine whether the requisite separation exists: (i) separate accounting records (the Rule adds the requirement that such records be "accurate"); (ii) facilities separation; (iii) separate personnel (the Rule adds records and workstations to this requirement); and (iv) the extent to which identification of the Title X project is present and abortion-related materials are absent. *Compare* 84 Fed. Reg. at 7789, *with* 53 Fed. Reg. at 2945. This fact alone should put an end to AMA's cursory assertion that the separation requirements are "vague," AMA Mem. at 31, and set "a boundless, discretionary standard," *id.* at 13.[2]

* * *

For all these reasons, neither group of Plaintiffs appears to contend that the Rule reflects an impermissible interpretation of section 1008, and *Rust* squarely forecloses any such claim.

[2] Notwithstanding AMA's insinuations, there is nothing unusually vague about the separation requirements and, in any event, the preamble encourages providers to contact the program office with questions, 84 Fed. Reg. at 7766. And in requiring that a Title X project provide assurance "satisfactory to the Secretary" that it is not encouraging, promoting, or advocating for abortion, the Rule provides four specific examples of "[t][he types of documentary evidence that might be required" to demonstrate such assurance, and states that "[t]o the extent that additional documentation is required by the Secretary at a later date, future guidance will be communicated to grantees." *Id.* at 7758. Although their complaints include vagueness claims, Plaintiffs did not include such claims in their motions, presumably because it is meritless. Indeed, the New York plaintiffs in *Rust* raised a similar vagueness argument, and the Supreme Court did not even bother to address it. *See* Brief for Petitioners at 44-45 n.48, *New York v. Sullivan* (No. 89-1392), 1990 WL 505760 ("The separation requirement, as well as the counseling, referral and advocacy ban are unconstitutionally vague. . . . A Title X project cannot know what is required or prohibited by the physical separation requirement or, for that matter, by the prohibitions against 'encouraging', 'counseling' or 'promoting' 'abortion as a method of family planning.'").

B. Neither The Nondirective Provision Nor The ACA Silently Overrules *Rust*

Rust's on-point statutory holding—and the remarkable overlap between Plaintiffs' arguments and the ones *Rust* rejected—disposes of the claim that the materially indistinguishable Rule is unlawful. By necessity, Plaintiffs therefore take a more creative approach, arguing that two subsequent provisions—(1) a single line requiring that any pregnancy counseling provided in a Title X program be "nondirective," in a rider Congress began adding to HHS appropriations acts in 1996, and (2) section 1554 of the ACA, codified at 42 U.S.C. § 18114, which mentions neither abortion nor abortion-related activities—silently supplant *Rust*. *See* AMA Mem. at 20.

This argument—that Congress silently overruled portions of *Rust* by enacting two separate statutes and leaving the language of section 1008 unchanged—not only misconstrues the appropriations rider and section 1554, but "runs foursquare into [the] presumption against implied repeals." *Nat'l Ass'n of Home Builders v. Defs. of Wildlife*, 551 U.S. 644, 664 (2007). Even putting aside this presumption, any argument that the two provisions supersede *Rust* is implausible. Neither the nondirective provision nor section 1554 mentions abortion, section 1008, or *Rust*, and neither provision was accompanied by any legislative history suggesting that Congress intended to overrule *Rust*. Indeed, when Congress *did* attempt to pass legislation that would have permitted abortion referrals within the Title X program, that legislation was vetoed. *See infra* pp. 22-23. As explained further below, Plaintiffs' argument based on these two provisions fails.

1. The Nondirective Provision Does Not Supplant *Rust*.

Since 1996, Congress has included a rider in its annual HHS appropriations act that—in addition to stating that funds appropriated to Title X projects "shall not be expended for abortions"—requires that "all pregnancy counseling shall be nondirective." *E.g.*, HHS Appropriations Act 2019, Pub. L. 115245, Div. B, 132 Stat. 2981, 3071. Consistent with this

requirement, the Rule permits providers to provide "[n]ondirective pregnancy counseling," which "may discuss abortion." 84 Fed. Reg. at 7789 (to be codified at 42 C.F.R. § 59.14(b)(1)(i), (e)(5)). The annual HHS appropriations language requires no more.

Plaintiffs nevertheless contend that the Rule violates the nondirective provision because the Rule (1) requires that providers refer pregnant patients for prenatal care, while (2) prohibiting referral for abortion as a method of family planning. *See* States Mem. at 12; AMA Mem. at 16. Accordingly, Plaintiffs read the nondirective provision to *require* that Title X providers make abortion referrals upon request and to bar HHS from mandating prenatal referrals. *See id.* But the nondirective provision says nothing about abortion referrals, much less mandates HHS to bankroll only programs that provide them. This is clear for at least three reasons.

a. For one, reading the nondirective provision to require abortion referrals conflicts with the Supreme Court's authoritative interpretation of Title X itself—*i.e.*, that Title X delegated authority to HHS to prohibit referrals for abortion as a method of family planning and to allow for mandatory referrals of pregnant patients for prenatal care. *See* *Rust*, 500 U.S. at 184-87. Plaintiffs' argument, then, must be that the nondirective provision implicitly repealed section 1008 and *Rust*.

But again, repeals by implications "are not favored and will not be presumed unless the intention of the legislature to repeal is clear and manifest." *Nat'l Ass'n of Home Builders*, 551 U.S. at 662 (internal quotation marks and brackets omitted). The same is true with respect to judicial interpretations of statutory provisions, such as the one in *Rust*: "A clear, authoritative judicial holding on the meaning of a particular provision should not be cast in doubt and subjected to challenge whenever a related though not utterly inconsistent provision is adopted in the same statute or even in an affiliated statute." *TC Heartland LLC v. Kraft Foods Grp. Brands LLC*, 137 S. Ct. 1514, 1520 (2017) (quoting ANTONIN SCALIA & BRIAN A. GARNER, READING LAW 331

(2012)); *see also, e.g.*, *Forest Grove Sch. Dist. v. T.A.*, 557 U.S. 230, 240 (2009) (requiring "a clear expression" of congressional intent to "abrogate" Supreme Court's interpretation of a statute). Even when an "earlier ambiguous provision has already been construed by the jurisdiction's high court to have a meaning that does not fit as well with a later statute as another meaning," any "[l]egislative revision of law clearly established by judicial opinion ought to be by express language or by unavoidably implied contradiction." SCALIA & GARNER, *supra*, at 331. Put differently, it makes no difference that section 1008 contains an *implicit* rather than *explicit* delegation of authority to HHS to prohibit referrals for abortion as a method of family planning. Given the Supreme Court's interpretation of section 1008 in *Rust*, if Congress intended to abrogate that interpretation, common sense suggests that it would have made its intent clear.

Here, Plaintiffs' argument that Congress silently supplanted the Supreme Court's decision in *Rust* and repealed part of Title X in an appropriations rider is particularly weak because the doctrine "disfavoring repeals by implication . . . applies with even *greater* force when the claimed repeal rests solely on an Appropriations Act." *TVA v. Hill*, 437 U.S. 153, 190 (1978). Because appropriations acts have "the limited and specific purpose of providing funds for authorized programs," *id.*, there is a "very strong presumption that they do not" substantively change existing law, *Calloway v. District of Columbia*, 216 F.3d 1, 9 (D.C. Cir. 2000).

Plaintiffs cannot overcome that "very strong presumption" here because the non-directive mandate expresses no "clear and manifest" intention to override the Supreme Court's interpretation of Title X in *Rust*. The provision neither mentions *Rust* nor alters the Title X statute, and Plaintiffs point to nothing in the legislative record evincing such an intent. Nor is there any conflict between the Rule and the appropriations rider. The latter provision addresses only "counseling," which is different than the actual *referral* of a patient for medical care. It does not

use the word "referral" or dictate terms upon which a Title X provider must make (or refrain from making) referrals for medical care outside of the Title X program. Congress and HHS have long recognized that counseling a patient and referring a patient for particular services are different. *See, e.g.*, *supra* p. 6 (discussing 1981 guidance); *infra* p. 21 (discussing 1993 guidance); *infra* pp. 22-23 (discussing failed 1992 legislation and nondirective mandate).

There is thus no conflict—much less an irreconcilable one—between Title X, as interpreted by HHS and the Supreme Court, and the nondirective provision. Instead, the Final Rule adopts a position that appropriately harmonizes the two statutes—prohibiting abortion referrals, consistent with the interpretation of Title X upheld in *Rust*, while requiring that pregnancy counseling (including counseling on abortion), to the extent it is offered, be nondirective. *See* 84 Fed. Reg. at 7730. The Court thus can give effect to the appropriations act, which does not govern referral activities, without encroaching upon section 1008 or the Supreme Court's interpretation in *Rust*.

Contrary to the States' argument, the fact that Congress has reenacted the nondirective mandate each year since the 2000 regulations (which incorporate the 1993 guidance) does not demonstrate that Congress implicitly ratified the interpretation embodied in those regulations. States Mem. at 11. First, "ratification may be effected through appropriation acts," but "the appropriation must plainly show" that Congress intended to do so. *Ex parte Endo*, 323 U.S. 283, 303 n.24 (1944). Here, Congress included no definition of the term "nondirective counseling" in its appropriations rider, much less any indication that it intended to adopt a particular HHS interpretation of that language. *Cf.* *New York v. Sullivan*, 889 F.2d 401, 408-09 (2d Cir. 1989) (upholding 1988 regulations and finding that "Congress has not reenacted Title X, and the reauthorization of funding [through appropriations] does not imply Congress was aware of, much less endorsed every expenditure of funds by the agency"), *aff'd by* *Rust*, 500 U.S. 173.

Second, the 1993 guidance (in place when Congress first enacted the nondirective mandate) makes clear that the definition of counseling does not, standing alone, include referrals. To the contrary, it requires, in distinct phrases, that Title X projects (1) provide nondirective counseling, and (2) refer patients for abortion upon request. *See* 58 Fed. Reg. 7464 (Feb. 5, 1993) (requiring providers "provide nondirective counseling . . . *and* to refer her for abortion, if that is the option she selects") (emphasis added). The 2000 regulations also repeatedly use the terms "counseling" and "referral" separately. 65 Fed. Reg. at 41,272-75, 41,279 (July 3, 2000). Congress, in its appropriations rider, chose only to include the former term, while excluding reference to the latter.

Finally, even if Congress had implicitly ratified the 2000 regulations, "the ratification of one agency policy by Congress does not preclude a change in that policy." *Massachusetts v. Sec'y of HHS*, 899 F.2d 53, 61 (1st Cir. 1990) (en banc), *abrogated by Rust*, 500 U.S. 173 (citing *Motor Vehicle Mfrs. Ass'n v. State Farm Auto. Ins. Co.*, 463 U.S. 29, 45 (1983)). As the Supreme Court explained in *State Farm*, although an "agency's interpretation of a statute may be confirmed or ratified by subsequent congressional failure to change that interpretation, in the case before us, even an unequivocal ratification—short of statutory incorporation—of [the regulation] would not connote approval or disapproval of an agency's later decision to rescind the regulation." 463 U.S. at 45 (internal citations omitted); *see also Massachusetts*, 899 F.2d at 61 (rejecting similar ratification challenge to the 1988 regulations). The same is true here.

b. Even putting aside the strong presumption against implied repeals and silent legislative abrogations of Supreme Court statutory interpretations (and the even stronger presumption against implied repeals in appropriations bills), Plaintiffs' attempt to equate "counseling" and "referrals" fails. "Counseling" does not, in its common usage, necessarily include within its definition the act of "referral." While the former is defined in purely verbal

terms, *i.e.*, the "furnishing of advice or guidance," Black's Law Dictionary (10th ed. 2014), the latter entails the further, active step of "sending or directing to another for information, service, consideration, or decision," *id*. And again, counseling and referrals are treated separately in the 1988 regulations, *Rust*, the 2000 regulations, and most notably, Congress's *failed* attempt to overturn *Rust* with the Family Planning Amendment Act of 1992, discussed in the next paragraph.

c. If there were any doubt that the non-directive provision did not impliedly repeal section 1008 and *Rust*—and that "counseling" does not mean "referrals" within the context of the Title X program—the immediate aftermath of *Rust* should erase it. In an explicit attempt to overturn that decision, Congress set out to "reverse[] the regulations issued in 1988 and upheld by the Supreme Court in 1991 to restrict the provision of information on abortion to Title-Ten patients." H.R Rep. No. 102-204, accompanying H.R. 3090 (Sept. 13, 1991). Both houses of Congress passed a bill, the "Family Planning Amendments Act of 1992," that would have amended Title X to explicitly condition Title X funding upon a project's agreement to "provide to individuals information regarding pregnancy management options" upon request. *See* S.323, 102nd Congress (1991-1992). The bill defined "pregnancy management options" to mean "nondirective counseling *and referrals* regarding (A) prenatal care and delivery; (B) infant care, foster care, and adoption; and (C) *termination of pregnancy*." *Id*. (emphases added).

That bill was vetoed, *see* Message From the President, Senate Document 102-28, 102nd Congress (1991-1992), and when Congress returned in 1996 to enact the nondirective provision, which *did* become law, it used entirely *different* language. The nondirective provision addresses counseling, but says nothing about referral. It says nothing about *Rust*. And it does not even require counseling, but merely provides that *if* pregnancy counseling occurs, it must be nondirective. "Few principles of statutory construction are more compelling than the proposition

that Congress does not intend *sub silentio* to enact statutory language that it has earlier discarded in favor of other language." *INS v. Cardoza-Fonseca*, 480 U.S. 421, 442–43 (1987) (citation omitted). And this history confirms that the term "counseling" refers only to counseling, not also to referrals, and that the rider in no way intends to or actually supersedes *Rust* (much less by *requiring* abortion referrals in Title X).

Plaintiffs make several other meritless arguments related to the nondirective provision:

- Plaintiffs' contention that the Rule violates the nondirective provision in requiring referral of a pregnant patient for prenatal care, *see* States Mem. at 12; AMA Mem. at 16, simply repeats their error of conflating counseling and referral. Relatedly, the States contend that "HHS creates an untenable and internally inconsistent definition of referrals" by "characteriz[ing] unsolicited and mandatory referrals as nondirective in the prenatal care context, yet consider[ing] patient-requested referrals to be directive in the abortion context." States Mem. at 22-23. Not so. The prohibition on abortion referrals comes from section 1008's restriction on funding projects where abortion is a method of family planning—not from the nondirective provision, which concerns counseling, not referrals. And the requirement that a Title X project *refer* a pregnant woman for medically necessary prenatal health care has nothing to do with the requirement that pregnancy *counseling* be nondirective. Rather, it reflects HHS's judgment that "such care is medically necessary to maintain or improve the health of both the mother and the unborn baby." 84 Fed. Reg. at 7759. (Similarly, HHS included adoption referrals in the Final Rule not because of the nondirective provision but because, when Congress created the Infant Adoption Awareness Grant Program, Congress provided for Title X project personnel to be trained in giving adoption referrals. *See id.* at 7730, 7733.) There is no inconsistency here.

- Plaintiffs contend that limiting pregnancy counseling to advanced practice providers violates the nondirective provision. States Mem. at 13. But the nondirective provision concerns *what* is allowed as part of pregnancy counseling, not *who* is qualified to provide it. In addition, as HHS explained, the nondirective provision does not even mandate that counseling occur—it simply requires that any pregnancy counseling that *is* offered be nondirective. *See infra* p. 35. And as discussed below, HHS considered the relevant comments on this issue and made a rational decision to require that nondirective counseling within the Title X program be provided by licensed medical professionals with a relevant graduate degree (a category which includes physician assistants and advanced practice registered nurses).

- Plaintiffs contend that the pregnancy counseling authorized by the Rule is directive in requiring that "'abortion must not be the only option presented' and also that '[p]hysicians or APPs should discuss the possible risks and side effects to both mother and unborn child of any pregnancy option presented.'" States Mem. at 13-14 (quoting 84 Fed. Reg. at 7747). But discussing multiple options with a patient and presenting the risks and side effects of each option is the paradigm of nondirective counseling. As HHS explained, its approach "is designed to assist the patient in making a free and informed decision," presenting each option in a "factual, objective, and unbiased manner." 84 Fed. Reg. at 7747. The fact that a patient might *later* obtain an abortion *outside* the auspices of Title X is not a justification for withholding information *within* the Title X project—nor does it support Plaintiffs' atextual claim that a neutral presentation of multiple options is somehow "directive."

In short, Congress prohibited HHS from using Title X to fund pregnancy counseling unless it is nondirective, and the Rule faithfully implements that prohibition by specifying that projects

can provide pregnancy counseling, including about abortion, but only if it is nondirective. Plaintiffs are not likely to succeed on the merits of this claim.

2. Section 1554 of the ACA Does Not Supplant *Rust*.

Plaintiffs' claim based on section 1554 of the ACA fares no better. That provision states that, "[n]otwithstanding any other provision of [the Affordable Care] Act, the Secretary of Health and Human Services shall not promulgate any regulation that"

> (1) creates any unreasonable barriers to the ability of individuals to obtain appropriate medical care;
>
> (2) impedes timely access to health care services;
>
> (3) interferes with communications regarding a full range of treatment options between the patient and the provider;
>
> (4) restricts the ability of health care providers to provide full disclosure of all relevant information to patients making health care decisions;
>
> (5) violates the principles of informed consent and the ethical standards of health care professionals; or
>
> (6) limits the availability of health care treatment for the full duration of a patient's medical needs.

42 U.S.C. § 18114.

To start, Plaintiffs have waived any challenge based on section 1554. A plaintiff "must first utilize the opportunity for comment [on an agency regulation] before it may raise issues" in federal court, or else arguments are "waived." *Nutraceutical Corp. v. Von Eschenbach*, 459 F.3d 1033, 1041 n.9 (10th Cir. 2006) (quotation marks omitted) (collecting cases). "Th[is] rule applies with no less force to a statutory interpretation claim not brought to an agency's attention," because "respect for agencies' proper role in the *Chevron* framework requires that the court be particularly careful to ensure that challenges to an agency's interpretation of its governing statute are first raised in the administrative forum." *Nuclear Energy Inst., Inc. v. EPA*, 373 F.3d 1251, 1298 (D.C.

Cir. 2004); *see also* *Univ. Health Servs., Inc. v. Thompson*, 363 F.3d 1013, 1019 (9th Cir. 2004). Here, Plaintiffs challenge regulations that are the product of notice-and-comment rulemaking, but never allege that they (or any other party) raised any purported inconsistency between the Rule and section 1554 during the rulemaking process, and the government is aware of no such objection.

Waiver aside, this argument is meritless. It is extraordinary to now claim, for example, that "[t]he ACA's plain text could not be clearer," States Mem. at 14, when *none* of the Plaintiffs (or, as best as the Government can tell, anyone else) noticed any supposed conflict between the Rule and section 1554 during the notice-and-comment process. And before turning to specifics, consider the fundamental implausibility of Plaintiffs' argument. It is a basic principle that Congress "does not alter the fundamental details of a regulatory scheme in vague terms or ancillary provisions—it does not, one might say, hide elephants in mouseholes." *Whitman v. Am. Trucking Ass'ns*, 531 U.S. 457, 468 (2001). Plaintiffs contend, however, that Congress (1) abrogated a Supreme Court decision on an extremely controversial subject; (2) after it had tried and failed to do so expressly; (3) in a provision that does not mention abortion, pregnancy, Title X, section 1008, or *Rust*; (4) without generating any meaningful legislative history; and (5) in a manner that was so subtle in effecting this transformational change that not even Plaintiffs thought to invoke it in their comments opposing the Rule. That is, to put it mildly, an unlikely proposition.

Turning to specifics, Plaintiffs cannot seriously contend that section 1554 repealed by implication section 1008 as interpreted in *Rust*. Section 1554 does not refer to abortion or even pregnancy; it does not refer to section 1008; and it does not refer to *Rust*. And as far as Defendants are aware, this provision was not the subject of any meaningful legislative history before the ACA's enactment, and Plaintiffs provide none.

Nor are section 1554 and section 1008 in "irreconcilable conflict." As discussed further below, section 1554—which is not codified in, or an amendment to, the PHSA and which applies only "notwithstanding any other provision of [the Affordable Care] Act"—does not even apply to section 1008 (which is not part of the ACA). Beyond that, section 1554 can quite comfortably be read as simply not speaking to the issue of *funding* of abortion as a method of family planning within the Title X program. Indeed, since section 1554 does not refer to either funding of abortion or Title X, it neither "covers the whole subject of [section 1008]" nor "is clearly intended as a substitute." *Branch v. Smith*, 538 U.S. 254, 273 (2003).

Plaintiffs' argument also conflicts with section 1554's text and multiple interpretive principles. Start with the text. All six subjects of section 1554's sub-sections—unreasonable barriers to appropriate medical care, impediments to timely access to health care services, interference with medical communications, restrictions on disclosure of relevant information, violation of ethical standards and principles of informed consent, and limitations on the availability of health care treatment—involve the *denial* of information or services to patients. The Rule, however, denies nothing. It is merely a limit on what the government chooses to fund. As *Rust* explained, when the government places restrictions on the permissible use of Title X funds, it "is not *denying* a benefit to anyone, but is instead simply insisting that public funds be spent for the purposes for which they were authorized." 500 U.S. at 196 (emphasis added). "By requiring that the Title X grantee engage in abortion-related activity separately from activity receiving federal funding, Congress has . . . merely refused to fund such activities out of the public fisc, and the Secretary has simply required a certain degree of separation from the Title X project in order to ensure the integrity of the federally funded program." *Id.* at 198.

In any event, section 1554 expressly applies "[n]otwithstanding any other provision *of this Act*," 42 U.S.C. § 18114 (emphasis added)—that is, the ACA. *See* Pub. L. No. 111-148 (Mar. 23, 2010). Section 1008, however, is not part of the ACA (it was enacted as section 1008 of the PHSA, not the ACA). Nor are sections 1001 and 1006 of the PHSA, which authorize the Secretary to award grants and issue Title X regulations. Had Congress intended section 1554 to sweep beyond the ACA, it could have simply specified that section 1554 applies "notwithstanding any other provision of law." Such language is frequently used in American law in general, and in the ACA specifically; 21 times, by the government's count. *See, e.g.*, 42 U.S.C. § 18032(d)(3)(D)(i). By its own terms, section 1554 does not apply to Title X of the PHSA or its implementing regulations.

That reading also comports with common sense. Section 1554's sub-sections are quite open-ended. Nothing in the statute specifies, for example, what constitutes an "unreasonable barrier[]," "appropriate medical care," "all relevant information," or "the ethical standards of health care professionals." And as noted above, there is—as best as the government can tell—nothing in the ACA's legislative history that sheds light on this provision. Under these circumstances, it is a substantial question whether section 1554 claims are reviewable under the APA at all. *See Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 410 (1971) (APA bars judicial review of agency decision where, among other circumstances, "'statutes are drawn in such broad terms that in a given case there is no law to apply'") (internal quotation marks omitted). Even within the ACA, HHS routinely issues regulations placing criteria and limits on what the government will fund, and on what will be covered in ACA programs. Under Plaintiffs' standardless interpretation of section 1554, it is far from clear that the Government could ever impose any limit on any parameter of a health program—even if the program's own statute requires it—or how a court could possibly evaluate such challenges by applying the section's majestic

generalities. In any event, even if section 1554 claims are reviewable, it is inconceivable to imagine that Congress intended to subject the entire U.S. Code to these general and wholly undefined concepts—and that it did so without leaving any meaningful legislative history.

Other principles point in the same direction. In addition to the presumption against hiding elephants in mouseholes, *see supra* p. 26, "it is a commonplace of statutory construction that the specific governs the general," *Morales v. Trans World Airlines, Inc.*, 504 U.S. 374, 384 (1992). That is particularly true where Congress has enacted a "comprehensive scheme and has deliberately targeted specific problems with specific solutions." *RadLAX Gateway Hotel, LLC v. Amalgamated Bank*, 566 U.S. 639, 645 (2012). "The general/specific canon is perhaps most frequently applied to statutes in which a general permission or prohibition is contradicted by a specific prohibition or permission." *Id*. Under such circumstances, "[t]o eliminate the contradiction, the specific provision is construed as an exception to the general one." *Id*. Thus, even if section 1554 applied to regulations implementing section 1008 (it does not), even if sections 1554 and 1008 were in conflict (they are not), and even if Plaintiffs had preserved this challenge (they have not), section 1008 as interpreted in *Rust* would prevail over section 1554. Section 1554 is at best a general prohibition of certain types of regulations (very broadly described). Section 1008, however, is a much more specific prohibition. It applies to funding of abortion as a method of family planning within the Title X program. And in *Rust*, the Supreme Court held that section 1008 authorized HHS to adopt regulations materially indistinguishable from the ones challenged here. *See supra* pp. 7, 10. Section 1554, by contrast, does not speak specifically to abortion or, for that matter, to Title X at all. Plaintiffs are unlikely to succeed on the merits of this claim.

C. *Rust* Forecloses AMA's Title X Claim

AMA's contention that the Rule violates the requirement that Title X services remain "voluntary" is likewise meritless. AMA Mem. at 2 (citing 42 U.S.C. §§ 300, 300a-5); *see also id.* at 4, 16. Both of the Title X provisions AMA cites predate *Rust*, neither mentions abortion, and *Rust* rejected this particular argument. *Rust* acknowledged the general Title X voluntariness principle, 500 U.S. at 178, yet held that the Secretary's physical separation requirements, as well as the abortion counseling, referral, and advocacy restrictions, reflected a permissible interpretation of the Title X statute. *See supra* pp. 7, 10. *Rust* aside, Title X services are required to be "voluntary" in the sense that accepting family planning services under the program "shall not be a prerequisite to eligibility for or receipt of any other service or assistance from, or to participation in, any other program of the entity or individual that provided such service or information." 42 U.S.C. § 300a-5. The Rule specifically abides by this requirement in 42 C.F.R § 59.5(a)(2), which is unchanged from the 2000 rules. The Title X voluntariness principle thus has nothing to do with the issues in this case.

D. The Final Rule Is Not Arbitrary and Capricious

Much of what remains of Plaintiffs' arguments amounts to garden variety arbitrary-and-capricious claims. These arguments face a high hurdle. Agency action must be upheld in the face of such attacks so long as the agency "examine[s] the relevant data and articulate[s] a satisfactory explanation for its action[,] including a rational connection between the facts found and the choice made." *State Farm*, 463 U.S. at 43 (citation omitted). Under this deferential standard of review, "a court is not to substitute its judgment for that of the agency . . . and should uphold a decision of less than ideal clarity if the agency's path may be reasonably discerned." *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 513-14 (2009) (citations omitted); *see also Alaska Oil & Gas Ass'n*

v. Jewell, 815 F.3d 544, 554 (9th Cir. 2016) ("arbitrary and capricious" standard establishes a "high threshold" for setting aside agency action, which is "presumed valid and is upheld if a reasonable basis exists for the decision"). The Final Rule—the major components of which have already been upheld by the Supreme Court—easily satisfies this highly deferential review.

1. *Rust* Establishes that It is Not Arbitrary and Capricious for HHS to Place Conditions on Title X Funds that Require Physical Separation and Restrict Activities that Promote Abortion as a Method of Family Planning

HHS had a simple and compelling basis for promulgating the Final Rule: to ensure compliance with federal law, and in particular section 1008's command that "none of the funds appropriated" for Title X "be used in programs where abortion is a method of family planning." 83 Fed. Reg. at 25,505. HHS reads this statute, as it did in 1988, to establish "a broad prohibition on funding, directly or indirectly, activities that treat abortion as a method of family planning." 84 Fed. Reg. at 7723; *see also* 53 Fed. Reg. at 2922 (section 1008 "creates a wall of separation between Title X programs and abortion as a method of family planning"). Based on that interpretation, HHS determined that the intervening 2000 regulations are inconsistent with section 1008 to the extent they "require referral for abortion as a method of family planning, allow the use of funds for building infrastructure that could be used for abortion services, and do not require clear physical separation between Title X activities and abortion-related services." 84 Fed. Reg. at 7723. HHS thus determined that the Final Rule is necessary to rectify the problems with the 2000 regulations and to properly implement section 1008.

The Supreme Court has already approved of this reasoning. In *Rust*, it determined that: (1) Title X authorizes HHS to prohibit abortion "counseling, referral, and advocacy within the Title X project," 500 U.S. at 184; (2) Title X authorizes HHS to require physical separation of Title X and non-Title X projects, *id.* at 188-90; and (3) HHS's interest in ensuring compliance with its

interpretation of section 1008 justified separation and counseling and referral requirements materially indistinguishable from those in the Rule, *id*. at 184-91.

The Supreme Court's rejection of the arbitrary and capricious challenges in *Rust* is equally controlling here. In response to comments contending that HHS had not "provided sufficient reasons or evidence to justify the physical and financial separation requirements," HHS explained that the Supreme Court has already upheld the separation requirements "as a legitimate interpretation of the Congressional mandate in section 1008." 84 Fed. Reg. at 7764. Similarly, HHS noted that the Court in *Rust* already considered and endorsed the same restrictions on abortion referrals adopted in the Final Rule. *See id*. at 7746; *see also Rust*, 500 U.S. at 193. That by itself was sufficient justification. Just as it was in 1988, the policy and legal judgment embodied in the Rule is permissible, and is not arbitrary and capricious.

2. HHS Adequately Justified the Separation and Referral Provisions

For the reasons explained above, *Rust* squarely controls here. But even if *Rust* were not dispositive, HHS also detailed the problems of the prior regulations and adequately explained the need to impose anew the separation, counseling, and referral provisions.

Program Integrity Requirements: HHS observed that allowing Title X projects to operate in shared spaces with non-Title X activities increases the risk that Title X and other funds will be comingled, that Title X funds will be used for prohibited purposes, and that the public will be deprived of the clear statutorily required assurance that taxpayer dollars are not being used to fund projects where abortion is a method of family planning. 84 Fed. Reg. at 7764-65.

HHS explained that these concerns are particularly acute because Title X projects use flexible grants that give considerable "latitude and versatility to grantees on how funds are used." 83 Fed. Reg. at 25,508. This flexibility raises the specter of projects using Title X funds to build

infrastructure used to support abortion, which HHS chronicled. *See* 84 Fed. Reg. at 7773 (citing report that Title X funds are used to address "staff-related issues," for "operational investments," and towards "infrastructure and general operations"). In particular, HHS noted that various comments expressing support for the 2000 regulations themselves showed that, as a matter of economic reality, those requirements had the effect of indirectly supporting abortion-related activities. *Id.* at 7776 (comments arguing that separation requirements would "increase the cost of doing business" confirms the need for the Rule because if "the collocation of a Title X clinic with an abortion clinic permits the abortion clinic to achieve economies of scale, [Title X funds] would be supporting abortion as a method of family planning"). In this context, HHS determined that even using the "strictest accounting and charging of expenses, a shared facility greatly increases the risk of confusion and the likelihood that a violation of the Title X prohibition will occur." *Id.* at 7764; *cf. Marina Mercy Hosp. v. Harris*, 633 F.2d 1301, 1304 (9th Cir. 1980) ("In a program as complex and ripe with potential abuse as Medicare, the Secretary has broad discretion to control excessive costs by adopting general prophylactic rules."). Indeed, Plaintiffs' own assertions that a loss of Title X funding may force abortion clinics to close confirm the legitimacy of the agency's concerns. *Compare* Black Decl. ¶ 56 (asserting that "without Title X funding, [Planned Parenthood South Atlantic] will likely have to close" various clinics, including its "Wilmington Health Center"), *with id.* ¶ 34 (noting that the Wilmington Health Center provides abortions).

Moreover, while HHS was not required to submit empirical evidence in support of its Rule, *see infra* p. 35, the Secretary cited a study showing that abortions are increasingly being performed at "sites that focus primarily on contraceptive and family planning services," *i.e.*, precisely the type of sites that receive Title X funds. *See* 84 Fed. Reg. at 7765. HHS also pointed to examples of overbilling in the Medicaid program as demonstrating a need for clarity with respect to

permissible and impermissible activities. Although the States dismiss the NPRM's reference to examples of overbilling in the Medicaid program, States Mem. at 28 n.31, HHS explained that these abuses of federal funds in a different program "illustrate the need for clarity with respect to permissible and impermissible activities in connection with the Title X program and Title X funds," particularly given the confusion fostered by the existing regulatory regime. 84 Fed. Reg. at 7725. More generally, HHS explained, when abortions are performed at Title X facilities that are not clearly separated, it confuses the public about whether federal funds are being used for services that Title X prohibits (as evidenced by the fact that many commenters apparently assumed that abortion was a permissible method of family planning within the Title X program, *see id.* at 7729-30) and increases the likelihood that funds will be used for improper purposes. The more abortions that are performed at the type of nonspecialized clinics that often house Title X services, the higher both risks. *See id.* at 7765 ("The performance of abortions at nonspecialized clinics that also may provide Title X services increases the risk and potential both for confusion and for the co-mingling or misuse of funds.").

Counseling and Referral Restrictions: HHS explained at length how the 2000 regulations were in tension with a number of other federal conscience protection statutes and, with respect to referral for abortion at least, with section 1008 itself. 84 Fed. Reg. at 7746. As to abortion referrals, HHS explained that "[t]he primary focus of Title X remains on preconception family planning methods and services," and that "[i]n implementing section 1008 . . . the Department has a history of establishing prohibitions on abortion referral, even if at other times it has allowed or required such referrals." *Id.* HHS acknowledged the 2000 regulations "requir[ed] information, counseling and referrals for abortion as a method of family planning in certain cases" but stated that it "has now reconsidered this issue and believes the approach taken in this final rule is a better

interpretation of section 1008." *Id.* In reaching this conclusion, HHS reasoned—consistent with *Rust*, *see supra* pp. 7, 10—that "it is not necessary for women's health that the federal government use the Title X program to fund abortion referrals, directive abortion counseling, or give to women who seek abortion the names of abortion providers" because such information is available from other sources. 84 Fed. Reg. at 7746. HHS further explained that, consistent with the conscience statutes, it would not *require* nondirective pregnancy counseling of objecting grantees. It also noted that the nondirective provision "did not explicitly require pregnancy counseling, nor [did it] prohibit such counseling from discussing abortion if the counseling is nondirective." *Id.* at 7745.

3. Plaintiffs' Contrary Arguments Lack Merit

Because the Supreme Court in *Rust* held that the major components of the Rule flowed directly from HHS's permissible construction of section 1008 (which, as discussed above, has not changed since *Rust*), any challenge to those restrictions is necessarily limited. *See Arent v. Shalala*, 70 F.3d 610, 616 (D.C. Cir. 1995) (citing *Rust* as an example of a situation in which "what is permissible under *Chevron* is also reasonable under *State Farm*"). Plaintiffs nevertheless offer up a welter of arguments for why the Rule is arbitrary and capricious. None is persuasive.

a. Plaintiffs fault HHS for supposedly "not articulat[ing] new findings or information" to support the Rule. States Mem. at 20; *see also* AMA Mem. at 36-37. But as discussed, the Secretary described in detail why his concerns were more than theoretical. *See supra* pp. 32-35. In any event, the APA "imposes no general obligation on agencies to produce empirical evidence." *Stilwell v. Office of Thrift Supervision*, 569 F.3d 514, 519 (D.C. Cir. 2009) (Kavanaugh, J.). Contrary to the States' suggestion, States Mem. at 25, *National Fuel Gas Supply Corp. v. FERC*, 468 F.3d 831 (D.C. Cir. 2006) (Kavanaugh, J.), does not hold otherwise. In the context in which that case arose—FERC's regulation of the relationship between natural gas pipelines, which the

court termed "natural monopolies," *id.* at 834, and their non-marketing affiliates—D.C. Circuit precedent held that "FERC cannot impede vertical integration between a pipeline and its affiliates without 'adequate justification.'" *Id.* at 360 (citation omitted). To meet that standard, FERC tried to justify its challenged rule on the basis of (1) a "theoretical threat" of pipelines granting undue preferences to their affiliates, and (2) "record evidence" indicating that this type of abuse was "a real problem in the industry." *Id.* at 833-34. When the court found such evidence to be "non-existent," it predictably held that FERC acted arbitrarily and capriciously to the extent it "staked its rationale in part on a record of abuse." *Id.* at 843. *National Fuel* nowhere imposes a hitherto unrecognized obligation to submit empirical evidence on all agencies in support of their policy.

b. More broadly, the States dismiss *Rust* as "focus[ing] on the process behind, not the substance of, the 1988 Regulations," and note that in 1988 the Secretary partially relied on reports from the Government Accountability Office (GAO) and the Office of the Inspector General (OIG). States Mem. at 20-21. The States further argue that, because the data in those reports is supposedly outdated, *Rust*'s arbitrary and capricious analysis no longer applies. *Id.*

Supreme Court precedents do not have a shelf life, however, and that is particularly true here. First of all, *Rust* accepted the Secretary's determination that "the new regulations [were] more in keeping with the original intent of the statute" and "supported by a shift in attitude against the 'elimination of unborn children by abortion,'" 500 U.S. at 187, and the Secretary here likewise determined that the Rule reflected a superior interpretation of section 1008, *see supra* pp. 34-35. This is not a ground that is any less applicable now than it was 30 years ago, nor is it one that the Secretary must support with "new findings or information." States Mem. at 20.

The *Rust* Court similarly accepted the Secretary's explanation that the "prior policy failed to implement properly the statute and . . . was necessary to provide clear and operational guidance

to grantees about how to preserve the distinction between Title X programs and abortion as a method of family planning." 500 U.S. at 192-203. As explained above, the Secretary made a similar determination here. It makes no difference that HHS relied in part on the GAO and OIG reports in 1988—contrary to the States' argument, HHS did not cite or rely on these reports in the Rule. Instead, as in 1988, HHS adequately explained why the Rule reflects a better implementation of the statute and why the clear guidance prescribed in the Rule is useful.

c. Plaintiffs contend that HHS failed to account for supposed reliance interests engendered by the prior policy. AMA Mem. at 37 (citing *Encino Motorcars, LLC v. Navarro*, 136 S. Ct. 2117 (2016), and *Fox*); States Mem. at 30. As a threshold matter, the fact that many people "rely" on a particular program does not mean that every policy affecting that program "engender[s]" the type of "serious reliance interests" that the Supreme Court had in mind in *Fox*. *See, e.g.*, *Encino Motorcars*, 136 S. Ct. at 2126. In any event, even setting *Rust* aside, Plaintiffs have no legally cognizable reliance interests in the continued receipt of Title X grants under the conditions they prefer. In contrast to the agency action at issue in *Encino Motorcars*, which concerned private parties' substantive statutory rights, 136 S. Ct. at 2126-27, the challenged regulations here concern discretionary funding decisions. Title X grants are generally available for only one year, 42 C.F.R. § 59.8(b), and HHS regulations provide that "[n]either the approval of any application nor the award of any grant commits or obligates the United States in any way to make any additional, supplemental, continuation, or other award with respect to any approved application or portion of an approved application," *id.* § 59.8(c). A discretionary funding program cannot create legally cognizable reliance interests—and certainly not beyond the stated duration (generally one year) of a Title X grant. *Cf. Janus v. Am. Fed'n of State, Cty., & Mun. Emps.*, 138

S. Ct. 2448, 2484 (2018) (discounting asserted reliance interests because the relevant "contract provisions . . . will expire on their own in a few years' time").

d. Invoking the Supreme Court's decision in *Fox*, Plaintiffs suggest more broadly that HHS needed to offer a more "detailed explanation" because the Rule reflects a change in policy. AMA Mem. at 37; States Mem. at 30. But *Fox* squarely *rejected* the notion that a "heightened standard" should apply where an agency changes policy, 556 U.S. at 514, and held that "it suffices that the new policy is permissible under the statute, that there are good reasons for it, and that the agency *believes* it to be better, which the conscious change of course adequately indicates," *id.* at 515. HHS plainly satisfied that requirement.

Fox went on to explain that a "more detailed justification" is necessary only when a new policy "rests upon factual findings that contradict those which underlay its prior policy; or when its prior policy has engendered serious reliance interests that must be taken into account." 556 U.S. at 515. Neither circumstance is present here. As just explained, the Rule does not upend any legally cognizable reliance interests. And it is based upon HHS's renewed interpretation of section 1008 and, with respect to the program integrity requirements, the need for prophylactic measures to address the risk and the perception that taxpayer dollars will be used to fund abortion—not "factual findings that contradict those which underlay [the] prior policy." That policy and legal judgment—a judgment blessed by the Supreme Court—is legitimate even if it differs from Plaintiffs' judgment and the judgment of prior administrations. *See Nat'l Cable & Telecomm. Ass'n v. Brand X Internet Servs.*, 545 U.S. 967, 981 (2005) ("[T]he agency . . . must consider varying interpretations and the wisdom of its policy on a continuing basis, for example, in response to changed factual circumstances, or a change in administrations." (internal citation omitted)).

e. Consistent with the 1988 regulations upheld in *Rust*, the Rule mandates prenatal care referrals for all pregnant patients, 84 Fed. Reg. at 7789, based on HHS's determination that such care is medically necessary, *id.* at 7761. "Because prenatal care is essential in order to optimize the health of the mother and unborn child, and to help ameliorate the current health inequality as it relates to low income women," HHS explained, "referring low income pregnant women for prenatal care is of increased importance." *Id.* at 7762. HHS also noted that low income women are disproportionately likely to deliver before term and to deliver low birthweight babies, as well as less likely to access adequate prenatal services. *Id.* at 7761-62.

The States nevertheless contend that this aspect of the Rule is arbitrary and capricious. States Mem. at 22-23. Initially, the States contend that the Rule inconsistently treats referrals as directive in the abortion context and nondirective in the prenatal care context, but this is incorrect for reasons previously stated. *See supra* p. 23. More broadly, HHS's judgment that prenatal care is medically necessary is not subject to serious dispute. As HHS explained in 2011, "[p]regnant women, who do not receive adequate prenatal care, run the risk that complications will go undetected or may not be managed in a timely manner, which increases the possibility of adverse outcomes for the mother and baby."[3] Or as Oregon's own website currently states, "[e]arly prenatal care is important to identify and treat babies or mothers at risk for health conditions that can affect the pregnancy."[4] The State of Washington—the plaintiff in a similar challenge to the Rule—agrees: "Early initiation of prenatal care is an important way to improve maternal and infant health outcomes."[5]

[3]https://www.hrsa.gov/sites/default/files/quality/toolbox/pdfs/prenatalfirsttrimestercareaccess.pdf
[4] https://www.oregon.gov/OHA/PH/ABOUT/Documents/indicators/trimesterprenatalcare.pdf
[5] https://www.doh.wa.gov/Portals/1/Documents/1000/SHA-PrenatalCare.pdf

The States are thus left to argue that prenatal care is unnecessary for women who obtain abortions. States Mem. at 23. But this puts the cart before the horse. At the time of the consultations contemplated by the Rule, the patient has not yet *had* an abortion, and abortion-related services are not part of the Title X scheme. Since Title X likewise does not fund prenatal care *services*, the Rule simply (and reasonably) requires that pregnant women be given a prenatal care referral—as was required in the regulations *Rust* upheld. That a patient might *later* obtain an abortion *outside* the Title X project is no basis for withholding information *within* that project.

f. The States contend that the Rule's prohibition on referrals for abortion as a method of family planning is arbitrary and capricious because, in their view, referrals for abortion do not promote or encourage abortion. States Mem. at 23. This argument is difficult to fathom. A referral—sending a patient to a provider to obtain an abortion—*by definition* promotes and encourages any abortion that results.[6] Even if this proposition were somehow debatable, HHS's acceptance of it was certainly reasonable. And in any event, this argument is beside the point. Section 1008 prohibits use of Title X funds "in programs where abortion is a method of family planning." 42 U.S.C. § 300a-6. HHS reads that statute as establishing "a broad prohibition on funding, directly or indirectly, activities that treat abortion as a method of family planning," including abortion referrals, and the Supreme Court has already held that this interpretation is

[6] The States contend that HHS previously determined that referrals did "little, if anything, to encourage or promote the selection of abortion as a method of family planning." States Mem. at 23 (quoting 65 Fed. Reg. at 4125, but apparently referring to 65 Fed. Reg. at 41,274). But in this passage, HHS determined that the provision of additional "neutral, factual information about abortion providers *in the course of providing an abortion referral*" would "not encourage or promote the selection of abortion as a method of family planning *over and above the provision of the information previously considered permissible*." 65 Fed. Reg. at 41,274 (emphases added). In other words, having previously decided to permit referrals for abortion as a method of family planning, HHS decided that allowing additional information about listed providers would not have a meaningful additional effect. That does not support the claim that abortion referrals *themselves* do not promote or encourage abortion.

permissible. *See supra* p. 31. The statute does not require a separate determination that activities that treat abortion as a method of family planning also, as an empirical matter, "promote or encourage abortion."

g. Plaintiffs contend that "[l]imiting who can provide pregnancy counseling is irrational" and attack HHS's decision to require that nondirective pregnancy counseling be offered by a physician or an advanced practice provider. States Mem. at 24; *see also* AMA Mem. at 27 (arguing that this provision "lacks any justifications"). But it is hardly "irrational" to insist that those who provide nondirective pregnancy counseling using HHS funds be qualified to do so, since pregnancy is a medical condition, and pregnancy counseling discusses several medical options. In fact, HHS initially proposed to allow *only physicians* to provide either a list of providers to patients or nondirective counseling. *See* 83 Fed. Reg. at 25,531 (stating "[i]f asked, a medical doctor may provide a list of licensed, qualified, comprehensive health service providers (some, but not all, of which also provide abortion, in addition to comprehensive prenatal care)"); *id.* at 25,507 ("Recognizing [ ] the duty of a physician to promote patient safety, a doctor would be permitted to provide nondirective counseling on abortion."); *id.* at 25,518 ("[A] doctor, though not required to do so, would be permitted to provide nondirective counseling on abortion."). In response to comments, HHS decided to allow *both physicians and advanced practice providers* to provide nondirective counseling. 84 Fed. Reg. at 7761. HHS therefore considered which types of health care professionals to include, and reasonably drew the line at advanced practice providers, who have "advanced medical degrees, licensing, and certification requirements." *Id.* at 7728 n.41.

h. Plaintiffs contend that it was arbitrary and capricious for HHS to rely on the conscience protection statutes because—in their view—the prior regulations were facially neutral and did not violate those statutes. States Mem. at 25. First, Plaintiffs do not have any basis to

challenge a rule *allowing* them to provide nondirective counseling concerning abortion, just because it also allows others *not* to do so. And although Plaintiffs' briefs obscure this point, *see* AMA Mem. at 20, HHS did not rely on the conscience statutes for the separation requirements or the prohibition on abortion referrals as a method of family planning—the basis for those sets of requirements was section 1008. HHS relied on the conscience statutes for those portions of the Rule providing that objecting grantees are *not required* to engage in nondirective abortion counseling. *See supra* pp. 34-35.

But even putting this aside, Plaintiffs' analysis of the conscience statutes misses the point. Under the 2000 regulations, grantees were required to provide counseling and referrals for abortion. That requirement violated—or was at least in tension with—the conscience statutes because it effectively prevented providers with religious objections to doing so from receiving Title X grants. Indeed, Plaintiffs are wrong that the conscience statutes do not apply if an abortion referral mandate is facially neutral. *See, e.g.*, 42 U.S.C. § 238n(a) (proscribing discrimination in any program receiving federal financial assistance based on an entity's refusal to provide referrals for induced abortions). The 2000 regulations therefore effectively prevented providers with conscience objections from receiving Title X grants. Indeed, HHS had already acknowledged this problem when it implemented conscience protections in 2008 (that were later partially repealed in 2011). *See* 76 Fed. Reg. 9968 (Feb. 23, 2011); 73 Fed. Reg. 78,072 (Dec. 19, 2008). And in the Final Rule, HHS also noted that many grantees and Title X providers may not know of their rights under the conscience statutes and that, even if the previous abortion referral requirement was not in tension with those statutes, such a requirement may deter qualified providers from participating in Title X projects and otherwise create ambiguity. 84 Fed. Reg. at 7716-17. HHS's reliance on these statutes was not arbitrary and capricious.

i. The States object to the removal of the requirement that a Title X project provide "medically approved" family planning methods. States Mem. at 30. But as HHS explained, the States' complaint is with Congress, not HHS: "When Congress specified what family planning methods and services Title X projects must provide, Congress directed that the methods and services be ''acceptable and effective''; it did not specify that they be 'medically approved.'" 84 Fed. Reg. at 7732 (quoting 42 U.S.C. § 300(a)). Contrary to Plaintiffs' suggestion that HHS "barely acknowledge[d]" this change from the 2000 regulations, States Mem. at 31, HHS directly addressed it, *see* 84 Fed. Reg. at 7732, 7740-41, and explained that the "medically approved" language had proved unworkable, *see id.* at 7732 (explaining practical difficulty of enforcing the "medically approved" requirement). This response was an adequate justification for resorting to the statutory text, which already requires that any family planning services be "acceptable and effective," and which HHS rationally concluded would "sufficiently ensure[]" that Title X clients receive appropriate services. *Id*.

j. The States assert that HHS's new definition of "natural family planning" "disproportionately highlights non-contraceptive methods." States Mem. at 31. Plaintiffs' emphasis on contraception, however, does not derive from Title X, which provides that projects must "offer a broad range of acceptable and effective family planning methods and services (including natural family planning methods, infertility services, and services for adolescents.)" 42 U.S.C. § 300(a). The Rule simply defines this "broad range" to include, in addition to the statutory focus on "natural family planning methods" and "infertility services" (such as adoption), contraception, abstinence, and fertility-based awareness (which HHS explained is just a more recent term for the same kind of family planning methods encompassed by "natural family planning," *see* 84 Fed. Reg. at 7731). This is fully consistent with the text of Title X.

In any event, this criticism is much ado about not much at all. Although the States contend that this definition would reduce access to "a broad range of medically-approved contraceptive care," States Mem. at 31, HHS noted that "projects must also provide contraception, and can do so in proportion to the demand for such methods," 84 Fed. Reg. at 7731; *see also id.* at 7787 (to be codified at 42 C.F.R. § 59.5(a)(1)).

Plaintiffs also suggest that the Rule would invite entities that "refuse to offer information or services relating to medically-approved contraception" to participate in Title X and thus "degrade the quality of care patients receive." States Mem. at 32. But HHS addressed this concern by explaining that even if individual service sites might offer a limited number of family planning methods, each Title X project, as a whole, must "provide[] a broad range of family planning methods and services, including contraception and natural family planning." 84 Fed. Reg. at 7732.

k. Plaintiffs claim that the Rule undermines the provider-patient relationship and requires them to violate ethical standards. States Mem. at 25-27; AMA Mem. at 20. But HHS considered and responded to this precise issue. HHS explained:

> In general, medical ethics obligations require the medical professional to share full and accurate information with the patient, in response to her specific medical condition and circumstance. Under the terms of this final rule, a physician or APP may provide nondirective pregnancy counseling to pregnant Title X clients on the patient's pregnancy options, including abortion. . . . Within the limits of the Title X statute and this final rule, the physician or APP is required to refer for medical emergencies and for conditions which non-Title X care is medically necessary for the health and safety of the mother or child.

84 Fed. Reg. at 7724.

HHS's analysis of this issue was not only logical—as HHS recognized, it was also consistent with multiple Supreme Court decisions and other legal authorities. HHS noted that: (i) *Rust* upheld similar requirements and HHS "does not believe the Court in *Rust* upheld a rule that required the violation of medical ethics, regulations concerning the practice of medicine, or

malpractice liability standards"; (ii) "Federal and State conscience laws, in place since the early 1970s, have protected the ability of health care personnel to not assist or refer for abortions in the context of HHS funded or administered programs (or, under State law, more generally)"; (iii) "in *Roe v. Wade*, 410 U.S. 113 (1973), the Court favorably quoted a declaration that neither physician, hospital, nor hospital personnel shall be required to perform any act violative of personally held moral principles'' (quotation marks and brackets omitted); and (iv) in *National Institute of Family & Life Advocates v. Becerra*, 138 S. Ct. 2361 (2018) (*NIFLA*), "the Supreme Court upheld conscience objections to making certain statements, despite objections from professional medical organizations that similarly asserted medical ethics standards." 84 Fed. Reg. at 7748.

HHS thus did not ignore the concerns that Plaintiffs raise here. Instead, it considered them and simply adopted a different view—that the Rule's requirements, properly understood, are consistent with medical ethics obligations. And again, *Rust* upheld a nearly identical version of the counseling and referral restrictions that had the same implications. 500 U.S. at 199. In fact, Justice Blackmun argued in his dissent in *Rust* that "the ethical responsibilities of the medical professional demand" that Title X patients be "provide[d] with the full range of information and options regarding their health and reproductive freedom," including "the abortion option." *Id.* at 213-14. His view did not prevail.

l. AMA contends that the counseling and referral provisions are arbitrary and capricious because they are supposedly inconsistent with guidelines issued by HHS, along with the Centers for Disease Control (CDC), in 2014. AMA Mem. at 24. But this is just a rehash of Plaintiffs' challenge to HHS's departure from its prior policy governing abortion counseling and referrals. As explained above, HHS was entitled to depart from its previous policy and adopt the position, blessed by the Supreme Court in *Rust*, that section 1008 prohibits abortion referral as a

method of family planning and does not require the provision of abortion counseling. *See* 84 Fed. Reg. at 7716-7717. Just as HHS could permissibly depart from the 2000 regulations, it could adopt a position different from the one espoused in the 2014 guidance based on the reasoned justification discussed above. *See supra* p. 38.

m. Relying on statements by certain grantees that they will leave the Title X program if the counseling and referral provisions take effect, AMA predicts "grave public health consequences" if those grantees depart. AMA Mem. at 20-21. There are a number of problems with this claim. As previously noted, the Supreme Court has already upheld HHS's interpretation of section 1008, and HHS has adequately explained that it does not share Plaintiffs' views concerning professional and medical ethics. *See supra* pp. 44-45. AMA's reliance on these departure threats thus essentially amounts to a request that this Court constrain the authority of HHS beyond the limits imposed by Congress, by giving certain grantees veto power over otherwise legally permissible and reasoned policy judgments. That tactic did not work in *Rust*, and it should not work here either. *Cf.* Planned Parenthood Amicus Brief at 14 n.45, *Rust* (No. 89-1391), 1990 WL 10012649 ("Since many providers will not accept Title X funds under the unethical restrictions imposed by the regulations, they will be forced to close or drastically curtail services, depriving poor women of their sole source of family planning services.").

In any event, HHS considered the effect the Rule would have on Title X patients and concluded that the Rule would "contribute to more clients being served, gaps in service being closed, and improved client care." 84 Fed. Reg. at 7723. The agency later explained that it "expects that honoring statutory protections of conscience in Title X may increase the number of providers in the program," *id.* at 7780, and it pointed to data showing that a substantial number of medical professionals would limit the scope of their practice if conscience protections were not

put in place, *id.* at 7781 n.139. After analyzing this issue in detail, HHS concluded that the counseling and referral provisions "will result in more Title X applicants." *Id.* at 7781. More fundamentally, the very nature of the time-limited and discretionary Title X grant process presupposes that there will be turnover and replacement among grantees. *See supra* p. 37. There is thus no basis for rejecting the agency's conclusion on this point, or for substituting the preferences of a subset of current grantees for the Secretary's well-reasoned view.

n. AMA similarly accuses HHS of "fail[ing] to consider the harms to public health caused by the Separation Requirement" because, AMA claims, that requirement will force providers to leave the Title X program and patients will suffer uncoordinated care from those who remain. AMA Mem. at 39. But HHS considered both of these points. As to the prospect of providers leaving, HHS acknowledged that "such calculations would be purely speculative, and, thus, very difficult to forecast or quantify," but ultimately concluded that it "does not anticipate that there will be a decrease in the overall number of facilities offering services, since it anticipates other, new entities will apply for funds, or seek to participate as subrecipients, as a result of the final rule." 84 Fed. Reg. at 7781. As to coordination, HHS likewise explained that "[i]t is not uncommon for people to have different health care providers for different health care needs" and elaborated that "[i]f Title X services and abortion services are separate, it is no more difficult for Title X providers to maintain two electronic records, one for Title X services and another for abortion services, than to keep abortion services and other services separate within the same [electronic medical records (EHR)] system." *Id.* at 7767. HHS went on to note that, because of the "growing interoperability of EHRs and other health IT, it is a simpler matter for one provider to share a patient's EHR with another provider," meaning that "any risk associated with

mishandling or missing patient data should be minimized." *Id*. This analysis was not arbitrary and capricious.

o. HHS estimated, based on Congressional Research Service data, that 10% of clinics that receive Title X funding offer abortion as a method of family planning in addition to their Title X-funded activities, and the agency concluded that for those providers who would need to make changes, coming into compliance would cost between $20,000 to $40,000 per affected site. 84 Fed. Reg. at 7781-82. Plaintiffs insist that the costs of compliance will be significantly higher for some providers. States Mem. at 30; AMA Mem. at 38-39. But the four-factor approach set forth in the Rule permits consideration of providers' particular circumstances, and HHS explained that "[t]he rule also allows case-by-case determinations on whether physical separation is sufficiently achieved to take the unique circumstances of each program into consideration." 84 Fed. Reg. at 7766. In any event, this is a facial challenge. Even assuming some current grantees will incur compliance costs that exceed HHS's estimates, that would not render every application of the Rule invalid.

p. HHS explained that "it is not necessary for women's health that the federal government use the Title X program to fund abortion referrals, directive abortion counseling, or give to women who seek abortion the names of abortion providers," and noted that "[i]nformation about abortion and abortion providers is widely available and easily accessible, including on the internet." 84 Fed. Reg. at 7746. Plaintiffs describe this latter factual claim as "astonishing," AMA at 22, and "stunning," States Mem. at 26, and AMA accuses HHS of ignoring that some people may not have ready access to a phone or the Internet. AMA Mem. at 22-23. But HHS was simply making the observation that information about abortion remains available outside the Title X project. Whether Plaintiffs agree with HHS's framing is beside the point. The question is whether

the government must fund abortion-related information and services that are outside the scope of the congressionally created program. *Rust* held that it does not—at a time when the Internet was in its infancy. *See* 500 U.S. at 203 ("Under the Secretary's regulations, however, a doctor's ability to provide, and a woman's right to receive, information concerning abortion and abortion-related services *outside the context of the Title X project* remains unfettered." (emphasis added)); *id.* ("It would undoubtedly be easier for a woman seeking an abortion if she could receive information about abortion from a Title X project, but the Constitution does not require that the Government distort the scope of its mandated program in order to provide that information.").

q. Finally, Plaintiffs repeatedly attack the physical separation requirements as arbitrary and capricious, contending that those requirements are "erroneous and irrational," as well as a "radical departure" from previous policy. States Mem. at 27. But *Rust* upheld materially identical requirements against both statutory and constitutional challenges, and those requirements were themselves a departure from what came previously. *See supra* p. 15. Plaintiffs insist "that providers comply with Title X funding segregation requirements" and that there is no evidence of improper use of funds. States Mem. at 28. But again, HHS's decision to reinstate the physical separation requirements was not based on grantees' failure to observe existing regulatory limits. Rather, HHS no longer believes that existing procedures are sufficient to ensure compliance with section 1008, as interpreted by HHS and as sanctioned in *Rust*. In addition to *Rust* itself, HHS provided numerous cogent reasons for that conclusion including, *inter alia*, that (1) Title X projects use flexible grants that give considerable latitude to grantees, (2) this flexibility raises the specter of Title X funds being used to build infrastructure that supports abortion, (3) the prior requirements, as a matter of economic reality, had the effect of indirectly supporting abortion-related activities, (4) abortions are increasingly being performed at the types of sites that receive

Title X funds, (5) examples of overbilling in the Medicaid program reinforced the need for additional clarity in the Title X program, (6) more abortions performed at nonspecialized clinics that provide Title X services create both a risk of comingling of funds and public confusion (as demonstrated by commenters' erroneous belief that abortion was a permissible method of family planning within the Title X program). *See supra* pp. 32-34.

Given HHS's stated rationale, the fact that HHS already has procedures in place to ensure compliance with a prior interpretation of section 1008 *that it has now rejected*, s*ee* States Mem. at 28, adds nothing to the calculus. HHS concluded that it need not "suffer the flood before building the levee," *Stillwell*, 569 F.3d at 519, and adopted the separation requirements to increase transparency, promote accountability, and "facilitate auditing and enforcement of program requirements," 84 Fed. Reg. at 7765. Such "changes in policy" are permissible so long as the agency provides a rational explanation, *see Int'l Rehab. Sciences Inc. v. Sebelius*, 688 F.3d 994, 1001 (9th Cir. 2012), which, as discussed above, HHS has done here. *See* New England Power Generators Ass'n v. FERC, 879 F.3d 1192 (D.C. Cir. 2018) ("So long as any change is reasonably explained, it is not arbitrary and capricious for an agency to change its mind in light of experience, or in the face of new or additional evidence, or further analysis or other factors indicating that the agency's earlier decision should be altered or abandoned.").

E. Plaintiffs' Notice-And-Comment Claims Are Meritless

Plaintiffs also claim the NPRM provided no notice with respect to the requirement that nondirective pregnancy counseling come from physicians or "advanced practice providers." AMA Mem. at 25-26; States Mem. at 32. But a "final regulation that varies from the proposal, even substantially, will be valid as long as it is 'in character with the original proposal and a logical outgrowth of the notice and comments.'" *Hodge v. Dalton*, 107 F.3d 705, 712 (9th Cir. 1997)

(citation omitted). To determine whether notice was adequate, courts ask whether a complaining party should have anticipated that a particular requirement might be imposed, and whether a new round of notice and comment would provide the first opportunity for interested parties to offer comments that could persuade the agency to modify its rule. *Envt'l Def. Ctr. v. EPA*, 344 F.3d 832, 851 (9th Cir. 2003). Plaintiffs received sufficient notice under this standard. As discussed, the question of which types of providers and/or staff may engage with and provide information to patients was presented, HHS received comments objecting to those proposed restrictions, and HHS adopted a *less restrictive* approach in response. *See supra* p. 41.

Plaintiffs nonetheless contend that the NPRM failed to give sufficient notice because it referred only to nondirective counseling *on abortion* rather than nondirective counseling *on pregnancy*. States Mem. at 33; AMA Mem. at 26 n.6. But nothing in the NPRM suggested that HHS was drawing a distinction between nondirective abortion counseling and nondirective pregnancy counseling more generally with respect to this issue, nor is there any apparent reason why it would do so. Indeed, after specifying that "a doctor, though not required to do so, would be permitted to provide nondirective counseling on abortion," HHS cited to the nondirective provision and its requirement (which HHS quoted) that "all pregnancy counseling shall be nondirective." 83 Fed. Reg. at 25,518 & n.55. Thus, the question of which types of providers and/or staff may engage with and provide information to patients was squarely presented.

F. The States' Regulatory Impact Analysis Argument Fails

The States also contend that "HHS failed to disclose sufficient information in its regulatory impact analysis to satisfy the APA's notice requirement, because it did not sufficiently identify and quantify the costs and benefits of the intended rulemaking." States Mem. at 34. As an initial matter, HHS did sufficiently assess the costs and benefits of the Rule. *See* 83 Fed. Reg. at 25,523-

526. As HHS explained in the NPRM, however, it performed this assessment based on Executive Orders 12,866 and 13,563. *Id.* at 25,521. Alleged violations of these "Executive Orders cannot give rise to a cause of action" under the APA. *Fla. Bankers Ass'n v. U.S. Dep't of Treasury*, 19 F. Supp. 3d 111, 118 n.1 (D.D.C. 2014), *vacated on other grounds*, 799 F.3d 1065 (D.C. Cir. 2015).

In addition, "[a]n Executive Order devoted solely to the internal management of the executive branch—and one which does not create any private rights—is not subject to judicial review," *Meyer v. Bush*, 981 F.2d 1288, 1297 n.8 (D.C. Cir. 1993), and Executive Orders 12,866 and 13,563 are precisely such orders. While Executive Order 12,866 directs agencies to "assess both the costs and the benefits of the intended regulation," Exec. Order 12,866, § 1(b)(6) (Sept. 30, 1993), in a section titled "Judicial Review," it states:

> This Executive order is intended only to improve the internal management of the Federal Government and does not create any right or benefit, substantive or procedural, enforceable at law or equity by a party against the United States, its agencies or instrumentalities, its officers or employees, or any other person.

Id. § 10. Executive Order 13,563, which "supplement[s] and reaffirms" Executive Order 12,866, Exec. Order 13,563, § 1(b) (Jan. 18, 2011), contains nearly identical language: "This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person." *Id.* § 7(d). This claim gets the States nowhere.

G. *Rust* Forecloses AMA's First Amendment Claim

The Supreme Court in *Rust* held that the counseling, referral, advocacy, and program integrity provisions of the 1988 regulations (1) did not violate the First Amendment rights of program participants; (2) did not improperly condition funding on the relinquishment of a constitutional right; and (3) did not violate a woman's Fifth Amendment right to choose abortion. *See* 500 U.S. at 192-203. Although the States do not reprise any of these constitutional issues in

their motion, AMA contends that the referral provisions here unconstitutionally impose content- and viewpoint-based restrictions as well as impermissibly compel speech. AMA Mem. at 28. This claim is clearly barred by *Rust* and, to its credit, AMA appears to agree.[7]

In *Rust*, the Supreme Court expressly considered—and rejected—the contention that the 1988 "regulations violate the First Amendment by impermissibly discriminating based on viewpoint because they prohibit all discussion about abortion as a lawful option—including counseling, referral, and the provision of neutral and accurate information about ending a pregnancy—while compelling the clinic or counselor to provide information that promotes continuing a pregnancy to term." 500 U.S. at 192; *see id.* at 192-200. As the Court explained, the 1988 regulations simply "refus[ed] to fund activities, including speech, which are specifically excluded from the scope of the project funded," and the Constitution generally permits "the Government [to] choose not to subsidize speech." *Id.* at 193-94, 200.

Given this controlling precedent, AMA contends that *Rust* "was wrongly decided" and has "been undermined by nearly 30 years of experience with the Title X program and recent Supreme Court precedent confirming that medical speech is deserving of First Amendment protection of the highest order." AMA Mem. at 28. But AMA accepts "the Supreme Court's repeated admonition that lower courts must leave to the Supreme Court the prerogative of overruling its own decisions," *id.* at 28-29 (internal quotation marks omitted), rendering any extended discussion of AMA's constitutional arguments unnecessary here. Only the Supreme Court can reconsider *Rust*.

In any event, AMA is wrong to suggest that recent precedent—*NIFLA* and *Janus*—calls

[7] Although the States' Complaint contends that the Rule is unconstitutionally vague and places an impermissible condition on First Amendment rights, *see* Compl., No. 6:19-cv-00317-MC, ECF No. 1 ¶¶ 316-323, 331-336, the States do not assert these claims in their preliminary injunction motion. The government therefore does not address them in this brief.

Rust into question. AMA Mem. at 29-30. Neither decision has anything to do with *Rust*. *NIFLA* did not address government *subsidization* of speech at all, but a law purporting to *compel* certain pregnancy clinics to provide particular notices without any connection to the receipt of government funding. *See* 138 S. Ct. at 2368-78. *Janus* likewise invalidated an Illinois fee scheme that *compelled* public employees to subsidize speech with which they disagreed. *See* 138 S. Ct. at 2459-86. Understandably, neither decision even mentions *Rust* given the settled rule that as a general matter, "if a party objects to the condition on the receipt of federal funding, its recourse is to decline the funds," even "when the objection is that a condition may affect the recipient's exercise of its First Amendment rights." *Agency for Int'l Devel. v. All. For Open Soc'y Int'l, Inc.*, 570 U.S. 205, 214 (2013) (collecting cases); *see also id.* at 216-17 (reaffirming *Rust*). And again, even if those decisions could plausibly be read as calling *Rust* into question—which they cannot—*Rust* would still be binding here. *See Rodriguez de Quijas v. Shearson/Am. Exp., Inc.*, 490 U.S. 477, 484 (1989) ("If a precedent of this Court has direct application in a case, yet appears to rest on reasons rejected in some other line of decisions, the Court of Appeals should follow the case which directly controls, leaving to this Court the prerogative of overruling its own decisions.").[8]

Finally, AMA argues that the Rule's provision requiring that nondirective pregnancy counseling be offered only by either a physician or an advanced practice provider imposes a "speaker-based ban." AMA Mem. at 31. AMA contends that this "ban" was "not at issue in *Rust*," but does not appear to explicitly argue that it violates the First Amendment. *See id*. That is wise—

[8] AMA also suggests that *Rust* "failed to appreciate" that the materially indistinguishable restrictions upheld in that case supposedly infringe the rights of patients as well as doctors. AMA Mem. at 30-31. But neither the 1988 regulations nor the Final Rule place any limitations on speech outside the federally-funded Title X program. In any event, in addition to rejecting providers' First Amendment claims, the Court also carefully considered and rejected arguments that the restrictions violated a woman's Fifth Amendment right to choose abortion and impermissibly interfered with the doctor-patient relationship. *See Rust*, 500 U.S. at 192-203.

such an argument would be plainly meritless. "[W]hen the government appropriates public funds to promote a particular policy of its own it is entitled to say what it wishes." *Rosenberger v. Rector and Visitors of Univ. of Va.*, 515 U.S. 819, 833 (1995) (discussing *Rust*). The Rule is merely a government decision *not to fund* nondirective pregnancy counseling in Title X unless the counseling is given by certain medical professionals, *i.e.*, those qualified "due to their advanced education, licensing, and certification to diagnose and treat patients while advancing medical education and clinical research." 84 Fed. Reg. at 7728. The Rule does not discriminate on the basis of content or viewpoint. Indeed, even if the Rule directly regulated entry into a profession—which, as a mere funding decision, it does not—it would not violate the First Amendment. *See Lowe v. SEC*, 472 U.S. 181, 228 (1985) ("Regulations on entry into a profession, as a general matter, are constitutional if they have a rational connection with the applicant's fitness or capacity to practice the profession." (citation omitted)).

II. PLAINTIFFS WILL SUFFER NO IRREPARABLE HARM

Showing irreparable harm absent an injunction is "necessary" to obtain such relief. *Ctr. for Food Safety v. Vilsack*, 636 F.3d 1166, 1171 n.6 (9th Cir. 2011); *Winter*, 555 U.S. at 19. A party "seeking preliminary relief [must] demonstrate that irreparable injury is *likely* in the absence of an injunction." *Winter*, 555 U.S. at 22. Plaintiffs cannot carry that burden.

A. The States

The States' primary claim of irreparable harm is that the Rule will negatively impact the health of state residents. *See* States Mem. at 35-38. Because these allegations "do not rise to the level of a concrete, particularized, actual or imminent injury against the state itself, that is independent from alleged harm to private parties," *Oregon v. Legal Servs. Corp.*, 552 F.3d 965, 972 (9th Cir. 2009), they cannot establish that the States even have standing to bring this action,

much less that they have satisfied the demanding irreparable injury standard. Although the "doctrine of *patens patriae* allows a sovereign to bring suit on behalf of its citizens" in certain circumstances, *Washington v. Chimei Innolux Corp.*, 659 F.3d 842, 847 (9th Cir. 2011), it is well-established that a state "'does not have standing as *parens patriae* to bring an action against the Federal government,'" *Sierra Forest Legacy v. Sherman*, 646 F.3d 1161, 1178 (9th Cir. 2011) (quoting *Alfred L. Snapp & Son, Inc. v. Puerto Rico*, 458 U.S. 592, 610 n.16 (1982)).

The States also contend that the Rule's "interference" with their "sovereign interest" in regulating the medical profession is irreparable. States Mem. at 38. But again, the Rule merely sets conditions on receipt of federal funds; it does not directly regulate the States or interfere with their interests in enforcing measures they deem necessary to regulate the medical profession.

In addition, the States assert irreparable harm to their proprietary interests, namely that, in the event that the Rule leads to Title X providers leaving the program and patients losing access to care, the States will "incur treatment costs in their state Medicaid and other programs that they would not otherwise have incurred." States Mem. at 39. But again, this claimed injury stems from a Rule that regulates "*someone else*"—*i.e.*, entities that provide family planning services with Title X funds, and depends on "the response of the regulated . . . third party to the government action"—and perhaps on the response of others as well (*i.e.*, Title X patients). *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 562 (1992). The States have not shown that the attenuated chain of events needed to create these speculative harms are imminently likely to occur. And the "Hobson's choice" the States describe—between accepting Title X funds and imposing conditions on sub-recipients that are allegedly unlawful, States Mem. at 40—does not establish irreparable injury: Because the States are unlikely to succeed on the merits of their argument that these conditions are unlawful, they face no dilemma here.

B. AMA Plaintiffs

AMA asserts that the Final Rule will (1) lead to a reduction in Title X providers and services, (2) interfere with the provider-patient relationship, and (3) harm patients and public health. None of these assertions is sufficient to establish irreparable harm.

1. Impact on Title X Services

First, AMA asserts that "all Planned Parenthood affiliates, numerous states, and other providers" will choose to forego Title X funds rather than comply with the Final Rule, which will result in "closures, layoffs, and service cutbacks." AMA Mem. at 40-41. Again, this argument rests on the erroneous assumption that the Rule is unlawful; an entity's choice not to comply with a legal funding condition plainly does not create an irreparable injury. And while AMA also suggests that the providers who choose instead to comply with the Rule will "be forced to divert precious resources to" compliance, AMA Mem. at 41, "ordinary compliance costs are typically insufficient to constitute irreparable harm," *Freedom Holdings, Inc. v. Spitzer*, 408 F.3d 112, 115 (2d Cir. 2005) (collecting cases). AMA offers no reason why this case should be treated any differently. To the contrary, the "providers" it describes—unlike regulated parties who must absorb significant costs to comply with federal regulations—can simply forgo receiving taxpayer funds if it would be more costly on balance to comply. And if the costs of compliance are less than Title X funding, the providers will come out ahead. Either way, there is no irreparable injury here. *See* *United States v. City of Los Angeles*, 595 F.2d 1386, 1391 (9th Cir. 1979) (federal agency actions "cannot be enjoined simply because those actions may require recipients of congressional largesse to expend large amounts of time and [monetary] resources").

2. Harm to Provider-Patient Relationship

Next, Plaintiffs claim that the Rule will "force providers to choose between violating their ethical responsibilities and leaving the Title X program." But the Rule does no such thing. *See* 84 Fed. Reg. at 7724 (explaining that the counseling and referral requirements are consistent with medical ethics obligations). To the extent providers believe that it is necessary to make abortion referrals, they are free to do so. They simply cannot, consistent with the requirements of Section 1008, use federal Title X funds for that purpose. *See* *Rust*, 500 U.S. at 203 ("[A] doctor's ability to provide, and a woman's right to receive, information concerning abortion and abortion-related services outside the context of the Title X project remains unfettered.").

To the extent the AMA Plaintiffs suggest that the Final Rule will "cause patients to lose trust in their providers and the medical system as a whole," AMA Mem. at 43, they do not establish, with concrete examples of particular patients of any named provider plaintiff, that such harm is imminently likely to occur during the pendency of this litigation if an injunction is not entered. *See, e.g.*, Megregian Decl. ¶ 38 (certified nurse-midwife plaintiff assuming that, at some undetermined point in the future, the Rule will "lead inevitably to an erosion of my patients' trust").

3. Harm to Patients and Public Health

Finally, AMA argues that the Final Rule "will have devastating consequences on patients." AMA Mem. at 43. In making these allegations, Plaintiffs impermissibly "attempt[] to redirect the focus of the irreparable harm inquiry to third parties," but "'[a] plaintiff seeking a preliminary injunction must establish that *he is* likely to suffer irreparable harm in the absence of preliminary relief.'" *Exeltis USA Inc. v. First Databank, Inc.*, No. 17-cv-04810-HSG, 2017 WL 6539909, at *9 (N.D. Cal. Dec. 21, 2017) (quoting *Winter*, 555 U.S. at 20) (ellipsis omitted). In any event, AMA has not demonstrated that the public health harms it describes are "of such *imminence* that

there is a clear and present need for equitable relief to prevent irreparable harm." *Chaplaincy of Full Gospel Churches v. England*, 454 F.3d 290, 297 (D.C. Cir. 2006). By Plaintiffs' own theory, this harm will only materialize if (1) a significant number of sub-recipient providers choose to leave the Title X program rather than comply with the Final Rule; and (2) without such funding, such providers would "shorten hours, lay off clinicians, and close health centers," AMA Mem. at 43; and (3) that, as a result, "diseases will go undetected, more women will have unwanted pregnancies, and prenatal care will be delayed," *id*. at 44. And this chain of hypotheticals in turn rests on the unstated assumption that new providers will not fill any gaps if current providers leave the program. But as discussed above, HHS concluded the opposite in the Rule, and that determination was not arbitrary and capricious. *See supra* pp. 46-47; *see also* 84 Fed. Reg. at 7756 (concluding that Rule will "expand[] the type and nature of the Title X providers . . . so as to fill gaps and expand family planning services").

III. THE BALANCE OF EQUITIES AND THE PUBLIC INTEREST WEIGH IN FAVOR OF DENYING PLAINTIFFS' MOTIONS

On the other side of the ledger, the government will "suffer[] a form of irreparable injury" if it "is enjoined by a court from effectuating statutes enacted by representatives of its people." *Maryland v. King*, 567 U.S. 1301, 133 S. Ct. 1, 3 (2012) (Roberts, C.J., in chambers) (citation omitted).[9] That is particularly true here, as the government has a compelling interest in following longstanding federal law prohibiting the use of Title X funds for programs where abortion is a method of family planning. *See* 42 U.S.C. § 300a-6. Granting Plaintiffs their desired injunction would require HHS to disburse taxpayer dollars in violation of Title X and would thwart lawful regulations intended to avoid any risk that federal funds will be used—or perceived to be used—

[9] When the federal government is the opposing party, the balance of equities and public interest merge. *See Nken v. Holder*, 556 U.S. 418, 435 (2009).

to subsidize abortion, an unquestionably irreparable injury to both the government and the public more generally.

The need to avoid that harm significantly outweighs any of Plaintiffs' asserted injuries. At bottom, Plaintiffs simply desire to receive government subsidies under the terms and conditions they prefer. But "the government may 'make a value judgment favoring childbirth over abortion, and implement that judgment by the allocation of public funds,'" by "subsidiz[ing] family planning services which will lead to conception and child birth, and declining to 'promote or encourage abortion.'" *Rust*, 500 U.S. at 192-93 (citation omitted). Accordingly, the balance of equities and public interest make preliminary injunctive relief inappropriate.

A preliminary injunction would particularly disserve the public interest given the nature of Plaintiffs' attacks against the Rule. *Rust* blessed highly similar regulations and, as discussed at length previously, Plaintiffs' argument that Congress silently abrogated *Rust* lacks merit. *See supra* Part I.B. Necessarily then, most of Plaintiffs' arguments amount to various assertions that HHS failed to adequately consider particular issues and topics in a rulemaking consisting of over 500,000 comments. Those arguments are wrong, *see supra* Part I.D, particularly since an agency "need not address every comment" but must only "respond in a reasoned manner to those that raise significant problems." *Reytblatt v. Nuclear Regulatory Comm'n*, 105 F.3d 715, 722 (D.C. Cir. 1997). Indeed, failing to respond to comments is not itself a sufficient basis for invalidating agency action. Rather, "[t]he failure to respond to comments is significant only insofar as it demonstrates that the agency's decision was not based on a consideration of the relevant factors." *Thompson v. Clark*, 741 F.2d 401, 409 (D.C. Cir. 1984). But even if the Court were later to accept some of these arguments, the likely remedy would be a remand without vacatur. *See Pollinator Stewardship Council v. EPA*, 806 F.3d 520, 532 (9th Cir. 2015) (vacatur less appropriate when

agency "could adopt the same rule on remand" by "offer[ing] better reasoning" or "by complying with procedural rules"); *La. Fed. Land Bank Ass'n, FLCA v. Farm Credit Admin.*, 336 F.3d 1075, 1085 (D.C. Cir. 2003) (remanding rather than vacating based on the conclusion that it was "not unlikely" that the agency "'[would] be able to justify a future decision to retain the [r]ule'" (citation omitted)). The Court should not issue a sweeping preliminary injunction against the Rule's operation when Plaintiffs would, at most, be entitled to far more limited relief at final judgment.

IV. ANY INJUNCTIVE RELIEF SHOULD BE LIMITED

A. Any Injunctive Relief Should Be Limited To The Plaintiffs

At a minimum, any injunction should be no broader than necessary to provide Plaintiffs relief, and should therefore be limited to redressing the injuries of the parties before this Court. As the Supreme Court recently confirmed, any "remedy" ordered by a federal court must "be limited to the inadequacy that produced the injury in fact that the plaintiff has established"; a court's "constitutionally prescribed role is to vindicate the individual rights of the people appearing before it"; and "[a] plaintiff's remedy must be tailored to redress the plaintiff's particular injury." *Gill v. Whitford*, 138 S. Ct. 1916, 1921, 1933-34 (2018); *see also Doe v. Shanahan*, 917 F.3d 694, 740 (D.C. Cir. 2019) (Williams, J., concurring in result) (recognizing the implications of *Gill* for nationwide injunctions). Equitable principles likewise require that an injunction "be no more burdensome to the defendant than necessary to provide complete relief to the plaintiffs." *Madsen v. Women's Health Ctr., Inc.*, 512 U.S. 753, 765 (1994) (citation omitted); *see also Trump v. Hawaii*, 138 S. Ct. 2392, 2429 (2018) (Thomas, J., concurring) (noting that nationwide injunctions "are legally and historically dubious"). These principles apply with even greater force to a preliminary injunction, an equitable tool designed merely to "preserve the relative positions of the

parties until a trial on the merits can be held." *Univ. of Tex. v. Camenisch*, 451 U.S. 390, 395 (1981); *accord Zepeda v. U.S. INS*, 753 F.2d 719, 728 n.1 (9th Cir. 1983).

Here, Plaintiffs fail to show that a nationwide injunction is necessary to redress their alleged injuries. Indeed, leading up to the Supreme Court's decision in *Rust*, every district court to enjoin the 1988 regulations limited that relief to the parties before it. *See W. Va. Ass'n of Cmty. Health Centers, Inc. v. Sullivan*, 737 F. Supp. 929, 956-57 (S.D.W. Va. 1990); *Planned Parenthood Fed'n of Am. v. Bowen*, 687 F. Supp. 540, 544 (D. Colo. 1988); *Massachusetts v. Bowen*, 679 F. Supp. 137, 148 (D. Mass. 1988). Plaintiffs provide no tenable reason why the Rule should be treated differently from how courts proceeded before.

To start, Plaintiffs' decision to bring APA claims does not necessitate a nationwide remedy. *Compare* States Mem. at 42, *with, e.g.*, *California v. Azar*, 911 F.3d 558, 582-84 (9th Cir. 2018) (vacating nationwide scope of injunction in facial challenge under the APA); *Los Angeles Haven Hospice, Inc. v. Sebelius*, 638 F.3d 644, 664-65 (9th Cir. 2011) (same). A court "do[es] not lightly assume that Congress has intended to depart from established principles" regarding equitable discretion, *Weinberger v. Romero-Barcelo*, 456 U.S. 305, 313 (1982), and the APA's general instruction that unlawful agency action "shall" be "set aside," 5 U.S.C. § 706(2), is insufficient to mandate such a departure. Indeed, the Supreme Court held that not even a provision directing that an injunction "shall be granted" was sufficient to displace traditional principles of equitable discretion, *Hecht Co. v. Bowles*, 321 U.S. 321, 328-30 (1944), and Congress is presumed to have been aware of that holding when it enacted the APA two years later. In fact, the APA confirms that, absent a special review statute, "[t]he form of proceeding for judicial review" is simply the traditional "form[s] of legal action, including actions for declaratory judgments or writs of prohibitory or mandatory injunction," 5 U.S.C. § 703, and that the statutory right of review does

not affect "the power or duty of the court to . . . deny relief on any . . . appropriate legal or equitable ground," *id.* § 702(1). The Supreme Court therefore has confirmed that, even in an APA case, "equitable defenses may be interposed." *Abbott Labs. v. Gardner*, 387 U.S. 136, 155 (1967). Accordingly, the Court should construe the "set aside" language in Section 706(2) as applying only to the named Plaintiffs, especially as no federal court had issued a nationwide injunction before Congress's enactment of the APA in 1946, nor would do so for more than fifteen years thereafter, *see Hawaii*, 138 S. Ct. at 2426 (Thomas, J., concurring).

Nor does the Rule's "nationwide impact" require a nationwide injunction. States Mem. 43. The Supreme Court recently explained that under Article III, the proper remedy in a constitutional vote-dilution challenge brought by an individual voter entailed "revising only such districts as are necessary to reshape the voter's district" rather than "restructuring all of the State's legislative districts[,]" *notwithstanding* that the alleged gerrymandering was "statewide in nature" rather than limited to each plaintiff's particular district. *Gill*, 138 S. Ct. at 1930-31. Likewise, the Ninth Circuit recently vacated the nationwide scope of an injunction against particular interim final rules, even though "the agencies' own regulatory impact analysis" estimated that the rules "would affect between 31,700 and 120,000 women *nationwide*." *California*, 911 F.3d at 572 (emphasis added). These holdings confirm that it is the scope of the plaintiff's injury and not the defendant's policy that governs the permissible breadth of an injunction under Article III.

Likewise, "Plaintiffs' expansive geographic presence" makes no difference. States Mem. at 43. That Plaintiffs are *geographically* dispersed is no basis for enjoining the Rule's application to *non-parties*. For example, one of the district courts that enjoined the 1988 regulations acknowledged that the plaintiffs before it included "national organizations" that "represent[ed] nearly 75% of Title X recipients and 285 subgrantees across the country," but nevertheless limited

its injunction to "the plaintiffs in this action." *Massachusetts*, 679 F. Supp. at 148. Likewise, the Ninth Circuit recently vacated the nationwide scope of an injunction even though the plaintiffs were five states located in just as many federal judicial circuits. *California*, 911 F.3d at 568 (plaintiffs were "California, Delaware, Maryland, New York, and Virginia").

Nationwide relief would be particularly harmful here given that three other district courts in California, Washington, and Maine are currently considering similar challenges. If the government prevails in all three other jurisdictions, a nationwide injunction would render those victories meaningless as a practical matter. It would also preclude appellate courts from testing Plaintiffs' factual assertions against the Rule's operation in other jurisdictions. For example, in *Rust* itself, the claim that the separation requirements in the 1988 regulations would "be applied in an arbitrary manner" was refuted by the fact that in the states where those regulations "ha[d] been implemented," there had been "no issues of compliance." Brief for Respondent at 45 n.48, *Rust* (No. 89-1391), 1990 WL 10012655; *see also* California, 911 F.3d at 583 ("The Supreme Court has repeatedly emphasized that nationwide injunctions have detrimental consequences to the development of law and deprive appellate courts of a wider range of perspectives."). In addition, other states—especially those that have taken measures to ensure that their own funds are not used to subsidize family planning through abortion—have welcomed the Rule. *See* No. 3:19-cv-01184-EMC (N.D. Cal.), ECF No. 59-1 (amicus curiae brief of ten states in support of the Rule); s*ee also* *Planned Parenthood of Greater Ohio v. Hodges*, 917 F.3d 908, 910 (6th Cir. 2019) (en banc) (upholding Ohio law prohibiting state health department from funding organizations that "[p]erform nontherapeutic abortions"). There is no reason why Plaintiffs' views on abortion funding should govern the rest of the country. *See* *California*, 911 F.3d at 583 ("The detrimental

consequences of a nationwide injunction are not limited to their effects on judicial decisionmaking. There are also the equities of non-parties who are deprived the right to litigate in other forums.").

B. Any Injunctive Relief Should Be Limited To Particular Provisions

Similarly, should the Court decide to enjoin any portion of the Rule, the Court should allow the remainder to go into effect. In determining whether severance is appropriate, courts look to both the agency's intent and whether the regulation can function sensibly without the excised provision(s). *MD/DC/DE Broadcasters Ass'n v. FCC*, 236 F.3d 13, 22 (D.C. Cir. 2001).

Here, HHS's intent is clear: the Rule provides that "[t]o the extent a court may enjoin any part of the rule, the Department intends that other provisions or parts of provisions should remain in effect." 84 Fed. Reg. at 7725. Nor is there any functional reason why the entire Rule must fall if the Court agrees with Plaintiffs' attacks on particular provisions. The separation requirements can function without the referral provisions and vice versa. And there is certainly no logical basis for enjoining the entire Rule if the Court agrees with some of Plaintiffs' various challenges to more ancillary provisions (*e.g.*, the "medically approved" argument or the definition of "advanced practice provider"). None of these provisions should be enjoined, but there is no compelling justification for extending any injunctive relief beyond any particular offending provision(s).[10]

CONCLUSION

Accordingly, Plaintiffs' motion for preliminary injunction should be denied.

[10] Plaintiffs argue in passing that if the Court does not enjoin the Rule, it should stay the Rule's effective date under 5 U.S.C. § 705. *See* States Mem. at 43-44. As the States correctly observe, courts considering requests for such relief apply the same test as when considering a request for a preliminary injunction. Plaintiffs have not satisfied that standard. And even if they had, as discussed in this section, nationwide relief would not be appropriate.

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Respectfully submitted,

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