No. 19-35394

United States Court of Appeals for the Ninth Circuit

STATE OF WASHINGTON et al.,

Plaintiffs-Appellees,

against

ALEX M. AZAR II, in his official capacity as Secretary of Health and Human Services, et al.,

Defendants-Appellants.

On Appeal from the United States District Court for the Eastern District of Washington

BRIEF FOR THE CITY OF NEW YORK, NEW YORK CITY HEALTH + HOSPITALS AND 11 LOCAL GOVERNMENTS AS AMICI CURIAE IN SUPPORT OF APPELLEES AND AFFIRMANCE

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TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES ii

INTRODUCTION 1

STATEMENT OF INTEREST 4

SUMMARY OF ARGUMENT 10

ARGUMENT 11

AMICI WILL BE IRREPARABLY HARMED BY THE FINAL RULE 11

A. Amici face the irreparable loss of direct funding and an increase in indirect costs. 11

B. Amici's residents face irreparable harms to their health, finances, and overall wellbeing. 19

C. The federal government's speculation that other providers will fill the gaps is unsupported by the evidence. 26

CONCLUSION 33

CERTIFICATE OF COMPLIANCE 36

TABLE OF AUTHORITIES

Page(s)

Cases

Am. Trucking Ass'ns v. City of Los Angeles,
559 F.3d 1046 (9th Cir. 2009) 14

Ariz. Cattle Growers' Ass'n v. United States Fish & Wildlife, BLM,
273 F.3d 1229 (9th Cir. 2001) 26

California v. Azar,
2019 U.S. Dist. LEXIS 71171 (N.D. Cal. Apr. 26, 2019) 24, 29

California v. Azar,
911 F.3d 558 (9th Cir. 2018) 11, 13, 14

Diaz v. Brewer,
656 F.3d 1008 (9th Cir. 2011) 18, 22

Freedom Holdings, Inc. v. Spitzer,
408 F.3d 112 (2d Cir. 2005) 13

Greenpeace Action v. Franklin,
14 F.3d 1324 (9th Cir. 1992) 29

Harris v. Bd. of Supervisors,
366 F.3d 754 (9th Cir. 2004) 18

Land Council v. McNair,
537 F.3d 981 (9th Cir. 2008) 29

M.R. v. Dreyfus,
663 F.3d 1100 (9th Cir. 2011) 18

Oregon v. Azar,
2019 U.S. Dist. LEXIS 71518 (D. Or. Apr. 29, 2019) 24

Trout Unlimited v. Lohn,
559 F.3d 946 (9th Cir. 2009) 25

TABLE OF AUTHORITIES (cont'd)

Page(s)

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595 F.2d 1386 (9th Cir. 1979) 14

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Court Documents

Essential Access Health, Inc. v. Azar, No. 19-cv-1195 (N.D. Cal.):

Decl. of Barbara Ferrer 7

Decl. of Kathryn Kost 19

Decl. of Shivaun Nestor 6, 12, 24

Oregon v. Azar, No. 6:19-cv-00317 (D. Or.):

Decl. of Melisa Byrd 21

Decl. of Dr. Blair Darney 22

Decl. of Lisa M. David 15

Decl. of Shannon Lightner 15

Decl. of Karen Nelson 15

Decl. of Lauren Tobias 15, 19

Decl. of Dr. Cheryl Zoll 21

Other Authorities

City of Chicago, *Mayor Emanuel Announces Chicago Hits Historic Low Teen Birthrate* (January 15, 2018) 7, 8, 20

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Page(s)

City of Columbus, *Sexual Health Programs*, https://perma.cc/DS45-DN55 8

City of Columbus, *Women's Health and Wellness Center*, https://perma.cc/ZHB5-ZA7A 8

Kellyanne Conway, *Key Findings on Conscience Rights Polling* (April 8, 2009) 27

Lizzie Johnson, *Doctors fear Trump change could lead to more teen pregnancies*, S.F. Chronicle (July 17, 2017) 20

Megan S. Kilgore & Elizabeth C. Brown, City of Columbus, *Investing in reproductive health isn't just good for women and their families—it's good for the economy* (June 14, 2018) 8

Maryland passes bill pulling out of Trump family-planning rule, Baltimore Sun (April 3, 2019) 13

NYC Health + Hospitals Corp., *2014 HHC Report to the Community* 5

Office of Population Affairs, *Title X Family Planning Directory* (December 2018) 7

Office of Population Affairs, *Title X Family Planning Annual Report: 2017 Summary* (August 2018) 4, 19, 24

Herminia Palacio, N.Y.C. Deputy Mayor for Health and Human Services, Comment to Proposed Rule HHS-OS-2018-0008 (July 30, 2018) 5, 16, 20, 21

Catherine E. Pugh & Leana S. Wen, Baltimore City Health Department, Comment to Proposed Rule HHS-OS-2018-0008 (July 30, 2018) 9, 23

TABLE OF AUTHORITIES (cont'd)

Page(s)

Scott M. Stringer, *Title X Funding in NYC: A Critical Resource that Must Be Protected* (Aug. 1, 2017) 4, 19

INTRODUCTION[1]

The undersigned amici curiae—the City of New York, New York City Health + Hospitals, the City and County of San Francisco, the Cities of Baltimore, Chicago, Columbus, Los Angeles,[2] and 6 other local governments throughout the country—submit this brief in support of appellees' challenge to the Compliance with Statutory Program Integrity Requirements Rule (the "Final Rule") adopted by the U.S. Department of Health and Human Services (HHS). Of particular relevance here, the Final Rule imposes a gag requirement prohibiting recipients of Title X funding from providing complete and unbiased information to pregnant patients about their options; requires the unnecessary and arbitrary physical and financial separation of clinics funded by Title X from any services relating to abortion, including referral and counseling; and revokes the requirement that family-

[1] All parties have consented to the filing of this brief. No party's counsel authored the brief in whole or in part. No party or party's counsel contributed money that was intended to fund preparing or submitting the brief. And no person other than amici contributed money that was intended to fund preparing or submitting the brief.

[2] The City of Los Angeles and the County of Los Angeles are separate entities.

planning information provided under the Title X program be evidence-based.

As appellees show, the Final Rule is unlawful. Amici submit this brief to show that implementation of the Final Rule will cause significant and irreparable harm to local governments that rely on Title X funding to provide vital health services. All amici currently derive significant benefits from funds provided under Title X to clinics in our communities who serve and care for amici's residents, and some amici receive Title X funding. Imposition of the Final Rule will subject amici to two distinct sets of harms.

First, amici face irremediable financial and nonfinancial harms unless the preliminary injunction is restored. Title X providers in our communities face the choice of (a) complying with the Final Rule, which would impose massive costs for clinics to implement onerous physical and financial separation and restrain healthcare providers' ability to give complete information to their patients, or (b) forgoing participation in Title X, which will greatly reduce funding for much-needed family-planning programs. Some amici will confront this choice directly as Title X recipients, generally through subgrants from statewide

grantees, and all are likely to be financially affected by the choices of providers in our communities.

Second, the residents of all our communities would be harmed as clinics face the choice between complying with the Final Rule or declining Title X funding. Title X recipients provide critical health services to amici's low-income residents. Many current Title X recipients have stated that they cannot or will not abide by the Final Rule, and those that attempt to do so will incur substantial, unnecessary costs that would otherwise be used for patient care. This reduction of, and disruption to, vital services would lead to negative public-health outcomes, even outside the reproductive-health context, because Title X recipients also provide preventive care to their patients. If amici make up the shortfall in funding out of our own budgets, we will necessarily divert vital public funds from other endeavors.

This Court should vacate its stay of the preliminary injunction and affirm the district court's order.

STATEMENT OF INTEREST

Amici have a critical interest in this case. In the undersigned cities and counties, Title X funds go to providers who serve low-income and historically underserved populations. As described by the HHS, Title X providers serve "a vulnerable population, most of whom [are] female, low income, and young."[3] Sixty-seven percent of those served have incomes at or below the poverty level, 22% identify themselves as black or African-American and 33% identify as Latinx.[4] Six in ten of those patients who use a provider funded by Title X identify it as their primary source of health care.[5] The following briefly summarizes the specific uses and benefits of Title X funding in several of our jurisdictions.

New York City. Twenty-two New York City-based healthcare providers received Title X funding between 2012 and 2015.[6] Ten of the

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[3] Office of Population Affairs, *Title X Family Planning Annual Report: 2017 Summary* (August 2018), https://perma.cc/Q33C-MUWH.

[4] *Id.*

[5] Scott M. Stringer, *Title X Funding in NYC: A Critical Resource that Must Be Protected* (Aug. 1, 2017), https://perma.cc/A8K2-9ZZT.

[6] *Id.*

providers are run by amicus New York City Health + Hospitals (NYC H+H) as a subgrantee of the New York State Department of Health. NYC H+H is a public-benefit corporation that provides health care for 1.4 million patients annually, including 500,000 uninsured patients.[7] NYC H+H It is the largest public healthcare system in the United States. Beyond NYC H+H, about a dozen organizations receive Title X funding to operate more than fifty health centers throughout New York City.[8] New York City has announced that its public health system, including NYC H+H, "will cease participating in the federal Title X program for as long as the" Final Rule is in effect.[9]

In total, New York City organizations have received $27.3 million dollars in Title X funding between 2012 and 2015 and used that money

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[7] NYC Health + Hospitals, *2014 HHC Report to the Community*, https://perma.cc/QT2D-GCEZ.

[8] Herminia Palacio, N.Y.C. Deputy Mayor for Health and Human Services, Comment to Proposed Rule HHS-OS-2018-0008, at 1 (July 30, 2018) https://www.regulations.gov/document?D=HHS-OS-2018-0008-178635.

[9] NYC Health + Hospitals, *To Protect Access to Abortion at Nation's Largest Public Hospital System, Mayor de Blasio and NYC Health + Hospitals Reject Federal Funding Tied to New "Gag Rule"* (June 28, 2019), https://perma.cc/GZ9N-C4GU.

to provide services to about 150,000 people per year, mostly uninsured, low-income young women.[10] Through these providers, residents of all backgrounds, income levels, and immigration statuses are able to access vital healthcare services such as breast- and cervical-cancer screenings, preventive care, contraceptive education, and HIV and sexually transmitted infection (STI) testing.

San Francisco. The San Francisco Department of Public Health (SFDPH) operates the majority of San Francisco-area health clinics that receive Title X funding. It uses Title X funding to fund family-planning projects for over 6,000 patients at 10 sites.[11] For example, SFDPH uses Title X funds to educate the public on important topics relating to family planning and reproductive health. SFDPH uses Title X funds to support its "Go Folic" project to increase community awareness of the importance of folic acid supplementation, which prevents birth defects. SFDPH also uses Title X funds to support a public education campaign to combat chlamydia, rates of which have increased in San Francisco

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[10] *Id.* at 5.

[11] *Essential Access Health, Inc. v. Azar*, No. 19-cv-1195 (N.D. Cal.), Decl. of Shivaun Nestor, ECF No. 36, at ¶ 3.

and across California. In addition to family-planning services, these sites also offer other care, including primary care.[12] Clinics operated by other organizations also rely on Title X funding to provide substantial numbers of patients with vital health and family-planning services.

Los Angeles. Twenty-three health agencies operate 117 clinics providing Title X services within Los Angeles County, a substantial portion of which are in the City of Los Angeles.[13] Collectively, those agencies receive more than $5 million per year in Title X funding, which they use to serve about 260,000 patients.[14]

Chicago. There are 28 clinics operating in Chicago that receive Title X funding, including a number of clinics receiving subgrants from the Illinois Department of Public Health.[15] Through the efforts of public-health service providers in Chicago, including Title X grant recipients, Chicago achieved a historic low teen birthrate in 2016 and a

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[12] *Id.*

[13] *Essential Access Health, Inc. v. Azar*, No. 19-cv-1195 (N.D. Cal.), Decl. of Barbara Ferrer, ECF No. 31, at ¶ 6.

[14] *Id.*

[15] Office of Population Affairs, *Title X Family Planning Directory* (December 2018), https://perma.cc/7DWA-3N4U.

47% decline since 2011.[16] In part, the decline came about as a result of efforts by Chicago's Title X recipients to provide "education on birth control, [and] information to encourage making informed sexual choices and healthy relationships in select … high schools, in addition to testing and treatment for sexually transmitted infection."[17] These efforts go hand-in-hand with the services provided by Title X–funded organizations to improve the health and well-being of all Chicago residents.

Columbus. Columbus is a subgrantee of the Ohio Health Department and, along with other Title X funding recipients, serves more than 10,000 Columbus residents each year.[18] Columbus provides services akin to those provided by other Title X recipients, such as

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[16] City of Chicago, *Mayor Emanuel Announces Chicago Hits Historic Low Teen Birthrate* (January 15, 2018), https://perma.cc/28KB-EPP6.

[17] *Id.*

[18] Megan S. Kilgore & Elizabeth C. Brown, City of Columbus, *Investing in reproductive health isn't just good for women and their families—it's good for the economy* (June 14, 2018), https://perma.cc/4J67-ZZ4H.

family planning, breast-cancer screening, contraception, STI/HIV testing, and sexual-health clinics.[19]

Baltimore. The Baltimore City Health Department oversees the City's Title X funding, which is distributed to 23 sites run by the Health Department, Baltimore Medical System, Family Health Centers of Baltimore, Johns Hopkins Hospital, and University of Maryland Medical System. Title X funding supports clinics in Baltimore that not only provide reproductive-health services, but also vital healthcare services such as cancer screenings, contraception, HIV testing and counseling, substance-use and mental-health screenings, and specialist referrals that many Baltimore residents would not otherwise be able to afford. One in three women in Baltimore is in need of publicly funded healthcare services to access contraception.[20]

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[19] *See* City of Columbus, *Sexual Health Programs*, https://perma.cc/DS45-DN55; City of Columbus, *Women's Health and Wellness Center*, https://perma.cc/ZHB5-ZA7A.

[20] Catherine E. Pugh & Leana S. Wen, Baltimore City Health Department, Comment to Proposed Rule HHS-OS-2018-0008, at 1 (July 30, 2018), https://www.regulations.gov/document?D=HHS-OS-2018-0008-161578.

SUMMARY OF ARGUMENT

Amici will be irreparably harmed if the preliminary injunction is not restored and the Final Rule is allowed to remain in effect. Cities and counties that directly provide services and receive Title X grants will be forced either to decline Title X funds or to attempt to comply with the Final Rule. They face significant, unrecoverable fiscal harms no matter what course they choose—in compliance costs, or from loss of funding. And many amici, whether they provide Title X services directly or not, will face harms when they must use their own resources—foregoing other services to the community to do so—to try to ameliorate the damage to the community from the withdrawal of funding.

All amici also face the prospect of irreparable harm to their residents. Many providers in amici's communities have already indicated that they cannot or will not comply with the Final Rule. Patients' access to high-quality care at those providers will be impaired or delayed as former Title X recipients will be overstretched or unable to provide care entirely. Even if other Title X–compliant facilities open in our communities, there will be significant disruptions to care as women transition to new providers, choosing from a much smaller pool.

The result will be damage to women's physical, emotional, and economic well-being, along with their children and families. The harm will fall particularly heavily on the low-income and young women that Title X is intended to serve.

The federal government assures the Court that these concerns are overblown because a new cadre of Title X providers will fill any possible gap in coverage—or, at the least, that HHS could have reasonably so concluded. But the evidence that HHS relied on is irrelevant to Title X, and its speculation that there will be no gaps in coverage amounts to wishful thinking, not reasoned decision making. The evidence presented to HHS and in the district court, from the plaintiffs, amici, and others, shows that there will be irreparable harm to women across the country if the injunction is not restored.

ARGUMENT

AMICI WILL BE IRREPARABLY HARMED BY THE FINAL RULE

A. Amici face the irreparable loss of direct funding and an increase in indirect costs.

Amici and their constituents rely on the funds dedicated by Congress under Title X for critical healthcare services. While not all amici receive direct funding from Title X and provide services, all

benefit from the provision of care in our communities, and all will face substantial costs if the Final Rule is not enjoined. Although economic harms are not ordinarily irreparable, they may be where, as here, it will be impossible "to recover monetary damages." *California v. Azar*, 911 F.3d 558, 581 (9th Cir. 2018). Even a successful challenge to the Final Rule will not allow the plaintiffs, or other grantees, to seek money damages against the federal government for any lost grant amounts. *See id.* (explaining that APA challengers may seek only relief "'other than money damages'" (quoting 5 U.S.C. § 702)).

New York (through NYC H+H), San Francisco, Columbus, and Baltimore operate city public-health providers that are direct recipients of Title X funding and are subject to the Final Rule's new requirements, with no lead time to either comply with certain aspects of the Final Rule or lose funding for which they applied months ago. While the physical and financial separation requirements do not go into effect immediately, compliance with those provisions will be expensive. Clinics will need to construct physical barriers between differing portions of their facilities—or secure a separate location—and

implement administrative separation, all in dense, high-cost cities.[21] The separation is not only costly on its own, but sacrifices economies of scale for large providers.[22] The providers, if they choose to abide by the Final Rule, will also have to devote significant time and attention to training their healthcare professionals on what they can and cannot say in accordance with the gag requirement.

Moreover, harms to some direct recipients of Title X funds are inevitable because they may not have the option of complying even if they wish to. For example, Baltimore receives funds as a subgrantee of the Maryland Department of Health, and Maryland's legislature passed a law barring participation in the Title X program while the Final Rule

[21] *See, e.g.*, *Essential Access Health, Inc. v. Azar*, No. 19-cv-1195 (N.D. Cal.), Decl. of Shivaun Nestor, ECF No. 36, at ¶ 13 (stating that San Francisco's "clinics cannot bear the cost of setting up separate facilities, so SFDPH will have to forego Title X funds").

[22] The elimination of economies of scale is, bizarrely, not a side-effect, but a deliberate goal of HHS. *See* 84 Fed. Reg. 7714, 7766 (2019). That the Final Rule explicitly seeks to *increase* the cost of providing care to the very people Title X is intended to benefit further shows that it is arbitrary and capricious.

is in effect.[23] And New York has announced it will cease participation in Title X while the Final Rule is in effect.[24] These harms are irreparable because direct providers will be unable to recover either lost grant money or the costs of compliance, even if the plaintiffs are ultimately successful in vacating the Final Rule. *See California v. Azar*, 911 F.3d at 581.

The federal government argues that these are ordinary regulatory compliance costs which cannot constitute irreparable harms (Brief for Appellant ("App. Br.") 44). But the cases it cites for this proposition are inapposite. In one, the harm was not irreparable because the plaintiffs would have largely been "recompensed after trial," *Freedom Holdings, Inc. v. Spitzer*, 408 F.3d 112, 115 (2d Cir. 2005), and in the other, the federal funds would have been restored to the grantees if they prevailed in the litigation, *see United States v. Los Angeles*, 595 F.2d 1386, 1390–91 (9th Cir. 1979). More fundamentally, the federal government's argument flies in the face of this Court's recent precedent, on an

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[23] *Maryland passes bill pulling out of Trump family-planning rule*, Baltimore Sun (April 3, 2019), *available at* https://perma.cc/J9HV-ZWFN.

[24] *See supra* note 9.

analogous issue, holding that the economic harm to states as a result of an HHS regulation governing reimbursement for contraceptives was irreparable. *See California v. Azar*, 911 F.3d at 581.

Further, compliance costs are only one aspect of the irreparable harms amici face. For example, direct recipients of Title X funds also face irreparable harm in the form of the forced choice to comply with an unlawful regulation, on penalty of loss of critical funding. The Final Rule, as explained in detail by the plaintiffs (*see* Brief for Appellees 25–42) is arbitrary and capricious under the APA, violates the Nondirective Mandate and the Affordable Care Act, and infringes on the First Amendment rights of healthcare providers. A forced choice between compliance with an unlawful condition and losing significant funds is itself an irreparable harm. *See Am. Trucking Ass'ns v. City of Los Angeles*, 559 F.3d 1046, 1058 (9th Cir. 2009). Complying with the Final Rule while awaiting a final judgment in this case, if the preliminary injunction is not upheld, will require not only significant fiscal outlays, but also alter the very nature of Title X providers' reproductive-health programs in ways that cannot be remedied for patients treated while the case is ongoing.

Cities and counties that do not directly receive funds will face substantial fiscal burdens as a result of the loss of funding to Title X providers in our communities. In total, public and private Title X funding recipients serve more than 150,000 people per year in New York City, 16,000 people in Baltimore, 10,000 in Columbus, and tens of thousands more in other amici jurisdictions. Many clinics in our communities have already indicated that they are unable or unwilling to comply with the Final Rule and will be forced to close or limit the number of patients that they will be able to serve.[25] The funds provided to nongovernmental Title X providers within amici's communities will either need to be replaced from municipal and county coffers or some other source, or their constituents will not be served. Given the effectiveness of Title X funding in achieving critical public-health goals, many local governments will scramble to fill the gap in funding, drawing funds from other vital public programs.

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[25] *See, e.g.*, *Oregon v. Azar*, No. 6:19-cv-00317 (D. Or.), Decl. of Lauren Tobias, ECF No. 66, at ¶ 43 (NY); Decl. of Lisa M. David, ECF No. 46, at ¶¶ 39–40 (NY); Decl. of Karen Nelson, ECF No. 57, at ¶¶ 16–17 (MD); Decl. of Shannon Lightner, ECF No. 54, at ¶¶ 32–33 (IL).

Beyond the health impacts that amici's residents would face as a result of these funding shortfalls, which are discussed further below, those residents will also face the heightened financial costs of unintended pregnancies and health complications, some of which, in turn, will be borne by amici through their provision of public healthcare funding. Pregnancy, delivery, and early childhood-related care are expensive, especially compared with many family-planning services offered by Title X providers.[26] Pregnancies can impose a significant financial burden, particularly on low-income and uninsured individuals and families. Some of these costs will be borne by amici through their provision of public healthcare and governmental services for low-income mothers. Indeed, it is precisely the low-income women served by Title X providers who will be most likely to require government assistance if they become pregnant. For those who become pregnant, effective prenatal care separately provided by Title X recipients reduces risks to both mother and child, preventing potentially costly and harmful complications. Thus, decreasing access to a full range of family-

[26] Palacio, *supra* note 8, at 5.

planning services not only would perpetuate a cycle of poverty that amici have adopted policies to break, but would also strain amici's public-health finances as they deal with an increase in both unintended pregnancies and health problems.

Moreover, the Final Rule will strain amici's finances through increased Medicaid costs. As of 2016, over a third of Title X patients were Medicaid recipients. Recent analyses have shown that every $1 invested in Title X saves more than $7 in Medicaid-related costs, thereby saving taxpayer contributions towards Medicaid, which, in many cases, are administered at least in part by local governments such as amici.[27] As a result, the Final Rule could impose additional financial strain both on those who lose access to services and on the Medicaid system by tipping the ratio of services towards more pregnancy-related care rather than cost-effective family-planning services.

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[27] *Id.*

B. Amici's residents face irreparable harms to their health, finances, and overall wellbeing.

Beyond the fiscal costs to amici, tens of thousands of amici's constituents face the prospect of losing access to the public health care and family-planning services on which they rely as a result of the Final Rule, a harm the federal government essentially ignores in this litigation. The loss of critical services and the concomitant risk of unplanned pregnancies, undetected cancers, and other serious health issues all constitute irreparable harms. *See*, *e.g.*, *Diaz v. Brewer*, 656 F.3d 1008, 1012 (9th Cir. 2011) (upholding finding that the "health problems of [individuals] facing loss of healthcare" was an irreparable harm); *M.R. v. Dreyfus*, 663 F.3d 1100, 1114 (9th Cir. 2011) (holding that "beneficiaries of public assistance may demonstrate a risk of irreparable injury by showing that enforcement of a proposed rule may deny them needed medical care" (quotation marks omitted)); *Harris v. Bd. of Supervisors*, 366 F.3d 754, 766 (9th Cir. 2004) (holding that "medical complications … due to delayed treatment" are irreparable harms).

The consequences of that loss of access will be severe. Those members of our communities face the loss of what is, in many cases,

their primary source of health care.[28] Even for those who may find another provider that is in compliance with the regulation and available to provide Title X services, continuity of care will be disrupted.[29] If patients are unable to find quality family-planning services, they will face an increased risk of unintended pregnancies and health complications.[30] The costs and consequences of disputed care are most acute for the type of time-sensitive services that Title X clinics provide. These are not only risks to our residents' health, but also a potentially large and unplanned expense. The high costs of unintended pregnancies fall most sharply on low-income and uninsured women. The Final Rule

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[28] *See* Stringer, *supra* note 5 (explaining that "six in ten women who obtain care from a publicly funded family planning clinic consider that clinic to be their primary source of health care"); Office of Population Affairs, *Title X Family Planning Annual Report: 2017 Summary*, at 1 (August 2018), https://perma.cc/K686-X5BL ("For many clients, Title X providers are their only ongoing source of health care and health education.").

[29] *See Oregon v. Azar*, No. 6:19-cv-00317 (D. Or.), Decl. of Lauren Tobias, ECF No. 66, ¶ 45.

[30] *See Essential Access Health, Inc. v. Azar,* No. 19-cv-1195, Decl. of Kathryn Kost, ECF No. 29, ¶¶ 119–22 (describing case studies of states that did not accept Medicaid funding for family planning).

threatens not only our residents' health, but also their financial well-being.

Moreover, all amici have focused in recent years on reducing the incidence of teen pregnancy and STIs. Especially in the last two decades, many amici have made substantial progress on this front, and the disruption and reduction in services that the Final Rule will occasion could undo the progress that amici have made. For example, in New York City, the pregnancy rate among adolescents ages 15–19 decreased by 60% from 2000 to 2015. These results have been achieved in large part due to access to affordable contraception, including through programs like Title X.[31] Likewise, in 2016, Chicago achieved a historic low teen birthrate—a 47% decline since 2011.[32] And San Francisco cut the teen birth rate in half between 2009 and 2015.[33] These gains are at risk not only because the Final Rule would limit

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[31] Palacio, *supra* note 8, at 4.

[32] City of Chicago, *Mayor Emanuel Announces Chicago Hits Historic Low Teen Birthrate* (January 15, 2018), https://perma.cc/28KB-EPP6.

[33] Lizzie Johnson, *Doctors fear Trump change could lead to more teen pregnancies*, S.F. Chronicle (July 17, 2017), *available at* https://perma.cc/253H-SUWY.

access to services, but also because the rule requires providers to "encourage family participation," in health services provided to minors, 84 Fed. Reg. at 7717–18; 7787, which has the probable effect of delaying or discouraging minors from accessing care.[34]

The harm extends beyond the provision of contraception and family-planning services because Title X recipients provide a broad range of other services. The critical services provided by Title X recipients include screening for a variety of conditions, including STIs, HIV, breast and cervical cancer, high blood pressure, and diabetes.[35] HHS itself touts Title X's role in funding these screenings, explaining that "Title X-funded STD and HIV services provide testing necessary for preventing disease transmission and adverse health consequences" and that "Title X-funded cervical and breast cancer screenings contribute to early detection and treatment."[36]

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[34] *See Oregon v. Azar*, No. 6:19-cv-00317 (D. Or.), Decl. of Melisa Byrd, ECF No. 40, ¶ 8; Decl. of Dr. Cheryl Zoll, ECF No. 69, ¶ 14.

[35] Palacio, *supra* note 8, at 5.

[36] Office of Population Affairs, *Title X Family Planning Annual Report: 2017 National Summary*, at ES-2 (August 2018), https://perma.cc/K686-X5BL.

The Final Rule substantially disrupts Title X recipients' ability to provide these critical healthcare services, which not only has the direct effect of harming patients' health now, but also could lead to serious secondary effects in the future. For example, STI/HIV cases that go undetected risk the further spread of those diseases, and the longer the diseases are untreated, the higher the risk of individuals developing long-term health complications.[37] The incidence of cervical cancer in the United States has markedly declined due to widespread screening; the Final Rule risks limiting access to cervical-cancer screening for the poor and uninsured.[38] The Final Rule also increases the risks to maternal health from associated complications and co-morbidities, such as high blood pressure and diabetes.[39] The harm from these health problems will be irreparable absent the preliminary injunction. *See Diaz*, 656 F.3d at 1012.

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[37] *See*, *e.g.*, *Oregon v. Azar*, No. 6:19-cv-00317 (D. Or.), Decl. of Dr. Blair Darney, ECF No. 45, ¶ 17, 21 (noting gaps in care for sexually transmitted infections and cancer screening as a result of the lack of Title X funding).

[38] *Id.* ¶ 22.

[39] *Id.* ¶ 22.

The loss of funding would exacerbate existing inequities because the harm would fall disproportionately on low-income and minority women. In New York, 60% of those served by Title X providers have incomes below the federal poverty level (FPL), and 32% lack health insurance. For individuals served by Planned Parenthood in New York City, 60% are either Black or Latinx, and 66% of patients have incomes at or below the FPL.[40] In Baltimore in 2017, 86% had incomes at or below the FPL, 50% were using Medicaid, and nearly 25% were uninsured.[41] In San Francisco, 60% of the patients served by the San Francisco Department of Public Health's Title X–funded clinics are Black or Latinx, and only 1% have private health insurance.[42] The numbers are similar for Title X funding nationwide.[43] Imposition of the

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[40] *Id.*

[41] Catherine E. Pugh & Leana S. Wen, Baltimore City Health Department Comment to Proposed Rule HHS-OS-2018-0008, at 1 (July 30, 2018), https://www.regulations.gov/document?D=HHS-OS-2018-0008-161578.

[42] *Essential Access Health, Inc. v. Azar*, No. 19-cv-1195 (N.D. Cal.), Decl. of Shivaun Nestor, ECF No. 36, at ¶ 4.

[43] Sixty-seven percent of those served by Title X providers had incomes at or below the poverty level, 22% identified themselves as black or African-American and 33% identified as Latinx. *See* Office of Population

(cont'd on next page)

Final Rule will strike another blow at these populations who have historically been denied equitable health care and depend on Title X–funded services for access to high-quality and unbiased care.

In lieu of a substantive response, the federal government dismisses these harms as "speculation" (App. Br. 44). But amici, as well as numerous other recipients of Title X funds, have stated unequivocally and in detail how they will be harmed and how patient care *will* decrease under the Final Rule. *See Oregon v. Azar*, 2019 U.S. Dist. LEXIS 71518, at *56–57 (D. Or. Apr. 29, 2019) (decision below) (finding that the "likely harm to the public health, in the form of an increase in sexually transmitted disease and unexpected pregnancies, is not speculative"); *California v. Azar*, 2019 U.S. Dist. LEXIS 71171, at *6 (N.D. Cal. Apr. 26, 2019) (explaining that the "Final Rule threatens to decimate the network of Title X providers in California and drastically restrict patients' access to a wide range of vital services, including contraceptive resources and screenings for sexually transmitted

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Affairs, *Title X Family Planning Annual Report: 2017 Summary*, at ES-1, 12 (August 2018), https://perma.cc/K686-X5BL.

infections, reproductive cancers, and HIV"). The federal government's failure, or inability, to substantively respond to these irreparable harms is further evidence that the stay should be vacated and the preliminary injunction should be affirmed.

C. The federal government's speculation that other providers will fill the gaps is unsupported by the evidence.

The federal government argues (App. Br. 38–45) both that there will be no irreparable harm to amici and their residents and that the decision to approve the Final Rule was lawful because HHS permissibly concluded that there will not "be a decrease in the overall number of facilities offering services," 84 Fed. Reg. at 7782. HHS contended that other providers, who were put off from providing Title X services by the previous regulations, will join the program and seamlessly fill any gap in care that might arise from the withdrawal of current providers. *See id*. at 7780. According to the government, HHS "pointed to data" (App. Br. 42) purportedly showing that an expanded pool of potential providers could "fill [any] gaps" left by current Title X providers leaving the program, 84 Fed. Reg. at 7756. While it is true that an agency's predictive judgments are entitled to "deferential review," *Trout*

Unlimited v. Lohn, 559 F.3d 946, 959 (9th Cir. 2009), its conclusion must be based on evidence, not merely "speculation." *Ariz. Cattle Growers' Ass'n v. United States Fish & Wildlife, BLM*, 273 F.3d 1229, 1244 (9th Cir. 2001).

With that in mind, one might expect that HHS cited some high-quality evidence that there are plenty of healthcare providers—or even a *single* provider—waiting for the Final Rule to go into effect so that they can begin to apply for grants and provide Title X care. It did not. One might also expect a careful and thorough consideration of how many patients are likely to lose access to care from those providers that will eliminate or reduce Title X services under the Final Rule, and a comparison of those losses with providers likely to enter the program and how many patients they might serve. HHS did no such analysis.

Instead, the sole piece of "data" that HHS "pointed to" was a decade-old online poll of "faith-based" medical providers that asked questions about conscience rules, not Title X. *See* 84 Fed. Reg. at 7780,

n.139.[44] At the outset, as the poll's statement of methodology forthrightly explains, it was "not intended to be representative of the entire medical profession" nor was it even representative of the "the entire membership rosters of" the faith-based medical organizations whose members were polled.[45] Aside from not being representative of the medical community, or even of the groups polled, conclusions should also not be drawn from the poll's results because the "[r]espondents who participated in the survey were self-selecting."[46]

Its lack of scientific rigor aside, the poll is not even relevant to the question of whether the respondents would rush to fill the gaps left by current Title X providers leaving the program. The poll did not ask respondents whether, if the Final Rule were in effect, they would

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[44] In the Final Rule, HHS erroneously claims that the online poll on which it relies was conducted in May 2011, 83 Fed. Reg. 7780 n.138, but the poll was actually conducted in April 2009, *see* Freedom2Care and The Christian Medical Association, *National Poll Shows Majority Support Healthcare Conscience Rights*, *Conscience Law*, at 2 (May 3, 2011), *available at* https://perma.cc/PR46-UC9Q. A different "scientific poll," the results of which HHS does not mention in the Final Rule, was conducted in 2011. *Id.* at 1.

[45] Kellyanne Conway, *Key Findings on Conscience Rights Polling* (April 8, 2009), at 4, *available at* https://perma.cc/N3CW-9VYQ.

[46] *Id.*

provide Title X services. Indeed, nothing like the Final Rule was even in the works when the poll was conducted in 2009. Instead, the poll was related to protections for medical providers who objected to performing certain procedures on religious grounds and asked respondents whether they would be "forced to leave medicine if coerced into violating the faith tenets and medical ethics principles that guide their practice of medicine" and whether they would "limit the scope of their practice of medicine if conscience rules were not in place." 84 Fed. Reg. at 7780–81, nn.138–39.

The answers to those questions tell us precisely nothing about whether any of those practitioners would open up Title X clinics or provide Title X services under the Final Rule. The poll also does not include the geographic location of the respondents, so nothing in it tells us whether the respondents are in amici cities, or if they would be willing to relocate to provide services. Finally, many of the respondents were dentists and pharmacists, who could not provide Title X services if

they wanted to.[47] The poll simply had nothing whatsoever to do with Title X. *See California v. Azar*, 2019 U.S. Dist. LEXIS 71171, at *114 (noting that the "poll did not ask doctors anything about Title X specifically").

Justifying a decision by pointing to irrelevant data is not the kind of predictive judgment about a matter within the expertise of the agency to which this Court must defer. While agencies making predictive judgments on matters within their unique expertise are accorded substantial deference, the agency "must explain the conclusions it has drawn from its chosen methodology, and the reasons it considers the underlying evidence to be reliable." *Land Council v. McNair*, 537 F.3d 981, 994 (9th Cir. 2008); *see also Greenpeace Action v. Franklin*, 14 F.3d 1324, 1333 (9th Cir. 1992) (holding that the agency may rely on "substantial—though not dispositive—scientific data" but not on "mere speculation"). HHS's mere citation to inapposite data utterly fails to meet this standard.

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[47] *See* Conway, *supra* note 43, at 4 (explaining that the survey polled "2,865 members of the Christian Medical and *Dental* Association" and "206 members of the Christian *Pharmacists* Fellowship International") (emphases added).

The federal government also argues (App. Br. 39) that a suit brought by the Obria Group, which was initially awarded a grant prior to the issuance of the preliminary injunctions in this and related cases, vindicates HHS's speculation that new providers will close the gap left by those leaving Title X because of the Final Rule.[48] In fact, it proves the opposite. Instead of a rush of previously excluded providers applying for Title X funds and filling any gaps in care, HHS can point only to a *single* provider who might be able to serve "an additional 4,000 patients annually" in Southern California using Title X funds.[49] That 4,000 patients might be served in Southern California is cold comfort to the 150,000 patients in New York, or the 16,000 patients in Baltimore, or even the hundreds of thousands of other patients in Southern California who could lose care the preliminary injunction is not upheld.

In sum, the Final Rule will have disastrous effects on the fiscal and physical health of amici and our residents. HHS is unable to show that these harms will not befall amici if the Final Rule is not enjoined, and its argument instead highlights the utter dearth of evidence in the

[48] *See Obria Grp. v. Azar*, No. 8:19-cv-905 (C.D. Cal.), Compl. ¶ 1–3.
[49] *Id.* ¶ 4.

administrative record to support its prediction that new providers will be able to close the gap.

CONCLUSION

The district court's order should be affirmed.

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July 5, 2019

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

I hereby certify that this brief was prepared using Microsoft Word 2010, and according to that software, it contains 6,313 words, not including the table of contents, table of authorities, this certificate, and the cover.

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