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No. 19-35386(L)

IN THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

STATE OF OREGON, ET AL.

Plaintiff-Appellee,

v.

ALEX M. AZAR II, IN HIS OFFICIAL CAPACITY AS SECRETARY OF THE UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, ET AL.

Defendants-Appellants.

AMERICAN MEDICAL ASSOCIATION, ET AL., Plaintiffs-Appellees,

v.

ALEX M. AZAR II, IN HIS OFFICIAL CAPACITY AS SECRETARY OF THE UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, ET AL.

Defendants-Appellants.

On Appeal from for the District of Oregon Nos. 6:19-cv-00317-MC; 6:19-cv-00318-MC (McShane, J.)

BRIEF OF AMICI CURIAE PUBLIC HEALTH AND HEALTH POLICY DEANS, CHAIRS, AND SCHOLARS AND THE AMERICAN PUBLIC HEALTH ASSOCIATION IN SUPPORT OF PLAINTIFFS-APPELLEES AND AFFIRMANCE

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CORPORATE DISCLOSURE STATEMENT

Pursuant to Federal Rules of Appellate Procedure 26.1 and 29(a)(4)(A),

amicus curiae American Public Health Association certifies that it has no parent corporations or any publicly held corporations owning 10% or more of its stock.

Dated: July 3, 2019

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STATEMENT OF INTEREST OF AMICI CURIAE¹

This brief is submitted on behalf of the American Public Health Association and the academic department chairs, academic scholars and academic deans of educational institutions listed in Appendix A (collectively, "Public Health *Amici*"), in support of Plaintiffs-Appellees and affirmance.

The Public Health Amici are affiliated with educational institutions that focus on matters of public health policy, spanning policies that promote the health of individuals and populations and affect the accessibility and quality of care as well as health system performance. They are among the nation's leading experts in the field of health policy, with particular expertise in reproductive health and health care and access to reproductive health and other health care services within medically underserved communities and by medically vulnerable populations. The Public Health Amici seek to ensure the highest standard of sexual and reproductive health care for all people by promoting evidence-based policies and by conducting research according to the highest standards of methodological rigor.

¹ No counsel for a party has authored this brief in whole or in part, and no party or counsel for a party has made a monetary contribution intended to fund the preparation or submission of this brief. No person other than *amici* or their counsel has made a monetary contribution to the preparation or submission of this brief. Fed. R. App. P. 29(a)(4)(E).

Pursuant to Federal Rule of Appellate Procedure 29(a), the Public Health Amici submit this brief without an accompanying motion for leave to file or leave of court because all parties have consented to its filing.

INTRODUCTION

At stake in this case is access to family planning services, a seminal public health achievement.² As the lower court correctly concluded, Appellants' regulation is contrary to law; and as the court further found, the public record reveals Appellants' utter failure to consider the rule's impact on Title X clinics, medical and health professionals, and ultimately, millions of people who depend on Title X for birth control and preventive services.

If permitted to take effect, the rule will severely compromise access to essential health care. As stated in the extensive public comments in response to the proposed rule, many medical professionals are likely to disassociate themselves from the program because of the ethical problems and liability risks created by the rule's "gag" clause provisions. Many clinics offering full-spectrum reproductive health care will be forced out by the rule's costly and burdensome physical separation requirements. The access implications are severe: in 2014, Title X clinics accounted for half of the 1.3 million reduction in unintended pregnancies

² Ctrs. for Disease Control & Prevention, *Ten Great Public Health Achievements--United States, 1900-1999*, 281 JAMA 1481 (1999).

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that year; such pregnancies would have led to 619,000 unplanned births and 459,000 abortions.³ Without this network, rates of unintended pregnancies, unplanned births and abortions would have been 33% higher.⁴

Abundant evidence shows that, even as Appellants' rule drives current providers out of the program, they have no prospects for replacing these providers either near-term or in ensuing years, with the following adverse impacts: declining use rates for the most effective forms of birth control; a spike in unintended pregnancy; the loss of early pregnancy counseling and support to promote healthy births;⁵ a rise in infant mortality and childhood disability; ⁶ rising maternal mortality ⁷ (the U.S. rate already is the highest among wealthy nations);⁸ and a growing risk of untreated sexually transmitted disease. As family planning declines, abortion rates will rise given their sensitivity to the rate of unintended

³ Jennifer J. Frost, et al., *Contraceptive Needs and Services: 2014 Update*, GUTTMACHER INSTITUTE, at 13 (Sept. 2016), <u>https://bit.ly/2FIXzO8</u>.

⁴ *Id.* at 1.

⁵ Adam Sonfield et al., *Moving Forward: Family Planning in the Era of Health Reform*, GUTTMACHER INSTITUTE (2014), <u>https://bit.ly/2faWT6J</u>.

⁶ See, e.g., Hal C. Lawrence, *Testimony Before the Institute of Medicine Committee on Preventive Services for Women*, at 11 (Jan. 12, 2011), <u>https://bit.ly/2FKWeWO</u> (offering expert testimony regarding the impact of unintended pregnancy on women with pre-existing conditions).

⁷ *Family Planning*, HEALTHY PEOPLE 2020 (2019), <u>https://bit.ly/1VPUE9E</u>.

⁸ GBD 2015 Maternal Mortality Collaborators, *Global, regional, and national levels of maternal mortality, 1990–2015: a systematic analysis for the Global Burden of Disease Study 2015, 388* Lancet 1775, at Fig. 9 (2016), <u>https://bit.ly/</u> <u>2xW3qOG</u>.

pregnancy.9

ARGUMENT

I. By Radically Altering The Title X Provider Network, The Final Rule Undermines Access To Effective Care.

A. Appellants' Rule Bars Nondirective Counseling.

The district court correctly determined that Appellants' rule violates the 1996 Appropriations Act, *Oregon v. Azar*, No. 6:19-cv-00317, 2019 WL 1897475, at *8 (D. Or. Apr. 29, 2019), and the limits placed on agency rulemaking powers under the Patient Protection and Affordable Care Act ("ACA"). *Id.* Together these two laws significantly modify the laws that existed at the time that *Rust v Sullivan* was decided. These laws create an unequivocal agency duty to ensure nondirective counseling by all Title X providers and to refrain from undermining providers' full and transparent communications with their patients. Indeed, the ACA amendment explicitly underscores Appellants' obligation not to "interfere [] with communications regarding the full range of treatment options between the patient and the provider" or "restrict [] the ability of health care providers to provide full disclosure of all relevant information to patient making health care decisions" or to

⁹ Joerg Dreweke, U.S. Abortion Rate Reaches Record Low Amidst Looming Onslaught Against Reproductive Health and Rights, 20 Guttmacher Pol'y Rev. 15 (2017), <u>https://bit.ly/2LvDC14</u>; Joerg Dreweke, New Clarity for the U.S. Abortion Debate: A Steep Drop in Unintended Pregnancy Is Driving Recent Abortion Declines, 19 Guttmacher Pol'y Rev. 16 (2016), <u>https://bit.ly/2KQOTJz</u>.

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"violate [] the principles of informed consent and the ethical standards of health care professionals." *See* ACA §1554. The lower court correctly concluded that Appellants' counseling rule, regardless of its misleading verbiage, "blatantly requires" that pregnancy counseling be directive. Order at 16.

Employing deceptive headers suggesting mere "information about prenatal care" (§ 59.14(b)), the rule compels prenatal care referral regardless of a patient's choice of treatment. Aggressive interference is reflected in (1) a bar against counseling by trained counselors, (2) permitting patients to be informed of how to maintain the health of the "unborn child" during pregnancy, and (3) blocking provider referrals to providers with the necessary skills and experience to competently provide care for women electing to terminate a pregnancy. (§ 59.14(c)). Appellants' rule thus bars the nondirective counseling required by law, while contravening the agency's own published standard of care for family planning and associated services published by the Centers for Disease Control ("CDC") in 2013.¹⁰

¹⁰ See Loretta Gavin et al., Providing Quality Family Planning Services: Recommendations of CDC and the U.S. Office of Population Affairs, CTRS. FOR DISEASE CONTROL & PREVENTION: MORBIDITY & MORTALITY WEEKLY REPORT (2014), 14, <u>https://www.cdc.gov/mmwr/pdf/rr/rr6304.pdf</u> (Appendix A) (providing guidelines for women with a positive pregnancy test).

B. Appellants Ignored Extensive Evidence of the Threat to a Viable Title X Provider Network and the Adverse Health Care Effects that Falling Provider Participation Would Trigger.

The district court correctly concluded that Appellants failed to account for the extensive public comments submitted by professional medical societies regarding the conflict between the rule and professional ethical standards. Appellants' rebuttal relies on two completely irrelevant surveys of religious health care professionals conducted in 2011. Neither survey – one of Christian Medical Association ("CMA") members and another conducted by the Freedom2Care poll (p. 7781 note 139) – bears even the remotest relationship to the proposed rule. Unlike the overwhelming array of public comments submitted by the medical societies directly in response to the proposed rule, neither of Appellants' surveys address the proposed rule. Yet Appellants assert that it is reasonable that these unrelated surveys can overcome a public comment record replete with professional concerns on the unfounded expectation that the rule "presumably" (p. 7781) will motivate religious providers to participate in Title X. Appellants' baseless speculation is not reasonable predictive judgment as they ignore evidence in the record regarding impact on medical professionals and clinics offering fullspectrum reproductive health care.

Appellants also ignore extensive research examining the impact of a 2011 Texas policy barring participation in its women's health program by full spectrum

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reproductive health care providers, such as Planned Parenthood. This policy led directly to a steep decline in access to care that other health care providers could not reverse. Between 2011 and 2016, enrollment in the Texas program fell by 24%,¹¹ and the percentage of enrollees receiving care fell by 39%. The state's exclusionary policy - reminiscent of Appellants' rule - triggered multiple negative health effects: a 35% reduction in use of the most effective forms of contraception, with the biggest losses in counties previously served by Planned Parenthood; escalating unintended pregnancy rates; and rising teen birth rates.¹² Between 2011 and 2014, the state experienced a 27% increase in Medicaid-funded births among women who had relied on care from a previously-funded clinic.¹³ Landmark research published in 2016 in the New England Journal of Medicine found a causal connection between the loss of access to Planned Parenthood clinics and a rise in Medicaid-insured pregnancies.¹⁴ A separate study found that the reduced access flowing from the Texas policy led to a 3.4% increase in teen births over four years,

¹¹ *Excluding Planned Parenthood has been Terrible for Texas Women*, CENTER FOR PUBLIC POLICY PRIORITIES (Aug. 2017), <u>https://bit.ly/2faahee</u>.

¹² Lawrence B. Finer & Mia R. Zolna, *Declines in Unintended Pregnancy in the United States, 2008-2011*, 374 New England J. Med. 843 (2016), <u>https://bit.ly/2LDmZR9</u>.

¹³ Amanda J. Stevenson et al., *Effect of Removal of Planned Parenthood from the Texas Women's Health Program*, 374 New England J. Med. 853 (2016); Zolna & Frost, *supra* note 3, at 11-12.

¹⁴ Stevenson et al., *supra* note 13.

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with effects concentrated in the years following initial implementation.¹⁵ This loss of access has persisted over time. For the 2017 fiscal year, one clinical provider, awarded funding to replace services previously furnished by Planned Parenthood, reportedly received \$1.6 million to serve 51,000 patients but only served 2,300 patients – less than 5% of its goal – at a cost of \$1.3 million.¹⁶ Despite this powerful evidence, Appellants' rulemaking failed to account for the impact of their rule on the existing Title X network, the feasibility (using relevant evidence) of replacing that network, and the length of time to complete the replacement. Nor did Defendants-Appellants consider the health and health care consequences of lost access.

Indeed, Appellants have completely ignored their own program administration experience under Title X and the community health centers program, § 330 of the Public Health Service Act. It can take years to open the doors of a new clinic as entities must be (i) recruited to apply for grants (many with no prior experience), (ii) determined to be qualified for funding; (ii) undergo a lengthy operational startup period; and (iv) recruit and train clinical and administrative staff.

¹⁵ Analisa Packham, *Family Planning Funding Cuts and Teen Childbearing*, 55 J. Health Econ. 168 (2017).

¹⁶ Sophie Novak, *Inside Texas' Failed Experiment to Replace Planned Parenthood with an Anti-Abortion Group*, Texas Observer (June 5, 2019), <u>https://bit.ly/2Iy2cv2</u>.

Defendants-Appellants appear to presume expanded participation by established community health centers to fill the void, a reliance mentioned throughout the preamble to the final rule.¹⁷ Community health centers are required to provide family planning services as a basic service. An estimated one-quarter of all health centers also participate in Title X. But Title X requires a more comprehensive scope of family planning than many health centers offer under § 330 alone.¹⁸ Only 25% participate today – far too low to replace the lost access, as shown by the Texas experience.¹⁹ Health centers would have to expand capacity, hire staff, and add services, a major undertaking that bumps up against their obligations to meet the health care needs of residents of all ages. Many health centers lack the necessary advanced skills and training²⁰ to offer the most advanced family planning methods and indeed, rely on Title X providers. Indeed, Texas health centers could not offset the loss of other community providers.

¹⁷ See, e.g., 84 Fed. Reg. 7714, 7754 ("and to allow for grantees, such as community health centers . . ."); see also 84 Fed. Reg. at 7727.

¹⁸ See Susan Wood et al., *Health Centers and Family Planning: Results of a Nationwide Study*, The George Washington University School of Public Health & Health Services Department of Health Policy (2013), <u>https://bit.ly/2XGiNq3</u>.

¹⁹ Leighton Ku et al., *Deteriorating Access to Women's Health Services in Texas: Potential Effects of the Women's Health Program Affiliate Rule*, Policy Research Brief No. 31, GEIGER GIBSON / RCHN COMMUNITY HEALTH FOUNDATION RESEARCH COLLABORATIVE (Oct. 2012), <u>https://bit.ly/2XK3AEg</u>.

²⁰ Kari White et al., *Providing Family Planning Services at Primary Care Organizations after the Exclusion of Planned Parenthood from Publicly Funded Programs in Texas: Early Qualitative Evidence*, 53 Health Servs. Res. 2770 (2018).

Appellants' rule would replicate the Texas experience nationally. A nationwide study of health centers and family planning found that in 2017, only 6% of all health centers reported being able to increase their capacity by 50% or more.²¹ In its comments, the American College of Obstetricians and Gynecologists pointed out that health centers would be unable to absorb the approximately two million contraceptive patients who would lose access to care, noting that while the average community health center site serves 320 contraceptive clients annually, the comparable average figure for a Planned Parenthood clinic site is 2,950.²² The Guttmacher Institute similarly commented that other providers in 13 states would have to double their contraceptive client caseloads to maintain current provider access.²³

²¹ Susan Wood et al., *Community Health Centers and Family Planning in an Era of Policy Uncertainty*, Kaiser Family Foundation (2018), <u>https://bit.ly/</u> <u>2XEjPTA</u>.

²² Am. College of Obstetricians & Gynecologists, Comment Letter on Proposed Rule Regarding Compliance with Statutory Program Integrity Requirements (July 31, 2018), <u>https://bit.ly/2NndXdi</u> [hereinafter ACOG Comment Letter], at 12 (citing Kinsey Hasstedt, *Federally Qualified Health Centers: Vital Sources of Care, No Substitute for the Family Planning Safety Net*, 20 Guttmacher Pol'y Rev. 67 (2017), <u>https://bit.ly/2xtP98x</u>).

²³ Guttmacher Institute, Comment Letter on Proposed Rule Regarding Compliance with Statutory Program Integrity Requirements, at 12 (July 31, 2018), <u>https://bit.ly/2KPoQCL</u> [hereinafter Guttmacher Comment Letter], at 10 (citing Jennifer J. Frost & Mia R. Zolna, *Memo to Sen. Patty Murray Regarding Response to Inquiry Concerning the Impact on Other Safety-Net Family Planning Providers of "Defunding" Planned Parenthood*, GUTTMACHER INSTITUTE (June 14, 2017), <u>https://bit.ly/2KPh2Rh</u>.

Furthermore, the gag rule means that community health centers will have to abandon adherence to professional practice guidelines and, like other professionals, will have to direct their clinical staff to withhold material information from their patients, contrary to the CDC 2013 practice guidelines. The very same ethical and legal concerns that apply to medical professionals generally apply to health center clinicians, who are highly qualified and board-certified in their respective fields. There is no evidence that Appellants considered this fact.

Appellants also ignore the fact that the terms of Section 330 health center grants may deter Title X participation. These terms require the use of evidencebased protocols,²⁴ which in the case of health centers would be the 2013 CDC postconception guidelines developed in part by the Health Resources and Services Administration ("HRSA"), which administers § 330. HRSA's Health Center Program Compliance Manual requires "adhering to current evidence-based clinical guidelines, standards of care, and standards of practice. . . ."²⁵ The CDC postconception counseling guidelines explicitly require nondirective counseling.²⁶ As a result, health centers' core grant funding may be at risk if they follow Appellants'

²⁴ Section 330 of the Public Health Service Act (42 U.S.C. § 254b) provides the statutory basis for DHHS/HRSA grants to federally qualified community health centers.

²⁵ *Health Center Program Compliance Manual*, HRSA, 44 (Aug. 2018), <u>https://bit.ly/325CJC8</u>.

²⁶ These guidelines encompass both preconception care and pregnancy testing and counseling. Gavin et al., *supra* note 10.

rule.²⁷

Health centers also face medical liability for clinical practices that negligently fall below the professional standard of medical care. Under principles of medical liability, the fact that a third-party payer (such as a Title X grantor) conditions payments on (i) withholding crucial information from patients and (ii) engaging in mandatory counseling and referral for care that patients may not want is *not* a defense to allegations of medical malpractice or professional misconduct.²⁸ In their comments, professional societies also pointed to the *Wickline* problem.²⁹

The problem is even more complicated for community health centers, whose medical liability coverage is through the Federal Tort Claims Act ("FTCA"), ³⁰ which conditions coverage on compliance with professional standards of care. Failure to adhere to § 330 grant rules results in loss of FTCA coverage, and Appellants' rule clearly precipitates this conflict.

²⁷ Sara Rosenbaum et al., *Community Health Center Financing: The Role of Medicaid and Section 330 Grant Funding Explained*, Kaiser Family Foundation (Mar. 26, 2019), <u>https://bit.ly/2XfliZF</u>.

²⁸ *Wickline v. State of California*, 192 Cal. App. 3d 1630 (Ct. App. 1986).

²⁹ ACOG Comment Letter (citing Sara Rosenbaum et al., *The Title X Family Planning Proposed Rule: What's At Stake for Community Health Centers?*, HEALTH AFFAIRS BLOG (June 25, 2018), <u>https://bit.ly/2tAkJil</u>).

³⁰ About the Federal Tort Claims Act (FTCA), HRSA, <u>https://bphc.hrsa.gov/</u><u>ftca/about/index.html</u>.

C. The Final Rule Undermines the Availability of Effective Family Planning Services by Discouraging the Most Advanced, Effective Treatments.

The final rule deprioritizes awards to projects capable of offering the most effective modern medical contraceptive technologies. Since Rust v Sullivan³¹ was decided in 1991, contraception science has advanced considerably through the development of prescribed Long Acting Reversible Contraception ("LARC").³² Yet the final rule strikes the term "medically" from the requirement that grantees offer contraception, while explicitly endorsing and encouraging far less effective "natural family planning or other fertility awareness-based methods." The rule clearly hews to priorities driven by ideology, not science. Indeed, the rule effectively de-emphasizes the availability of LARC while encouraging project participation by entities offering only "natural family planning" methods. Grantee effectiveness will be diminished, and patients may face longer travel to reach skilled, quality providers. Appellants make no effort to assess the access and health impact of relaxing the medical effectiveness standard.

D. The Final Rule's Separation Requirement Undermines the Availability of Effective Family Planning Services.

The rule goes beyond simply degrading the quality of care. The financial and

Id.

³² ACOG Practice Bulletin: Clinical Management Guidelines for Obstetrician-Gynecologists, No. 186, ACOG (Nov. 2017), <u>https://bit.ly/2Xho08l</u>.

physical separation requirements of the proposed rule, *Maintenance of Physical and Financial Separation*, 42 C.F.R. § 59.15, will severely undermine Title X grantee ability to provide family planning services. By requiring physical and financial separation, the rule effectively excludes providers, such as Planned Parenthood, that offer full-spectrum care or that are affiliated with providers that do offer such care.³³

The physical and financial separation requirements in the final rule will make Title X participation prohibitively costly, potentially causing many entities to pull out of the program altogether.³⁴ Multiple professional medical organizations expressed these views. For example, the American Medical Association ("AMA") noted the impact of the rule on continued participation by specialized reproductive health providers, such as Planned Parenthood,³⁵ as did ACOG³⁶ and the National

³³ Planned Parenthood clinics were the site of care for approximately 40% of all women receiving services under Title X nationwide. *See* Decl. of Kimberly Custer in Supp. of Plaintiffs' Mtn. for a Preliminary Injunction (Mar. 21, 2019), at 3 (ECF No. 43, Case No. 19-cv-318, D. Or.); *see also* Laurie Sobel et al., *Proposed Changes to Title X: Implications for Women and Family Planning Providers*, KAISER FAMILY FOUNDATION (Nov. 21, 2018), <u>https://bit.ly/2FxSH0q</u>.

³⁴ Nat'l Fam. Plan. & Reprod. Health Ass'n, Comment Letter on Proposed Rule Regarding Compliance with Statutory Program Integrity Requirements, at 16-17 (July 31, 2018), <u>https://bit.ly/2JfW8HP</u> [hereinafter NFPRHA Comment Letter].

³⁵ Am. Med. Ass'n, Comment Letter on Proposed Rule Regarding Compliance with Statutory Program Integrity Requirements, at 4 (July 31, 2018), <u>https://bit.ly/</u>2KPpd07.

³⁶ ACOG Comment Letter, at 11.

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Family Planning and Reproductive Health Association ("NFPRHA"). Yet Appellants fail to consider the impact of such a requirement on the size and scope of the Title X network, and therefore, on access.³⁷

All of these policies aimed at excluding current network providers and degrading the available level of care come together in another provision of the rule³⁸ that empowers the agency to exclude Title X project applicants before their applications reach the competitive review stage. This amounts to a highly politicized filter on the funding award process to favor projects that offer limited contraceptive access and engage only in highly directive counseling.

Exacerbating the circumstances for family planning providers, the final rule does not issue clear guidance on what constitutes sufficient "separation," instead offering a subjective "facts and circumstances" test that leaves grantees in the dark on how to deal with physical separation demands (down to entrances, exits, shared phone numbers, email addresses, websites, and separate personnel and health care records).³⁹ The rule creates boundless uncertainty in the name of program integrity, the consequences of which Defendants-Appellants fail to consider.

Furthermore, Defendants-Appellants disregard the cost of compliance. Existing estimates are confined to the narrow technical costs of compliance and

³⁷ NFPRHA Comment Letter, at 37.

³⁸ See 42 C.F.R. § 59.7.

³⁹ See 42 C.F.R. § 59.15.

fail to account for the possibility of a large provider exodus or the impact of such exodus on either health care access or health outcome.

II. The Final Rule Will Lead To Decreased Access To Family Planning And Life-Saving Preventive Care.

The public record overwhelmingly points to the fact that rather than promoting access, the final rule will undermine it. Title X enables access not only to the most effective forms of family planning but also to critical preventive related services such as screening and counseling for sexually-transmitted infections and HIV, preventive cancer screenings, and counseling and referrals for other needed care.

A. Decreased Access to Effective Contraceptive Threatens a Rise in Unplanned Pregnancies.

The Texas experience illustrates that, as the Title X network shrinks, so will access to care. The health, economic, and social consequences are enormous. By providing millions of patients with access to affordable and medically effective contraception, publicly funded family planning in 2010 helped women to avoid 2.2 million unintended pregnancies. If access is lost, unintended pregnancies, unplanned births, and abortions would be 66% higher than they currently are.⁴⁰

B. Decreased Access to Testing for Sexually Transmitted Infections Will Lead to More Preventable Illnesses.

As the Title X network shrinks, access to related care, such as testing for

⁴⁰ Sonfield et al., *supra* note 5.

sexually transmitted infections ("STI"), will decline. In 2017, STI testing and treatment represented nearly half of the services (48.7%) performed at Planned Parenthood clinics.⁴¹ Overall, Title X program providers performed nearly 6.5 million screening tests for STIs in 2017^{42} – especially crucial for low-income women, who experience both higher rates of STIs and lower access to care.⁴³ Appellants make no impact assessment and fail to recognize the risk of STI screening and treatment disruption that inevitably will contribute to a rise in preventable conditions that threaten women and children alike. Appellants' disregard for this risk is untimely. The CDC reports steady growth in STIs since 2013, including 2.3 million new cases of chlamydia, gonorrhea, and syphilis in 2017, surpassing the 2016 all-time high by more than 200,000 cases. ⁴⁴ The Texas experience showed these same results, with chlamydia and congenital syphilis infection rates well above the national average,⁴⁵ along with newly diagnosed cases

⁴¹ 2017-2018 Annual Report, PLANNED PARENTHOOD 23 (2018), <u>https://bit.ly/</u> <u>2tH6qtk</u>.

⁴² Dep't of Health & Hum. Servs., *Title X Family Planning Annual Report* 2017 Summary, <u>https://bit.ly/3236G5F</u>.

⁴³ Usha Ranji et al., *Financing Family Planning Services for Low-Income Women: The Role of Public Programs*, KAISER FAMILY FOUNDATION (May 11, 2017), <u>https://bit.ly/2xmVMtB</u>.

⁴⁴ Ctrs. for Disease Control & Prevention, *New CDC Analysis Shows Steep and Sustained Increases in STDs in Recent Years*, CDC NEWSROOM (Aug. 28, 2018), https://bit.ly/2MG6Yvr.

⁴⁵ Kinsey Hasstedt, *The State of Sexual and Reproductive Health and Rights In the State of Texas: A Cautionary Tale*, 17 Guttmacher Pol'y Rev. 14 (2014), <u>https://bit.ly/303jZB8</u>; Ctrs. for Disease Control & Prevention, *Sexually*

of HIV.⁴⁶

Of particular concern is the rule's impact on improving access to HIV screening and prophylaxis, a major Presidential priority.⁴⁷ By imposing limits on what Title X providers can (and cannot) communicate with their patients, the rule is likely to trigger widespread misunderstanding that will cause a chilling effect on provider-patient communications more generally, a result documented in past efforts to restrain how providers communicate with high-risk patients regarding conditions carrying social stigma such as HIV and other STIs. As known and trusted providers are pushed out of the program, the highest risk patients may disappear entirely, thereby imperiling their health while raising the public health threat to entire communities.⁴⁸

C. Decreased Access to Cancer Screenings Will Lead to Delayed Cancer Diagnosis.

Appellants have failed to consider the impact of a shrinking network on access to cervical cancer screening and clinical breast exams,⁴⁹ both features of the

Transmitted Disease Surveillance 2017, 71, 94 (Sept. 2018), <u>https://bit.ly/2Lpi71M</u>.

⁴⁶ *Diagnoses of HIV Infection in the United States and Dependent Areas*, CTRS. FOR DISEASE CONTROL & PREVENTION, 114 (Nov. 2018), <u>https://bit.ly/2T6FhKF</u>.

⁴⁷ HIV.gov, *What is "Ending the HIV Epidemic: A Plan for America"?*, <u>https://bit.ly/2DW9Deb</u>.

⁴⁸ amfAR, *Title X, the Domestic Gag Rule, and the HIV Response*, (2019), pp. 2-3, <u>https://bit.ly/2Ym0CTK</u>.

⁴⁹ C.I. Fowler et al., *Family Planning Annual Report: 2017 National Summary*, OFFICE OF POPULATION AFFAIRS, 41 (Aug. 2018), <u>https://bit.ly/2MIVN57</u>.

current Title X network,⁵⁰ under the CDC family planning guidelines.⁵¹ In 2017 alone, the existing network provided pap testing to 18% (649,266) of female family planning patients; 14% led to an indeterminate or abnormal result requiring additional evaluation or treatment.⁵² Likewise, the existing network performed more than 878,000 clinical breast exams (25% (878,491) of female patients); one in 20 (5% - 41,766 cases) led to a referral for further evaluation and ultimately, lifesaving care if needed.⁵³ In addition to cervical and breast cancer screenings, many members of the current Title X network also provide colposcopy screenings (to identify cervical abnormalities), including 57% of all Planned Parenthood clinics compared to only 19% of health department clinics.⁵⁴ The consequences of reducing the Title X network will be potentially irreversible consequences for medically underserved communities. Yet there is no evidence that Defendants-Appellants considered these risks in their impact assessments, choosing instead to "presume" sufficient replacement capacity.

⁵⁰ *Title X: The Nation's Program for Affordable Birth Control and Reproductive Health Care*, PLANNED PARENTHOOD, <u>https://bit.ly/2GHTuaM</u>.

Fowler, supra note 49, at 41.

⁵² Id.

⁵³ *Id.*

⁵⁴ Mia R. Zolna & Jennifer J. Frost, *Publicly Funded Family Planning Clinics in 2015: Patterns and Trends in Service Delivery Practices and Protocols*, at 13, GUTTMACHER INSTITUTE (2016), <u>https://bit.ly/2Ns5zcy</u>.

D. Reduced Access to Care Will Significantly Increase Medicaid Expenditures.

Although the rule's expected cost impact is apparent, Appellants make no effort to analyze its impact on federal and state Medicaid spending. Title X services lower Medicaid costs by reducing unplanned pregnancies, preventing the spread of disease, and reducing the health impact of conditions that can be detected and treated early. In 2010, for each dollar invested in publicly-funded family planning programs like Title X, the government saved \$7.09 in Medicaid-related costs.⁵⁵ Moreover, total public savings in 2010 reached approximately \$15.8 billion, including \$15.7 billion in savings from preventing unplanned births, \$123 million from STI/HIV testing, and \$23 million from pap and HPV testing and vaccines.⁵⁶ If access falls, the incidence of severe conditions and their attendant treatment costs will grow.⁵⁷ Research shows that contraceptive services can reduce Medicaid-associated maternity and infant care costs dramatically.⁵⁸ By severely reducing Title X network capacity, the final rule reverses these gains.⁵⁹

^{Jennifer J. Frost et al.,} *Return on Investment: A Fuller Assessment of Benefits and Cost Savings of the US Publicly Funded Family Planning Program*,
92 The Milbank Quarterly 667, 668 (2014), <u>https://bit.ly/2knull7</u> [hereinafter Frost et al., *Return on Investment*]; *Title X: The Nation's Program for Affordable Birth Control and Reproductive Health Care, supra* note 50.

⁵⁶ Frost et al., *Return on Investment, supra* note 55, at 668.

⁵⁷ *Id.* at 680.

⁵⁸ *Id.* at 696.

⁵⁹ See Stevenson et al., supra note 13.

CONCLUSION

The record below reflects wholly inadequate consideration given to the negative consequences of the final rule. The final rule will rapidly and dramatically shrink the Title X provider network, while deterring new qualified providers from participating. The health care, health, economic, and social consequences flowing from the rule are potentially enormous, but the record of Appellants' consideration of these adverse impacts is fundamentally deficient. By adopting a final rule bereft of a credible impact assessment of these easily anticipated consequences – and particularly in the context of a vast rulemaking record pointing to precisely these types of impacts – Appellants have acted arbitrarily and capriciously, in violation of the Administrative Procedure Act.

Dated: July 3, 2019

By: <u>Philip Shecter</u>

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CERTIFICATE OF COMPLIANCE

I certify that pursuant to Fed. R. App. P. 29, 32(a)(5), and 32(a)(7), the foregoing *amici curiae* brief is proportionally spaced, has a typeface of 14 point Times New Roman, and contains 4,728 words, excluding those sections identified in Fed. R. App. P. 32(f).

Dated: July 3, 2019

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CERTIFICATE OF SERVICE

I hereby certify that I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Ninth Circuit by using the appellate CM/ECF system on July 3, 2019. I certify that all participants in the case are registered CM/ECF users and that service will be accomplished by the appellate CM/ECF system

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