Nos. 19-431 & 19-454

In The Supreme Court of the United States

LITTLE SISTERS OF THE POOR
SAINTS PETER AND PAUL HOME,

Petitioner,

v.

COMMONWEALTH OF PENNSYLVANIA, ET AL.,

Respondents.

DONALD J. TRUMP, PRESIDENT OF
THE UNITED STATES, ET AL.,

Petitioners,

v.

COMMONWEALTH OF PENNSYLVANIA, ET AL.,

Respondents.

On Writs Of Certiorari To The United States Court Of Appeals For The Third Circuit

BRIEF OF AMICI CURIAE CENTER FOR HEALTH LAW AND POLICY INNOVATION OF HARVARD LAW SCHOOL, ET AL. IN SUPPORT OF RESPONDENTS

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INTEREST OF AMICI CURIAE[1]

Amici are the Center for Health Law and Policy Innovation of Harvard Law School; AIDS Alabama; AIDS Foundation of Chicago; AIDS Law Project of Pennsylvania; American Academy of HIV Medicine; Cascade AIDS Project (Portland, Oregon); Community Catalyst, Inc.; Equality California; Hepatitis Education Project; Legacy Community Health; Mississippi Center for Justice; National Viral Hepatitis Roundtable; North Carolina AIDS Action Network; Positive Women's Network-USA; Southern AIDS Coalition; and Treatment Action Group.

The Center for Health Law and Policy Innovation of Harvard Law School advocates for legal, regulatory, and policy reform to improve the health of underserved populations, with a focus on the needs of low-income people living with chronic illnesses and disabilities. All Amici promote access to health care and services for chronic disease communities, including people living with HIV and hepatitis C. Additionally, Amici have a significant history combating discrimination against people living with chronic illnesses. As such, Amici are uniquely positioned to provide insight on the importance of the coordinated, standardized package of

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[1] Amici submit this brief pursuant to Supreme Court Rule 37.3(a). Both parties have consented to the filing of amicus curiae briefs in support of either party. In compliance with Supreme Court Rule 37.6, Amici state that no counsel for a party authored this brief in whole or in part and that no person or entity other than Amici, its members, and its counsel contributed monetarily to the preparation or submission of this brief.

preventive services established by the Patient Protection and Affordable Care Act (the ACA) and certain harms to third parties that would and could arise should the judgment of the Third Circuit Court of Appeals be reversed. Amici write to articulate the harm to people at risk for and living with chronic illness that inescapably will arise should expanded religious exemptions to the contraceptive guarantee set forth in 45 C.F.R. § 147.132 (2019) be upheld as promulgated.

SUMMARY OF ARGUMENT

The expanded religious exemptions to the contraceptive guarantee set forth in 45 C.F.R. § 147.132 (2019) (the Rule) will cause significant harm to third parties, including people living with HIV, hepatitis C, and other medical conditions for whom contraceptives are an essential part of health care. Furthermore, although the Rule applies specifically to the contraceptive guarantee, this Court's decision could have far-reaching effects beyond the facts of this case. If the Court holds that the Rule is permissible under the Religious Freedom Restoration Act of 1993 (RFRA), future religious objectors could block vulnerable populations from accessing other forms of essential, life-saving preventive care included in the ACA's preventive services mandate (the Mandate). The Court should reaffirm its own well-established principle of "tak[ing] adequate account of the burdens a requested accommodation may impose on nonbeneficiaries," *Cutter v. Wilkinson*,

544 U.S. 709, 720 (2005) (citation omitted), and uphold the judgment of the Third Circuit Court of Appeals.

ARGUMENT

I. The Rule will impermissibly harm third parties entitled to coverage for preventive health care services under the Mandate.

This Court's jurisprudence on balancing third-party harm caused by governmental recognition of religious rights has not been distilled to a singular doctrinal test. Nevertheless, it is beyond argument that the principle directing courts to account for such harm is well established in the constitutional firmament. As commanded in *Cutter v. Wilkinson,* "courts must take adequate account of the burdens a requested accommodation may impose on nonbeneficiaries." 544 U.S. at 720 (citation omitted). That holding was built on an articulation, in *Estate of Thorton v. Caldor, Inc.*, 472 U.S. 703, 710 (1985), of "a fundamental principle of the Religion Clauses": "The First Amendment . . . gives no one the right to insist that in pursuit of their own interests others must conform their conduct to his own religious necessities." *Id.* (quoting *Otten v. Baltimore & Ohio R. Co.*, 205 F.2d 58, 61 (2d Cir. 1953)).

The absence, as yet, of a singular test spelling out a method by which to take account of third-party harm caused by religious accommodation does not erase the Court's requirement to consider it. Indeed, throughout the extensive litigation over the Mandate, this Court

has recognized third-party harm as a limiting factor on religious accommodation. In *Burwell v. Hobby Lobby Stores, Inc.*, 573 U.S. 682 (2014), in which the Court considered entitlement to accommodation from the Mandate's contraceptive guarantee for closely held for-profit corporations, the Court affirmed that "[i]t is certainly true that in applying RFRA 'courts must take adequate account of the burdens a requested accommodation may impose on nonbeneficiaries.'" 573 U.S. at 729 n.37 (quoting *Cutter v. Wilkinson*, 544 U.S. 709, 720 (2005)). *See also id*. at 739 (Kennedy, J., concurring) (stating that religious exercise must not "unduly restrict other persons . . . in protecting their own interests"); *id*. at 745 (Ginsburg, J., joined by Breyer, Kagan, and Sotomayor, JJ., dissenting) ("Accommodations to religious beliefs or observances . . . must not significantly impinge on the interests of third parties."); *id*. at 764 (Ginsburg, J., joined by Breyer, Kagan, and Sotomayor, JJ., dissenting) ("No tradition, and no prior decision under RFRA, allows a religion-based exemption when the accommodation would be harmful to others . . . ."). The Court also noted that "our decision in these cases need not result in any detrimental effect on any third party," *id.* at 729 n.37, because there existed other means to ensure that employees of an objecting entity maintain coverage, without cost-sharing, for the health care to which they are entitled by law.

The Court most recently considered the Mandate in *Zubik v. Burwell*, 136 S. Ct. 1557 (2016) (per curiam). In *Zubik*, employer-petitioners objected to the means by which the government accommodated

religious objections to the Mandate's contraceptive guarantee. Entities seeking an accommodation were required to submit notice to the government, upon which responsibility to "contract, arrange, pay, or refer for contraceptive coverage" would shift to an insurance company or third-party administrator. 26 C.F.R. § 54.9815-2713A (2015); 29 C.F.R. § 2590.715-2713A (2015); 45 C.F.R. § 147.131 (2015). Petitioners alleged that submitting notice imposed an ongoing substantial burden on religious beliefs in violation of RFRA. *Zubik*, 136 S. Ct. at 1559. This Court remanded the case, instructing that the parties be afforded "an opportunity to arrive at an approach going forward that accommodates petitioners' religious exercise while at the same time ensuring that women covered by petitioners' health plans 'receive full and equal health coverage, including contraceptive coverage.'" *Id.* at 1560 (citations omitted). In so doing, the Court reinforced its longstanding concern with balancing religious accommodation in a manner that minimizes third-party harm.

Whatever the level of third-party harm that suffices to overcome a claim for religious accommodation to government requirements, that level is met as applied here because the Rule fails to consider adequately the substantial, widespread effects—measured both in direct detriment and in opportunity cost to prevent future injury—that it will occasion. This is especially so in the context of explicit congressional intent to avoid the harm at issue. The purpose of this brief is to describe distinctly the harm that stands to be inflicted

on individuals living with or at risk for HIV, hepatitis C, and other chronic illness.[2]

II. The Rule will harm people living with chronic illness for whom contraception is a critical component of health care.

The Petitioners assert that a notice requirement presents a substantial burden to religious objectors. As a consequence, they seek sweeping exemptions, unprecedented in the recent history of the federal government's accommodation of religious belief. The Rule eviscerates the Mandate's contraceptive guarantee by allowing employers, schools, insurers, and other organizations to curtail some or all coverage of contraception and by impeding the government from making separate arrangements to ensure access to these services. In promulgating this Rule, Petitioners failed to consider adequately the harm such an evisceration would have on third parties. Instead, as the Third Circuit noted, Petitioners "downplayed this burden on women, contradicting Congress's mandate that women be provided contraceptive coverage." *Trump* Pet. App. 41a.

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[2] While this brief describes the harm to third parties that would arise under expanded religious exemptions and while Petitioners cannot (and do not) assert that RFRA authorizes the Administration's promulgation of moral exemptions, 45 C.F.R. § 147.133 (2019), similar harm would befall third parties should employers, schools, and other organizations be permitted to "edit" the mandated set of preventive services on the basis of moral objection.

The Rule would cause particular harm to people living with HIV, hepatitis C, and other medical conditions, for whom contraception is a critical component of health care. Because of the unique health concerns people living with these chronic illnesses face, it is important that standardized access to no-cost preventive care includes access to the full range of contraceptive methods as directed by the Mandate. Whereas prior to the Rule alternative arrangements for coverage were assured, the Rule limits meaningful access to the full range of contraception and will cause people living with chronic illnesses to face preventable harm in managing their health.

Access to contraceptive methods and the ability to prevent pregnancies allow people living with chronic illnesses to better control their health and avoid pregnancy-related detrimental health effects. Chronic conditions, such as hypertension or diabetes, can cause birth complications and pregnancy-related deaths.[3]

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[3] *Pregnancy Mortality Surveillance System*, Ctrs. for Disease Control & Prevention, https://www.cdc.gov/reproductivehealth/maternal-mortality/pregnancy-mortality-surveillance-system.htm (last updated Feb. 4, 2020) ("Studies show that an increasing number of pregnant women in the United States have chronic health conditions such as hypertension, diabetes, and chronic heart disease. These conditions may put a pregnant woman at higher risk of pregnancy complications . . . . When combined, cardiovascular conditions (i.e., cardiomyopathy, other cardiovascular conditions, cerebrovascular accidents) were responsible for greater than one-third of pregnancy-related deaths in 2011-2016.") (citations omitted); *see* Jill M. Mhyre et al., *Influence of Patient Comorbidities on the Risk of Near-miss Maternal Morbidity or Mortality*, 115 Anesthesiology 963, 969 (2011) ("[C]lose to 60% of near-miss maternal morbidity or mortality events are

Pregnancy can lead to disease progression in some chronic conditions, such as lupus and chronic kidney disease, by exacerbating existing symptoms. *See*, *e.g.*, Alan Baer et al., *Lupus and Pregnancy*, 66 Obstetrical & Gynecological Surv. 639 (2011); Philip Webster et al., *Pregnancy in Chronic Kidney Disease and Kidney Transplantation*, 91 Kidney Int'l 1047 (2017). Meaningful access to contraception gives people the autonomy both to direct their reproductive futures and manage chronic illness. Without such access to contraception, people living with chronic illnesses would face barriers when managing their health and could face more dangerous health outcomes if they were to become pregnant.

Eliminating and fragmenting access to the full range of contraceptive methods, as allowed in the new Rule, would harm people taking medications that compromise the effectiveness of certain forms of birth control. In these situations, people are advised to switch to a contraceptive method that is not affected by the drug. For example, rifampin, an antibiotic used to prevent and treat tuberculosis and other bacterial infections, can accelerate the metabolism of certain drugs in the body and lower the effectiveness of hormone-based contraception (including "birth control pills, patches, rings, implants, and injections").[4] Patients on rifampin are thus counseled to use non-hormonal

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concentrated in approximately 10% of women with medical or obstetric conditions known at the time of admission to the labor and delivery unit.").

[4] *Rifampin*, MedlinePlus, https://medlineplus.gov/druginfo/meds/a682403.html (last updated Apr. 2019).

contraceptive methods. Similar warnings are given for medications such as Prezista (indicated for HIV), Kaletra (indicated for HIV), Carbatrol (indicated for epilepsy and trigeminal neuralgia), and Provigil (indicated for narcolepsy).[5] Without access to the full range of contraceptive methods, people living with chronic illnesses may be unable to access a form of birth

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[5] Prezista (darunavir) Tablet [Janssen], DAILYMED, https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=814301f9-c990-46a5-b481-2879a521a16f (last updated June 2019) ("Use of PREZISTA may reduce the efficacy of combined hormonal contraceptives and the progestin only pill. Advise patients to use an effective alternative (non-hormonal) contraceptive method or add a barrier method of contraception."); Kaletra (lopinavir-ritonavir) Tablet, Solution [AbbVie], DAILYMED, https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=8290add3-4449-4e58-6c97-8fe1eec972e3 (last updated Dec. 2019) ("Use of KALETRA may reduce the efficacy of combined hormonal contraceptives. Advise patients using combined hormonal contraceptives to use an effective alternative contraceptive method or an additional barrier method of contraception . . . ."); Carbatrol (carbamazepine) Capsule [Shire], https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=bc03e499-5bac-4293-bff4-6864153a624d (last updated Sept. 2018) ("Concomitant use of Carbatrol(R) with hormonal contraceptive products (e.g., oral and levonorgestrel subdermal implant contraceptives) may render the contraceptives less effective because the plasma concentrations of the hormones may be decreased . . . . Alternative or back-up methods of contraception should be considered."); Provigil (modafinil) Tablet [Cephalon], DAILYMED, https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=e16c26ad-7bc2-d155-3a5d-da83ad6492c8 (last updated Mar. 2020) ("Alternative or concomitant methods of contraception are recommended for patients taking steroidal contraceptives (e.g., ethinyl estradiol) when treated concomitantly with PROVIGIL and for one month after discontinuation of PROVIGIL treatment.").

control that remains effective when taken together with other necessary medication regimens.

The erosion of consistent and comprehensive access to contraception would also harm people living with chronic illness who take medications with teratogenic effects. Teratogenic medications can have severe impacts on fetal development resulting in significant abnormalities. People on these medications and their partners need access to contraception that works for their medical and personal preferences in order to prevent pregnancies while at a higher risk for fetal defects. Food and Drug Administration labels for a number of medications contain warnings to use effective contraception for a specific duration of time. These drugs include Rebetol (indicated for hepatitis C), Soriatane (indicated for severe psoriasis), Topamax (indicated for epilepsy and migraines), Lipitor (indicated for congestive heart failure and congenital heart disease), and Coumadin (indicated for blood clots).[6] People

[6] Rebetol (ribavirin USP) Capsules, Oral Solution [Merck], DAILYMED, https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=04d2b6f4-bd9b-4871-9527-92c81aa2d4d0 (last updated Jan. 2020) (including in black-box warning that, "[e]ffective contraception must be utilized during treatment and during the 6-month post-treatment follow-up period . . . ."); Soriatane (acitretin) Capsule [Stiefel], DAILYMED, https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=cec7851f-c7af-4e9e-a5e4-a585c70510d2 (last updated Oct. 2018) (including in black-box warning that, "SORIATANE also must not be used by females who may not use reliable contraception while undergoing treatment and for at least 3 years following discontinuation of treatment."); Lipitor (atorvastatin calcium) Tablet [Pfizer], DAILYMED, https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=c6e131fe-e7df-4876-83f7-9156fc4e8228 (last updated Dec. 2019) ("Advise females of

with chronic illnesses who lose meaningful access to the full range of contraceptive methods are at risk for treatment delays, health deterioration, and a loss of control over the management of their health.

III. The Rule creates a precedent so untethered to consideration of third parties that it will harm people who benefit from other essential, life-saving preventive care beyond contraceptives.

While the Rule is specific to requirements for contraceptive coverage, the Mandate encompasses other services that are likely to give rise to religious objections. Thus, if employers and other entities are permitted to "edit" the mandated package of preventive services according to their own subjective religious code without any meaningful limiting principle, it will become more difficult for individuals to access other essential, life-saving preventive care beyond

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reproductive potential of the risk to a fetus, to use effective contraception during treatment and to inform their healthcare provider of a known or suspected pregnancy . . . ."); Topamax (topimarate) Tablet, Capsule [Janssen], DAILYMED, https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=21628112-0c47-11df-95b3-498d55d89593 (last updated May 2019) ("Women of childbearing potential who are not planning a pregnancy should use effective contraception because of the risks of oral clefts and SGA . . . ."); Coumadin (warfarin sodium) Tablet [Bristol-Myers Squibb], DAILYMED, https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=d91934a0-902e-c26c-23ca-d5accc4151b6 (last updated Dec. 2019) ("Advise females of reproductive potential to use effective contraception during treatment and for at least 1 month after the final dose of COUMADIN.").

contraceptives.[7] Harm to third parties will intensify, licensing religious objectors to discriminate at will, without regard to the consequences of their decisions.

Petitioners' persistent conflation of religious objections to contraceptives and other potentially controversial health care services sounds the alarm. The preamble to the Rule, for example, cites 22 U.S.C. § 7631, "protecting entities from being required to use HIV/AIDS funds contrary to their 'religious or moral objection,'" as historical precedent. Religious Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act, 83 Fed. Reg. 57,536, 57,539 n.1 (Nov. 15, 2018). Similarly, Petitioners explicitly declined to distinguish HIV treatment and pre-exposure prophylaxis from other health care services in another set of rules promulgated to advance federal conscience laws. *See* Protecting Statutory Conscience Rights in Health Care; Delegations of Authority, 84 Fed. Reg. 23,170, 23,182 (May 21, 2019) (republished with immaterial correction on June 7, 2019). In response to concerns about the impact of proposed protections for religious

[7] There may be factual grounds to distinguish contraceptive coverage from coverage for other services. *See Hobby Lobby Stores*, 573 U.S. at 733 ("Other coverage requirements, such as immunizations, may be supported by different interests . . . and may involve different arguments about the least restrictive means of providing them."). However, Petitioners' finding of an ongoing substantial burden on religious rights and the remedy they offer in response thereto—that "no measure short of an exemption would resolve all [religious] objections," *Trump* Pet. at 27—are so unbalanced as to seemingly overwhelm or obliterate any countervailing interests.

objectors on people at risk for or living with HIV, the Department of Health and Human Services commented that, "[i]n the event that the Department receives a complaint with respect to HIV treatment, pre-exposure prophylaxis . . . the Department would examine the facts and circumstances of the complaint to determine whether it falls within the scope of the statute in question and these regulations." *Id*.

In creating a sweeping exemption from the Mandate untethered to adequate consideration of harm to third parties with respect to the contraceptive guarantee, the Rule paves the way for similar exemptions regarding coverage for other services.

A. The Mandate addresses other services used to prevent chronic conditions to which some religiously motivated actors object.

The Mandate encompasses a broad array of prevention services. It ensures access to screening for infectious diseases, such as HIV and viral hepatitis, and other conditions.[8] The Mandate ensures access

[8] *See* Ctrs. for Medicare & Medicaid Servs., *Preventive health services*, HealthCare.gov, https://www.healthcare.gov/coverage/preventive-care-benefits/ (last visited Mar. 22, 2020) (providing up-to-date information on the full range of services required under the Mandate). The preventive services that are included under the Mandate fall into four broad categories: (1) evidence-based screening and counseling that receive an "A" or "B" grade by the United States Preventive Services Task Force, an independent, volunteer panel of national experts; (2) immunizations that are recommended by the Advisory Committee on Immunization

to a range of medications, such as HIV pre-exposure prophylaxis (PrEP), and vaccinations, including vaccination against hepatitis B and vaccination against the human papillomavirus (HPV).[9] Several of these prevention-related services may conflict with religious beliefs and doctrine.

Common sources of tension between preventive health care and religious beliefs include religious opposition to medical intervention, generally,[10] and to specific technologies. For example, some religious adherents are opposed to vaccinations because of their

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Practices, a committee of immunization experts that is overseen by the Centers for Disease Control and Prevention; (3) preventive services for children and adolescents that are recommended by the federal government's Bright Futures Project; and (4) preventive services targeting women's health that are recommended by the federal Health Resources and Services Administration. *See* Patient Protection and Affordable Care Act § 1001, 42 U.S.C. § 300gg-13(a) (2018); 26 C.F.R. § 54.9815-2713(a) (2019); 29 C.F.R. § 2590.715-2713(a) (2019); 45 C.F.R. § 147.130(a) (2019).

[9] *See* Ctrs. for Medicare & Medicaid Servs., *Preventive health services*, HealthCare.gov, https://www.healthcare.gov/coverage/preventive-care-benefits/ (last visited Mar. 22, 2020).

[10] *See*, *e.g.*, *A Christian Science perspective on vaccination and public health*, Christian Science, https://www.christianscience.com/press-room/a-christian-science-perspective-on-vaccination-and-public-health (last visited Mar. 19, 2020) ("Most of our church members normally rely on prayer for healing. It's a deeply considered spiritual practice and way of life that has meant a lot to us over the years. So we've appreciated vaccination exemptions and sought to use them conscientiously and responsibly, when they have been granted.").

composition.[11] Controversy is also fueled by moral judgment of specific activities—such as certain sexual activity (e.g., homosexuality, premarital sex, and non-procreative sex)—and an association between the activity and an illness.[12] In this context, the promotion of preventive services may be viewed as condoning or enabling improper behavior. The examples below are illustrative of this third construct.

PrEP, a highly effective medication that a person who is HIV-negative can take to reduce their risk of acquisition, is a vital part of the Administration's *Ending the HIV Epidemic: A Plan for America* that launched in February 2019.[13] Consistent with the

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[11] *See*, *e.g.*, Secretariat of Pro-Life Activities, *Conscience Exemption for Vaccines based on Fetal Tissue from Abortions*, United States Conference of Catholic Bishops, http://www.usccb.org/beliefs-and-teachings/how-we-teach/catholic-education/upload/Vaccines-Conscience-Exemption-updated-April-2015.pdf (last updated Apr. 2015) ("The only vaccines readily available in the United States for some contagious diseases (e.g., rubella and Hepatitis A) have been manufactured using fetal tissue from induced abortions. This creates a problem of conscience for some Catholic parents.").

[12] *See generally* Peter Conrad & Kristin K. Barker, *The Social Construction of Illness: Key Insights and Policy Implications*, 51 J. Health & Soc. Behav. S67 (2010). *See also* National Research Council (US) Panel on Monitoring the Social Impact of the AIDS Epidemic, *The Social Impact of AIDS in the United States* 127-30 (1993) ("The AIDS epidemic is marked by one feature that has made it particularly problematic for religion, namely, the group initially hardest hit . . . is men who have sex with men. This fact has posed a problem to those religions that explicitly condemn homosexual activity as sinful.").

[13] *See Ending the HIV Epidemic: Prevent HIV*, Ctrs. for Disease Control & Prevention, https://www.cdc.gov/endhiv/prevent.html

Administration's initiative, persons at high risk of acquiring HIV will soon have access to no-cost coverage for PrEP under the Mandate.[14] However, vulnerable populations at high risk for HIV include gay and bisexual men who are sexually active, persons who engage in "transactional sex, such as for money, drugs, or housing," transgender women, and persons who inject drugs.[15] Some religious adherents thus object to PrEP (and other approaches to HIV prevention) on the basis that such health care "clearly raise[s] concerns about sanctioning or supporting immoral behaviors."[16]

(last updated Feb. 3, 2020) (identifying PrEP as a core component of a national initiative's four-prong strategy to prevent HIV infection).

[14] *See* U.S. Preventive Servs. Task Force, *Preexposure Prophylaxis for the Prevention of HIV Infection: US Preventive Services Task Force Recommendation Statement*, 321 JAMA 2203 (2019) [hereinafter *USPSTF PrEP Recommendation Statement*] (issuing an "A" grade recommendation to PrEP in June 2019). *See also* Coverage of Certain Preventive Services Under the Affordable Care Act, 80 Fed. Reg. 41,318, 41,321 (July 14, 2015) (establishing that "plans and issuers must provide coverage for new recommended preventive services for plan years (in the individual market, policy years) beginning on or after the date that is one year after the date the relevant recommendation or guideline under [Public Health Service Act] section 2713 is issued.").

[15] *USPSTF PrEP Recommendation Statement* at 2206.

[16] Tadeusz Pacholczyk**,** *Sorting Through 'Solutions' to the HIV/AIDS Pandemic*, Making Sense of Bioethics, Feb. 2018, at 1, 2, https://www.ncbcenter.org/files/4615/2148/3297/MSOB152_Sorting_Through_Solutions_to_the_HIV-AIDS_Pandemic_pdf. Pacholczyk, the Director of Education at the National Catholic Bioethics Center, denounces the promotion and use of PrEP:

> Writing . . . prescriptions [for PrEP] means cooperating in, or facilitating, the evil actions of others . . . . STD

For both chronic hepatitis B, which can lead to serious liver disease, and HPV, which can cause cervical cancer, there exist vaccinations that are highly effective at preventing disease.[17] According to the Administration, "[a]ll children need to get the hepatitis B vaccine—and some adults may need it, too."[18] "Everyone needs to get the HPV vaccine—doctors recommend that boys and girls get the HPV vaccine at age 11 or 12 to take advantage of the best immune

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> outbreaks and pandemics often have their origins in unchaste behaviors and morally disordered forms of sexuality . . . . We should not be supporting or facilitating behaviors involving multiple sexual partners. These sexual practices . . . are not only immoral in themselves, but also reckless . . . .

Id. *See also* Sarah K. Calabrese & Kristen Underhill, *How Stigma Surrounding the Use of HIV Preexposure Prophylaxis Undermines Prevention and Pleasure: A Call to Destigmatize "Truvada Whores"*, 105 Am. J. Pub. Health 1960, 1962 (2015) ("Ensuring that sex-negative messaging and moral appeals—as exemplified by the 'Truvada whore' stereotype—do not overshadow science and cloud the judgment of medical providers, policymakers, insurers, and potential PrEP users is essential to ensuring access to PrEP and achieving maximum benefit from this valuable biomedical technology.").

[17] *See generally* U.S. Dep't of Health & Human Servs., *Hepatitis B*, Vaccines.Gov, https://www.vaccines.gov/diseases/hepatitis_b (last updated Jan. 2018); U.S. Dep't of Health & Human Servs., *HPV (Human Papillomavirus)*, Vaccines.Gov, https://www.vaccines.gov/diseases/hpv (last updated Jan. 2018).

[18] U.S. Dep't of Health & Human Servs., *Hepatitis B*, Vaccines.Gov, https://www.vaccines.gov/diseases/hepatitis_b (last updated Jan. 2018).

response."[19] Accordingly, hepatitis B vaccination and the HPV vaccine are made available to individuals, without cost-sharing, under the Mandate.[20] Similar to HIV, however, hepatitis B and HPV are associated with sexual activity and, for hepatitis B, injection drug use. This association creates religious opposition on the basis that hepatitis B and HPV vaccinations are preventive services "administered in order to enable one's children to make Biblically sinful decisions."[21]

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[19] U.S. Dep't of Health & Human Servs., *HPV (Human Papillomavirus)*, Vaccines.Gov, https://www.vaccines.gov/diseases/hpv (last updated Jan. 2018).

[20] *See* Ctrs. for Medicare & Medicaid Servs., *Preventive health services*, HealthCare.gov, https://www.healthcare.gov/coverage/preventive-care-benefits/ (last visited Mar. 22, 2020).

[21] A Christian Statement on Vaccination and Religious Objection, https://olis.leg.state.or.us/liz/2019R1/Downloads/CommitteeMeetingDocument/171446 (2019) (written testimony against a vaccination mandate in Oregon for reasons including that, "[f]or most people, sexual contact or needle-sharing are the only ways to be exposed to infections such as HPV (sexual only) or Hepatitis B. Generally, these vaccines are administered in order to enable one's children to make Biblically sinful decisions."); *see also* Debora Mackenzie, *Will Cancer Vaccine Get to All Women?*, NEW SCIENTIST (Apr. 16, 2005) (expounding Family Research Council's then-position that "[g]iving the HPV vaccine to young women could be potentially harmful, because they may see it as a licence to engage in premarital sex").

B. The elimination of other controversial services from the guarantees of the Mandate would erect significant barriers to care and cause people to delay or forgo essential, life-saving services.

The nature of the Mandate is such that any application of the Rule's sweeping veto power to additional statutorily-mandated preventive services would cause severe harm to third parties. As recognized by Congress in its enactment of the ACA, certain health care services are of such a significant benefit to individuals and society that they should be required to be covered uniformly at no additional cost.[22]

The Mandate's preventive services reflect a broad range of public health interventions, including primary prevention (interventions that inhibit disease occurrence) and secondary prevention (interventions that involve detecting disease at an early stage) strategies.[23] The services encompassed therein—including those most vulnerable to religious objection—are

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[22] The ACA was designed to address the public health crisis resulting from low levels of preventive services, in part by coordinating the removal of cost barriers to preventive services across insurers and across the public and private payer systems. Howard Koh & Kathleen Sebelius, *Prevention Through the Affordable Care Act*, 363 New Eng. J. Med. 1296 (2010).

[23] For a resource discussing this framework for organizing preventive services, see L. Kay Bartholomew et al., *Planning Health Promotion Programs: An Intervention Mapping Approach* 256-57 (2d ed. 2006). *See also* Raymond L. Goldsteen et al., *Introduction to Public Health: Promises and Practice* 6-10 (2d ed. 2015).

essential to supporting and improving health and, in many cases, are life-saving.[24]

For example, PrEP, a primary prevention strategy, helps inhibit disease occurrence. PrEP has been associated with a reduced risk of HIV infection, which can have "significant health consequences."[25] Over 1.1 million people in the United States are "at substantial risk for HIV and should be offered PrEP." Press Release, Ctrs. for Disease Control & Prevention, HIV Prevention Pill Not Reaching Most Americans Who Could Benefit—Especially People of Color (Mar. 6, 2018). Yet the Centers for Disease Control and Prevention

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[24] The Mandate includes services that, after an independent systematic review of evidence, are determined with high certainty to have a "substantial" or "moderate" benefit to individuals. *Grade Definitions*, U.S. Preventive Servs. Task Force, https://www.uspreventiveservicestaskforce.org/Page/Name/grade-definitions (last updated June 2018). Other services covered by the Mandate are selected by consensus of medical and public health experts, upon extensive review of clinical data and in consideration of clinical guidelines set forth by health care professional organizations. *See generally* Ctrs. for Disease Control & Prevention, *Advisory Committee on Immunization Practices Policies and Procedures* (2018), https://www.cdc.gov/vaccines/acip/committee/downloads/Policies-Procedures-508.pdf; Am. Acad. of Pediatrics, *Bright Futures: Guidelines for Health Supervision of Infants, Children, and Adolescents* (4th ed. 2017); Inst. of Med., *Clinical Preventive Services for Women: Closing the Gaps* (2011).

[25] *USPSTF PrEP Recommendation Statement* at 2203. *See also* Roger Chou et al., *Preexposure Prophylaxis for the Prevention of HIV Infection: Evidence Report and Systematic Review for the US Preventive Services Task Force*, 321 JAMA 2214, 2216-17 (2019) (noting that several studies have found that people using PrEP had decreased HIV infection rates compared with people who used a placebo or no PrEP).

reports that only a fraction of eligible people obtain the drug. *Id*. Underutilization is particularly prominent among African-Americans and Latinos. *Id*. Following extensive review of available data in 2019, the United States Preventive Services Task Force concluded that PrEP is "of substantial benefit for decreasing the risk of HIV infection in persons at high risk of HIV infection, either via sexual acquisition or through injection drug use" and gave the preventive service its strongest level of recommendation. *USPSTF PrEP Recommendation Statement* at 2204.

Chronic hepatitis C is a salient example of an instance in which the Mandate, through a secondary prevention strategy, creates an opportunity to detect and therefore treat disease. The Mandate will soon require coverage, without cost-sharing, for hepatitis C screening for all adults aged 18-79.[26] Chronic hepatitis C is a serious infection that causes liver disease and, in 2017 alone, was an underlying or contributing cause of death for over 17,000 Americans.[27] Transmitted

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[26] *See* U.S. Preventive Servs. Task Force, *Screening for Hepatitis C Virus Infection in Adolescents and Adults: US Preventive Services Task Force Recommendation Statement*, 323 JAMA 970 (2020) (issuing a "B" grade recommendation to hepatitis C screening for all adults in March 2020).

[27] Ctrs. for Disease Control & Prevention, *Viral Hepatitis Surveillance: United States, 2017* (2019), https://www.cdc.gov/hepatitis/statistics/2017surveillance/pdfs/2017HepSurveillanceRpt.pdf. In 2016, the Centers for Disease Control and Prevention announced that the "annual hepatitis C-related mortality in 2013 surpassed the total combined number of deaths from 60 other infectious diseases reported to [the Centers for Disease Control and Prevention], including HIV, pneumococcal disease, and

through blood-to-blood contact and "[i]n the shadow of the opioid crisis, new hepatitis C infections more than tripled [over the last decade]."[28] Fortunately, there is effective treatment for the virus, which is associated with improved clinical outcomes including with respect to mortality and hepatocellular carcinoma.[29] Whereas researchers estimate that half of people with hepatitis C may be unaware of their status, screening is a central strategy to diagnosing infection and linking people to care.[30]

If employers, schools, and other entities are allowed a free hand to eliminate coverage for preventive services—like PrEP and hepatitis C screening—from the guarantees of the Mandate, substantial barriers dismantled by the ACA will be re-erected. First, people will bear the full financial cost of a removed service.

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tuberculosis." Press Release, Ctrs. for Disease Control & Prevention, Hepatitis C Kills More Americans than Any Other Infectious Disease (May 4, 2016).

[28] *Estimating Prevalence of Hepatitis C Virus Infection in the United States, 2013-2016*, Ctrs. for Disease Control & Prevention, https://www.cdc.gov/nchhstp/newsroom/2018/hepatitis-c-prevalence-estimates.html (last updated Nov. 2018).

[29] Roger Chou et al., *Screening for Hepatitis C Virus Infection in Adolescents and Adults: Updated Evidence Report and Systematic Review for the US Preventive Services Task Force*, 323 JAMA 976, 983 (2020).

[30] *See* Baligh R. Yehia et al., *The Treatment Cascade for Chronic Hepatitis C Virus Infection in the United States: A Systematic Review and Meta-Analysis*, 9 PLOS One, July 2014, at 4. *See also Estimating Prevalence of Hepatitis C Virus Infection in the United States, 2013-2016*, Ctrs. for Disease Control & Prevention, https://www.cdc.gov/nchhstp/newsroom/2018/hepatitis-c-prevalence-estimates.html (last updated Nov. 2018).

These outlays can be substantial. Out-of-pocket costs for PrEP, for example, can be as high as $13,000 per year.[31] In 2018, a three-dose series of the Gardasil 9 HPV vaccine cost between $400 and $500 without insurance.[32]

For some, the imposition of additional expense will deter them from accessing care.[33] Cost is a prominent barrier to the utilization of several such services.[34]

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[31] S.F. AIDS Found., *The Questions*, PrEP Facts, http://prepfacts.org/prep/the-questions/ (last visited Mar. 22, 2020).

[32] Sandee LaMotte, *FDA Approves Use of HPV Vaccine for Adults 27 to 45*, CNN (Oct. 5, 2018), htts://www.cnn.com/2018/10/05/health/gardasil-hpv-vaccine-approved-older-ages-bn/index.html.

[33] *See*, *e.g.*, Geetesh Solanki et al., *The Direct and Indirect Effects of Cost-Sharing on the Use of Preventive Services*, 34 Health Servs. Res. 1331 (2000). The authors describe direct and indirect effects of cost-sharing on preventive services:

> The direct effect occurs when increased cost-sharing reduces the probability that an individual will seek a specific preventive service. The indirect effect occurs when increased cost-sharing decreases the probability that an individual will make an office visit, thus reducing the probability of receiving . . . preventive services customarily provided as part of routine primary care.

Id. at 1332 (citation omitted).

[34] *See*, *e.g.*, Whitney S. Rice et al., *Accessing Pre-exposure Prophylaxis (PrEP): Perceptions of Current and Potential PrEP Users in Birmingham, Alabama*, 23 AIDS & Behav. 2966, 2973 (2019) ("PrEP users identified cost as a significant impediment to PrEP uptake . . . . Some current PrEP users complained of high prescription costs even after supplemented by insurance . . . . Others were concerned that their insurance providers may not cover PrEP and were not sure whether the expense would be worth the cost . . . ."); Trisha Arnold et al., *Social, Structural, Behavioral and Clinical Factors Influencing Retention in Pre-Exposure*

Sensitivity to the price of health care is particularly acute among communities that experience socioeconomic disparities; cost-sharing has been seen to have a disproportionate impact on low-income individuals, affecting both the utilization of medical services and adherence to illness-specific health care regimens.[35] The financial toxicity of chronic illness management can also make it difficult to absorb additional health

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Prophylaxis (PrEP) Care in Mississippi, 12 PLOS One, Feb. 2017, at 1, 4 ("Many participants indicated that structural factors such as cost, assistance with medical visit and medication payments affected their experiences taking PrEP."); Katie M. Keating et al., *Potential Barriers to HPV Vaccine Provision Among Medical Providers with High Rates of Cervical Cancer*, 43 J. Adolescent Health S61, S64 (2008) ("The high cost of the HPV vaccine to patients was another commonly reported concern among practices (66%) among both HPV vaccine providers and vaccine nonproviders.").

[35] *See*, *e.g.*, Katie M. Keating et al., *Potential Barriers to HPV Vaccine Provision Among Medical Providers with High Rates of Cervical Cancer*, 43 J. Adolescent Health S61, S64 (2008) (describing an exacerbated financial burden associated with HPV vaccine for people with Medicaid coverage and for the uninsured); Michael Chernew et al., *Effects of Increased Patient Cost Sharing on Socioeconomic Disparities in Health Care*, 23 J. Gen. Internal Med. 1131, 1135 (2008) ("[M]edication adherence [for diabetes mellitus and congestive heart failure] is more likely to decline when copayments increase for individuals in low-income areas."); Usha Sambamoorthi & Donna D. McAlpine, *Racial, Ethnic, Socioeconomic, and Access Disparities in the Use of Preventive Services Among Women*, 37 Preventive Med. 475, 482 (2003) ("[S]tudies have shown that even with insurance coverage, cost sharing in terms of co-payments, co-insurance, and deductibles in general exert a negative impact on receipt of preventive services and counseling. Women of more advantaged socioeconomic status are better able to afford the co-payments and deductibles.") (citation omitted).

care costs, even for essential preventive services.[36] It is for these exact reasons that government officials have cited *coverage* for PrEP as itself vital to ending the HIV epidemic.[37]

In addition, people would experience greater administrative burdens in the face of the Rule. The ability to excise mandated preventive services from a plan would result in increased fragmentation of coverage.

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[36] *See*, *e.g.*, Javier Valero-Elizondo et al., *Financial Hardship from Medical Bills Among Nonelderly U.S. Adults with Atherosclerotic Cardiovascular Disease*, 73 J. Am. C. Cardiology 727 (2019) (finding the costs of managing atherosclerotic cardiovascular disease to be burdensome for patients, especially those from low-income families and people who are uninsured); Susan Gubar, *The Financial Toxicity of Illness*, N.Y. Times (Feb. 21, 2019), https://www.nytimes.com/2019/02/21/well/live/the-financial-toxicity-of-illness.html (describing the financial burden of living with cancer); *PAF's Results of Two Survey Assessments of HIV Patients to Identify Root Causes of Financial Toxicity*, Patient Advocate Found., https://www.patientadvocate.org/article/pafs-results-of-two-survey-assessments-of-hiv-patients-to-identify-root-causes-of-financial-toxicity/ (last visited Mar. 22, 2020) (finding that 58% of HIV-positive respondents indicated experiencing a financial hardship in the previous 12 months due to medical care and that, in response to financial stress, 39% "reduced critical expenses").

[37] *See*, *e.g.*, N.Y. Dep't of Fin. Servs., Supplement No. 1 to Insurance Circular Letter No. 21 (2017) (July 23, 2019), https://www.dfs.ny.gov/industry_guidance/circular_letters/cl2019_s01_cl2017_21 ("Coverage for PrEP for the prevention of HIV infection, along with screening for HIV infection, is vital to ending the AIDS epidemic."); Press Release, Colo. Dep't of Regulatory Agencies, HIV Drug PrEP to be Classified as Preventive (June 12, 2019), https://www.colorado.gov/pacific/dora/news/hiv-drug-prep-be-classified-preventive ("We commend the [United States Preventive Services Task Force] for adding PrEP to the list of covered preventive treatments . . . . This puts a highly effective medication within reach of those who need it, and it will save lives.").

Individuals would have no way of knowing whether their employer, school, or health insurer objected to a service, with a consequence of greater confusion and decreased transparency. It would be more difficult for people to know what types of screening, medication, or other preventive services to request, and more difficult for health care providers to know what to offer.[38] The burden of this additional ambiguity will be particularly significant for people with low health literacy.[39]

Faced with these financial and administrative barriers, the withholding of additional services encompassed under the Mandate would inevitably cause individuals to delay or forgo essential, life-saving preventive health care to which they are otherwise entitled.

While this brief focuses primarily on the potential for direct harm to individuals, the potential for

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[38] *See*, *e.g.*, Katie M. Keating et al., *Potential Barriers to HPV Vaccine Provision Among Medical Providers with High Rates of Cervical Cancer*, 43 J. Adolescent Health S61, S64-65 (2008) ("Sixty-six percent of [practices surveyed] were concerned about the burden of determining insurance coverage for the HPV vaccine . . . . Respondents explained that insurance coverage varies by insurance company and insurance plan, and that determining insurance coverage is a time-consuming task that takes up substantial staff time.").

[39] Helen Levy & Alex Janke, *Health Literacy and Access to Care*, 21 J. Health Comm. 43, 47 (2016) ("Individuals with low health literacy are more likely to delay getting care and have more difficulty finding providers . . . . These barriers compound any subsequent difficulties that patients with low health literacy may face in terms of understanding and acting on information from clinical encounters.").

widespread, systemic detriment is significant.[40] Barring access to the Mandate's set of preventive services undercuts the Government's efforts to control downstream health care spending and also the effectiveness of Government-led public health interventions that address the spread of infectious diseases such as hepatitis B, hepatitis C, and HIV.[41] This Court has long recognized government's significant interest in the coordination of public health initiatives. In *Jacobson v. Massachusetts*, 197 U.S. 11 (1905), the Court recognized that the Government has an interest in uniformly mandating vaccines notwithstanding individual objections. When asked to balance the rights of government to protect the public's health against an individual's rights to bodily autonomy, the Court observed:

> There is, of course, a sphere within which the individual may assert the supremacy of his

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[40] An unrelenting prioritization of religious liberty over public health and safety is particularly disconcerting when the country is faced with a worldwide infectious disease pandemic (coronavirus disease 2019) and grapples with containment. Elana Schor, *Coronavirus Gathering Bans Raise Religious Freedom Questions*, Associated Press, Mar. 19, 2020, https://apnews.com/c6198ba98ea6d26b128044ea59b9b4da.

[41] *See*, *e.g.*, *What is 'Ending the HIV Epidemic: A Plan for America'?*, HIV.gov, https://www.hiv.gov/federal-response/ending-the-hiv-epidemic/overview (last updated Feb. 26, 2020) ("The efforts will focus on four strategies that together can end the HIV epidemic in the U.S.: Diagnose, Treat, Prevent, and Respond . . . . Prevent new HIV transmissions by using proven interventions, including PrEP . . . ."); U.S. Dep't of Health & Human Servs., *National Viral Hepatitis Action Plan 2017-2020* 14, 22-24 (2017) (recognizing the importance of hepatitis B and hepatitis C screening to the coordinated national response to viral hepatitis).

> own will, and rightfully dispute the authority of any human government, especially of any free government existing under a written constitution, to interfere with the exercise of that will. But it is equally true that in every well-ordered society charged with the duty of conserving the safety of its members the rights of the individual in respect of his liberty may at times, under the pressure of great dangers, be subjected to such restraint, to be enforced by reasonable regulations, as the safety of the general public may demand.

Jacobson, 197 U.S. at 29.

Considering the critical role the Mandate plays in ensuring access to a broad range of health care services to which religious actors may object, the Rule thus threatens severe harm to people at risk for and living with a broad range of conditions. While the Rule is specific to and therefore poses particular harm to people for whom contraceptives are an essential part of health care, the burden on nonbeneficiaries does not stop there. The Rule's justification under RFRA is so untethered to consideration of third-party harm as to open the door for similar exemptions from coverage for other controversial services. In so doing, the Rule will have far-reaching impacts. In light of this Court's recognition of third-party harm as a limiting principle to religious accommodation, the Rule cannot stand.

CONCLUSION

The Court should uphold the judgment of the Third Circuit Court of Appeals.

Respectfully submitted,

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April 2020