IN THE UNITED STATES COURT OF APPEALS
FOR THE FIRST CIRCUIT

COMMONWEALTH OF MASSACHUSETTS, Appellant, v. UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, *ET AL.*	No. 18-1514

MOTION OF THE GUTTMACHER INSTITUTE FOR LEAVE TO FILE *AMICUS CURIAE* BRIEF IN SUPPORT OF REVERSAL

Pursuant to Rule 29 of the Federal Rules of Appellate Procedure, the Guttmacher Institute hereby moves for an order allowing it to file the attached *amicus curiae* brief in support of reversal of the district court's judgment. In support of its motion, the Guttmacher Institute states:

MOVANT'S INTEREST AND RELEVANCE OF THE GUTTMACHER INSTITUTE'S *AMICUS CURIAE BRIEF*

1. *Amicus* is the Guttmacher Institute, a nonprofit, nonpartisan corporation and a leading research and policy organization dedicated to advancing sexual and reproductive health and rights in the United States and globally. The Guttmacher Institute's overarching goal is to ensure quality sexual and

reproductive health for all people worldwide by promoting evidence-based policies and conducting research according to the highest standards of methodological rigor. It produces a wide range of resources on topics pertaining to sexual and reproductive health and publishes two peer-reviewed journals. The information and analysis it generates on reproductive rights issues are widely cited by policymakers, the media, and advocates across the ideological spectrum.

2. The Guttmacher Institute has a strong interest in the issues presented in this appeal. In particular, *amicus* seeks to describe the extensive empirical evidence regarding the usage of contraception by women in the United States, the positive impact of the Affordable Care Act's contraceptive coverage guarantee, and the harm that will result if interim final rules at issue in this appeal become law.

CONSENT OF THE PARTIES

3. The Defendants-Appellees have consented to the filing of the proposed *amicus curiae* brief.

Respectfully submitted,

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Dated: September 24, 2018

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CERTIFICATE OF SERVICE

I certify that on September 24, 2018, true and correct copy of the foregoing Motion was served on all parties to this appeal, via CM/ECF, pursuant to First Circuit Rule 25.0(e)(2), because counsel for all parties are ECF Filers who will be served electronically by the Notice of Docket Activity.

/s/ M. Duncan Grant
M. Duncan Grant

NO. 18-1514

IN THE UNITED STATES COURT OF APPEALS
FOR THE FIRST CIRCUIT

COMMONWEALTH OF MASSACHUSETTS,

Appellant,

v.

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, *ET AL*.

On Appeal from the March 12, 2018, Order of the United States District Court for the District of Massachusetts, Civil Action No. 17-11930 (Gorton, J.), Denying Plaintiff's Motion for Summary Judgment and Granting Defendants' Motion for Summary Judgment

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BRIEF OF *AMICUS CURIAE* THE GUTTMACHER INSTITUTE IN SUPPORT OF REVERSAL

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CORPORATE DISCLOSURE STATEMENT

Pursuant to Federal Rule of Appellate Procedure 26.1, the Guttmacher Institute states that it has no parent corporation and that there is no publicly held corporation that holds 10% or more of its membership or ownership interests.

STATEMENT OF CONSENT

As set forth in the Guttmacher Institute's Motion for Leave to file this brief, all parties to this appeal have consented to the filing of this brief pursuant to Federal Rule of Appellate Procedure 29(a)(2).

CERTIFICATION PURSUANT TO RULE 29(a)(4)(e)

Pursuant to Federal Rule of Appellate Procedure 29(a)(4)(e), the Guttmacher Institute certifies (a) that no party's counsel authored the brief in whole or in part, (b) that no party or party's counsel contributed money that was intended to fund preparing or submitting the brief, and (c) that no person other than *amicus*, its members, and its counsel, contributed money that was intended to fund preparing or submitting the brief.

INTEREST OF *AMICUS CURIAE*

Amicus is the Guttmacher Institute, a nonprofit, nonpartisan corporation and a leading research and policy organization dedicated to advancing sexual and reproductive health and rights in the United States and globally. The Institute's overarching goal is to ensure quality sexual and reproductive health for all people worldwide by promoting evidence-based policies and conducting

research according to the highest standards of methodological rigor. It produces a wide range of resources on topics pertaining to sexual and reproductive health and publishes two peer-reviewed journals. The information and analysis it generates on reproductive rights issues are widely cited by policymakers, the media, and advocates across the ideological spectrum.

The Guttmacher Institute has a strong interest in the issues presented in this appeal. In particular, *amicus* writes to share the extensive empirical evidence regarding the usage of contraception by women in the United States, the positive impact of the Affordable Care Act's contraceptive coverage guarantee, and the harm that will result if interim final rules (IFRs) at issue in this appeal become law.

ARGUMENT

I. Summary of Argument

The Affordable Care Act's (ACA) contraceptive coverage guarantee has had a significant impact in reducing barriers to the use of contraceptives and in making them more affordable for the women who depend on them. If the IFRs become law, much of that positive impact could disappear. Allowing employers to exclude all or certain types of contraceptive methods would compromise women's ability to consistently use the methods that work best for them, thus putting them at heightened risk of unintended pregnancies and interfering with their ability to time and space wanted pregnancies. That, in turn, would increase the risk of detrimental health outcomes for both women and their children, and would have negative social and economic consequences by interfering with women's ability to achieve their educational, professional and family goals.

Many of the government's arguments are not fairly supported by the empirical evidence. For example, the government does not adequately consider the health benefit of contraception or the number of women at risk for unintended pregnancy who would be adversely affected by the IFRs; and coverage through other government-funded programs cannot replace the gains in access made possible by the ACA's contraceptive care guarantee.

II. Contraception Is Widely Used

More than 99% of the women aged 15–44 who have ever had sexual intercourse have used at least one contraceptive method. That is true across populations with a variety of religious affiliations.[1] Among women at risk of an unintended pregnancy (*i.e.*, women aged 15–44 who have had sexual intercourse in the past three months, are not pregnant or trying to conceive, and are not sterile for noncontraceptive reasons), 90% are currently using a contraceptive method.[2] A typical woman in the United States wishing to have two children will, on average, spend three decades—roughly 90% of her reproductive life—avoiding unintended pregnancy.[3]

Women and couples rely on a wide range of contraceptive methods, including oral contraceptives; condoms; female or male sterilization; hormonal or copper intrauterine devices (IUDs); other hormonal methods including the injectable, the ring, the patch and the implant; and behavioral methods, such as

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[1] Kimberly Daniels, et al., *Contraceptive methods women have ever used: United States, 1982–2010*, National Health Statistics Reports, 2013, No. 62, https://www.cdc.gov/nchs/products/nhsr.htm.

[2] *Id.*

[3] Adam Sonfield, et al., *Moving Forward: Family Planning in the Era of Health Reform*, Guttmacher Institute, 2014, https://www.guttmacher.org/report/moving-forward-family-planning-era-health-reform.

withdrawal and fertility awareness–based methods.[4] Most women rely on multiple methods over the course of their reproductive lives—for instance, as their relationships, life circumstances, and family goals evolve—with 86% having used three or more methods by their early 40s.[5]

Many people use two or more methods at once: 17% of female contraceptive users did so the last time they had sex.[6] For example, they may use condoms to prevent STIs and an IUD for the most reliable prevention of pregnancy. Or they may use multiple methods simultaneously—for instance, condoms, withdrawal and oral contraceptives—to provide extra pregnancy protection.

III. Women Need Access to the Full Range of Contraceptive Options

Using any method of contraception greatly reduces a woman's risk of unintended pregnancy. Sexually active couples using no method of contraception

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[4] Megan L. Kavanaugh and Jenna Jerman, *Contraceptive method use in the United States: trends and characteristics between 2008, 2012 and 2014*, Contraception, 2017, https://www.guttmacher.org/article/2017/10/contraceptive-method-use-united-states-trends-and-characteristics-between-2008-2012.

[5] *Contraceptive methods women have ever used: United States, 1982–2010*, *supra*.

[6] Megan L. Kavanaugh and Jenna Jerman, *Concurrent Multiple Methods of Contraception in the United States, poster presented at the North American Forum on Family Planning*, Atlanta, Oct. 14–16, 2017.

have a roughly 85% chance of experiencing a pregnancy in a one-year period, while the risk for those using a contraceptive method ranges from 0.05% to 28%.[7]

All new contraceptive drugs and devices (just like other drugs and devices) must receive approval from the U.S. Food and Drug Administration (FDA) and must be shown to be safe and effective through rigorous scientific testing. Thus, the federal government itself provides the oversight to ensure that contraception is safe and effective in preventing pregnancy.

Although using any method of contraception is more effective in preventing pregnancy than not using a method at all, having access to a *limited* set of methods is far different than being able to choose from among the full range of methods to find the *best* methods for a given point in a woman's life.

There are many features that people say are important to them when choosing a contraceptive method.[8] These include the effectiveness of the method; ease and convenience of use; concerns about and past experience with side effects,

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[7] Apana Sundaram, et al., *Contraceptive Failure in the United States: Estimates from the 2006-2010 National Survey of Family Growth*, Perspectives on Sexual and Reproductive Health, 2017, 49(1):7–16; James Trussel and Abigail Aiken, Contraceptive Efficacy" pp: 829-928 in Robert A. Hatcher, et al., Contraceptive Technology, 21st Ed. New York, NY: Ayer Company Publishers, Inc., 2018.

[8] Lauren N. Lessard, et al., *Contraceptive features preferred by women at high risk of unintended pregnancy*, Perspectives on Sexual and Reproductive Health, 2012, 44(2):194–200.

drug interactions or hormones; affordability and accessibility; how frequently they expect to have sex; their perceived risk of HIV and other STIs; the ability to use the method confidentially or without needing to involve their partner; and potential effects on sexual enjoyment and spontaneity.

Being able to select the methods that best fulfill a woman's needs and priorities is an important way to ensure that she will be satisfied with her chosen methods, and women who are satisfied with their current contraceptive methods are more likely to use them consistently and correctly.[9] Consistent contraceptive use in turn helps women and couples prevent unwanted pregnancies and plan and space those they do want. The two-thirds of U.S. women (68%) at risk of unintended pregnancy who use contraceptives consistently and correctly throughout a year account for only 5% of all unintended pregnancies. In contrast, the 18% of women at risk who use contraceptives but do so inconsistently account for 41% of unintended pregnancies, and the 14% of women at risk who do not use contraceptives at all or have a gap in use of one month or longer account for 54% of unintended pregnancies.[10]

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[9] Guttmacher Institute, *Improving contraceptive use in the United States*, 2008, https://www.guttmacher.org/report/improving-contraceptive-use-united-states.

[10] *Moving Forward: Family Planning in the Era of Health Reform*, *supra*.

IV. Eliminating Contraceptive Costs Leads to Improved Use and Reduced Risk of Unintended Pregnancy

Extensive empirical evidence demonstrates what common sense would predict: eliminating costs leads to more effective and continuous use of contraception. That is because cost can be a substantial barrier to contraceptive choice. The contraceptive methods that can be purchased over the counter at a neighborhood drugstore for a comparatively low cost—male condoms and spermicide—are far less effective than methods that require a prescription and a visit to a health care provider,[11] which have higher up-front costs.[12]

The most effective methods of contraception are long-acting reversible contraceptives (LARC), such as implants and IUDs. The total cost of initiating one of these methods generally exceeds $1,000.[13] To put that cost in perspective, beginning to use one of these devices costs nearly a month's salary for a woman working full-time at the federal minimum wage of $7.25 an hour. These costs are dissuasive for many women not covered by the contraceptive coverage

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[11] *Contraceptive Efficacy*, *supra.*

[12] James Trussell, et al., *Cost Effectiveness of Contraceptives in the United States*, Contraception, 2009, 79(1):5–14.

[13] Erin Armstrong, et al., Intrauterine Devices and Implants: A Guide to Reimbursement, 2015, https://www.nationalfamilyplanning.org/file/documents----reports/LARC_Report_2014_R5_forWeb.pdf.; David Eisenberg, et al., *Cost as a Barrier to Long-acting Reversible Contraceptive (LARC) use in Adolescents*, Journal of Adolescent Health, 2013, 52(4):S59–S63.

guarantee; one pre-ACA study concluded that women who faced high out-of-pocket IUD costs were significantly less likely to obtain an IUD than women with access to the device at low or no out-of-pocket cost; and only 25% of women who requested an IUD had one placed after learning the associated costs.[14] Even oral contraceptives, which are twice as effective as condoms in practice, require a prescription and have monthly costs. And although some stores offer certain pill formulations at steep discounts, access to those cost savings can require a woman to change to a different formulation than the one prescribed by her clinician and increases her risk of adverse health effects.

The government acknowledges that without coverage, many methods would cost women $50 per month, or upwards of $600 per year, and in doing so, implies that such costs are a minimal burden.[15] This is not true. For example, a national study found that about one-third of uninsured people and lower-income people in the U.S. would be unable to pay for an unexpected $500 medical bill, and

[14] Aileen Gariepy, et al., *The Impact of Out-of-Pocket Expense on IUD Utilization Among Women with Private Insurance*, Contraception, 2011, 84(6):e39–e42, https://escholarship.org/uc/item/1dz6d3cx.

[15] The government includes IUDs as one of the methods that costs $50 per month. That is not accurate because an IUD cannot be paid month to month, but instead requires a high up-front cost. Perhaps the government has confused an IUD with another method that has recurring monthly costs, such as the patch or the ring.

roughly another third would have to borrow money or put it on a credit card and pay it back over time, with interest.[16]

Without insurance coverage to defray or eliminate the cost, the large up-front costs of the more-effective contraceptive methods put them out of reach for many women who want them, driving them to less expensive and less effective methods. In a study conducted prior to the contraceptive coverage guarantee, almost one-third of women reported that they would change their contraceptive method if cost were not an issue.[17] A study conducted after enactment of the ACA had similar findings: among women in the study who still lacked health insurance in 2015, 44% agreed that having insurance would help them to afford and use birth control and 44% agreed that it would allow them to choose a better method for them; 48% also agreed that it would be easier to use contraception consistently if they had coverage.[18] Other studies have found that uninsured women are less likely

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[16] Bianca DiJulio, et al., *Americans' Challenges with Health Care Costs*, 2017, https://www.kff.org/health-costs/poll-finding/data-note-americans-challenges-with-health-care-costs/?utm_campaign=KFF-2017-March-Polling-Beyond-The-ACA.

[17] Jennifer Frost and Jacqueline Darroch, *Factors Associated with Contraceptive Choice and Inconsistent Method Use*, Perspectives on Sexual and Reproductive Health, 2008, 40(2):94–104.

18 Jonathan Bearak and Rachel Jones, *Did Contraceptive use Patterns Change After the Affordable Care Act? A Descriptive Analysis*, Women's Health Issues, 2017, 27(3):316–321, http://www.whijournal.com/article/S1049-3867(17)30029-4/fulltext.

to use the most expensive (but most effective) contraceptive methods, such as IUDs, implants, and oral contraceptives,[19] and are more likely than insured women to report using no contraceptive method at all.[20]

Reducing financial barriers is critical to increasing access to effective contraception. Before the ACA provision went into effect, 28 states required private insurers that cover prescription drugs to provide coverage of most or all FDA-approved contraceptive drugs and devices.[21] These programs gave women access at lower prices than if contraception were not covered, but (at the time) all states still allowed insurers to require cost-sharing. Experience from these states demonstrates that having insurance coverage matters.[22] Privately insured women

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[19] Kelly Culwell and Joe Feinglass, *The Association of Health Insurance with use of Prescription Contraceptives*, Perspectives on Sexual and Reproductive Health, 2007, 39(4):226–230.

[20] *Id.*; Kelly Culwell and Joe Feinglass, *Changes in Prescription Contraceptive Use, 1995–2002: the Effect of Insurance Coverage*, Obstetrics & Gynecology, 2007, 110(6):1371–1378.

[21] Guttmacher Institute, *Insurance Coverage of Contraceptives*, 2018, https://www.guttmacher.org/state-policy/explore/insurance-coverage-contraceptives.

[22] The government argues in the IFRs that the state mandates have not been effective, asserting that "Additional data indicates that, in 28 States where contraceptive coverage mandates have been imposed statewide, those mandates have not necessarily lowered rates of unintended pregnancy (or abortion) overall." The study the government relies on for this assertion was published in a law review rather than in a peer-reviewed scientific journal. *See* Michael J. New, *Analyzing the impact of state level contraception mandates on public health outcomes*, Ave

living in states that required private insurers to cover prescription contraceptives were 64% more likely to use some contraceptive method during each month a sexual encounter was reported than women living in states with no such requirement, even after accounting for differences including education and income.[23]

Although these state policies reduced women's up-front costs, other actions to eliminate out-of-pocket costs entirely—which is what the federal contraceptive coverage guarantee does—have even greater potential to increase women's ability to use methods effectively . For example, when Kaiser Permanente Northern California eliminated patient cost-sharing requirements for IUDs, implants, and injectables in 2002, the use of these devices increased

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Maria Law Review, 13(2):345–369 (2015). One basic flaw in this article is that, at the time, none of the state contraceptive coverage mandates eliminated out-of-pocket costs entirely, which is the major advance from the federal guarantee and the issue in this case. In addition, over the course of the period the article evaluated, . Conctraceptive coverage quickly became the norm in the insurance industry—even in states without mandates—thus minimizing potential differences between states with laws and states without them. *See* Adam Sonfield, et al. *U.S. insurance coverage of contraceptives and impact of contraceptive coverage mandates*, 2002, Perspectives on Sexual and Reproductive Health, 2004, 36(2):72–79, https://www.guttmacher.org/sites/default/files/pdfs/pubs/journals/ 3607204.pdf.

[23] Brianna Magnusson, et al., *Contraceptive Insurance Mandates and Consistent Contraceptive use Among Privately Insured Women*, Medical Care, 2012, 50(7):562–568.

substantially, with IUD use more than doubling.[24] Another example comes from a study of more than 9,000 St. Louis-region women who were offered the reversible contraceptive method of their choice (i.e., any method other than sterilization) at no cost for two to three years, and were "read a brief script informing them of the effectiveness and safety of" IUDs and implants.[25] Three-quarters of those women chose long-acting methods (i.e., IUDs or implants), a level far higher than in the general population. Likewise, a Colorado study found that use of long-acting reversible contraceptive methods quadrupled when offered with no out-of-pocket costs along with other efforts to improve access.[26]

Government-funded programs to help low-income people afford family planning services provide further evidence that reducing or eliminating cost barriers to women's contraceptive choices has a dramatic impact on women's ability to choose and use the most effective forms of contraception. Each year, among the women who obtain contraceptive services from publicly funded

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[24] Debbie Postlethwaite, et al., *A Comparison of Contraceptive Procurement Pre- and Post-Benefit Change*, Contraception, 2007, 76(5): 360–365.

[25] Jeffrey Peipert, et al., *Preventing Unintended Pregnancies by Providing No-Cost Contraception*, Contraception, 2012, 120(6):1291–1297.

[26] Sue Rickets, et al., *Game Change in Colorado: Widespread use of Long-Acting Reversible Contraceptives and Rapid Decline in Births Among Young, Low-Income Women*, Perspectives on Sexual and Reproductive Health, 2014, 46(3):125–132.

reproductive health providers, 57% select hormone-based contraceptive methods, 18% use implants or IUDs, and 7% receive a tubal ligation.[27] It is estimated that without publicly supported access to these methods at low or no cost, nearly half (47%) of those women would switch to male condoms or other nonprescription methods, and 28% would use no contraception at all.[28]

V. The ACA's Contraceptive Coverage Guarantee Has Had a Positive Impact

By ensuring coverage for a full range of contraceptive methods, services, and counseling at no cost, the ACA's contraceptive coverage mandate has had its intended effect of removing cost barriers to obtaining contraception. Between fall 2012 and spring 2014 (during which time the coverage guarantee went into wide effect), the proportion of privately insured women who paid nothing out of pocket for the pill increased from 15% to 67%, with similar changes for injectable contraceptives, the vaginal ring, and the IUD.[29] Similarly, another study found that since implementation of the ACA, the share of women of

[27] Jennifer Frost and Lawrence Finer, Unintended Pregnancies Prevented by Publicly Funded Family Planning Services: Summary of Results and Estimation Formula, Memo to Interested parties, Guttmacher Institute, June 23, 2017, https://www.guttmacher.org/sites/default/files/pdfs/pubs/Guttmacher-Memo-on-Estimation-of-Unintended-Pregnancies-Prevented-June-2017.pdf.

[28] *Id*.

[29] Adam Sonfield, et al., *Impact of the federal contraceptive coverage guarantee on out-of-pocket payments for contraceptives: 2014 update*, Contraceptive, 2015, 91(1):44–48.

reproductive age (regardless of whether they were using contraception) who had out-of-pocket costs for oral contraceptives decreased from 21% in 2012 to just 4% in 2014.[30]

These trends have translated into considerable savings for U.S. women: one study estimated that pill and IUD users saved an average of about $250 in copayments in 2013 alone because of the guarantee.[31] Before the ACA, contraceptives accounted for between 30–44% of out-of-pocket health care spending for women.[32]

Individual women themselves say that the ACA's contraceptive coverage guarantee is working for them. In a 2015 nationally representative survey of women aged 18–39, two-thirds of those who had health insurance and were using a hormonal contraceptive method reported having no copays; among those women, 80% agreed that paying nothing out of pocket helped them to afford and use their birth control, 71% agreed this helped them use their birth control

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[30] Laurie Sobel, et al., *The Future of Contraceptive Coverage*, Kaiser Family Foundation (KFF) Issue Brief, Menlo Park, CA: KFF, 2017, https://www.kff.org/womens-health-policy/issue-brief/the-future-of-contraceptive-coverage/.

[31] Nora Becker and Daniel Polsky, *Women Saw Large Decrease in Out-of-Pocket Spending for Contraceptives after ACA Mandate Removed Cost Sharing*, Health Affairs, 2015, 34(7):1204–1211.

[32] *Id.*

consistently, and 60% agreed that having no copayment helped them choose a better method for them.[33]

Demonstrating the population-level impact of the ACA's coverage provision (*e.g.*, a change in unintended pregnancy rates) is complicated, because the provision affects only a subset of U.S. women, and because there are so many additional variables that affect women's pregnancy intentions, contraceptive use and ultimately the unintended pregnancy rate in the population. The evidence on whether the ACA's provision has affected contraceptive use at the population level is not definitive, but some studies suggest the guarantee has had an impact on contraceptive use, among those benefiting from the provision.

A study using claims data from 30,000 privately insured women in the Midwest found that the ACA's reduction in cost sharing was tied to a significant increase in the use of prescription methods from 2008 through 2014 (before and after the ACA provision went into effect), particularly long-acting methods.[34] Another study of health insurance claims from 635,000 privately insured women nationwide showed that rates of discontinuation and inconsistent use of

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[33] *Did Contraceptive Use Patterns Change after the Affordable Care Act?, supra*.

[34] Caroline Carlin CS, et al., *Affordable Care Act's Mandate Eliminating Contraceptive Cost Sharing Influenced Choices of Women with Employer Coverage*, Health Affairs, 2016, 35(9):1608–1615.

contraception declined from 2010 to 2013 (again, before and after the ACA provision went into effect) among women using generic oral contraceptive pills after the contraceptive guarantee's implementation (among women using brand-name oral contraceptives, only the discontinuation rate declined).[35]

Two other studies, looking at the broader U.S. population, found no change in overall use of contraception or an overall switch from less-effective to more-effective methods among women at risk of unintended pregnancy before and after the guarantee's implementation.[36] However, both studies identified some positive trends among key groups. One of them found that between 2008 and 2014, among women aged 20–24 (the age group at highest risk for unintended pregnancy), LARC use more than doubled, from 7% to 19%, without a proportional decline in sterilization.[37] The other study showed that between 2012 and 2015, use of prescription contraceptive methods, and birth control pills in particular, increased among sexually inactive women, suggesting that more women were able to start a method before becoming sexually active or use a method such

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[35] Lydia Pace*, et al.*, *Early Impact of the Affordable Care Act on Oral Contraceptive Cost Sharing, Discontinuation, and Nonadherence*, Health Affairs, 2016, 35(9):1616–1624.

[36] *Did Contraceptive use Patterns change after the Affordable Care Act?, supra; Contraceptive Method use in the United States: Trends and Characteristics Between 2008, 2012 and 2014, supra*.

[37] *Id.*

as the pill for noncontraceptive reasons after implementation of the contraceptive coverage guarantee.[38]

There is also considerable empirical data from controlled experiments to confirm that the concept of removing cost as a barrier to women's contraceptive use is a major factor in reducing their risk for unintended pregnancy, and the abortions and unplanned births that would otherwise follow. For example, a study of more than 9,000 St. Louis-region women who were offered the reversible contraceptive method of their choice at no cost found that the number of abortions performed at St. Louis Reproductive Health Services declined by 21%.[39] Study participants' abortion rate was significantly lower than the rate in the surrounding St. Louis region, and less than half the national average.[40] Similarly, when access to both contraception and abortion increased in Iowa, the abortion rates actually declined.[41] Starting in 2006, the state expanded access to low- or no-cost family planning services through a Medicaid expansion and a privately funded initiative serving low-income women. Despite a simultaneous increase in access to

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[38] *Did Contraceptive use Patterns Change after the Affordable Care Act?*, *supra*.

[39] *Preventing Unintended Pregnancies by Providing No-Cost Contraception*, *supra*.

[40] *Id.*

[41] M. Antonia Biggs, *Did Increasing use of Highly Effective Contraception Contribute to Declining Abortions in Iowa?* Contraception, 2015, 91(2):167–173.

abortion—the number of clinics offering abortions in the state actually doubled during the study period—the abortion rate dropped by over 20%.

VI. Expanding Exemptions Will Harm Women

The IFRs would make it more difficult, once again, for those receiving insurance coverage through companies or schools that use the exemption (i.e., employees, students, and dependents) to access the methods of contraception that are most acceptable and effective for them. That, in turn, would increase those women's risk of unintended pregnancy and interfere with their ability to plan and space wanted pregnancies. These barriers could therefore have considerable negative health, social, and economic impacts for those women and their families.

Allowing employers or schools to exclude all contraceptive methods, services, and counseling from insurance plans—or to cover some contraceptive methods, services, and information, but not others—would prevent women from selecting and obtaining the methods of contraception that will work best for them. For example, Hobby Lobby objected to providing four specific contraceptive methods, including copper and hormonal IUDs, which are among the most effective forms of pregnancy prevention and also have among the highest up-front costs.[42]

[42] *See Burwell v. Hobby Lobby Stores, Inc.*, 134 S. Ct. 2751, 2800 (2014).

Allowing employers to restrict access to the full range of contraceptive methods and to approve coverage only for those they deem acceptable would place inappropriate constraints on women who depend on insurance to obtain the methods best suited to their needs. Moreover, in the absence of coverage, the financial cost of obtaining a method, and the fact that some methods have higher costs than others, would incentivize women to select methods that are inexpensive, rather than methods that are best suited to their needs and that they are therefore most likely to use consistently and effectively .

To the extent that expanding the exemptions would burden women's contraceptive use in these ways, it would be harmful to women's health. Contraception allows women to avoid unintended pregnancies and to time and space wanted pregnancies, which has been demonstrated to improve women's health and that of their families. Specifically, pregnancies that occur too early in a woman's life, or that are spaced too closely, negatively affect maternal health and increase the risk of harmful birth outcomes, including preterm birth, low birth weight, stillbirth, and early neonatal death.[43] Closely spaced pregnancies are

[43] Megan Kavanaugh and Ragnar Anderson, *Contraception and Beyond: The Health Benefits of Services Provided at Family Planning Centers*, Guttmacher Institute, 2013, http://www.guttmacher.org/report/contraception-and-beyond-health-benefits-services-provided-family-planning-centers.

associated with increased risk of adverse birth outcomes.[44] Contraceptive use can also prevent preexisting health conditions from worsening and new health problems from occurring, because pregnancy can exacerbate existing health conditions such as diabetes, hypertension, and heart disease.[45] Unintended pregnancy also affects women's mental health; notably, it is a risk factor for depression in adults.[46] For these reasons, the Centers for Disease Control and Prevention (CDC) included the development of and improved access to methods of

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[44] Amanda Wendt, et al., *Impact of Increasing Inter-Pregnancy Interval on Maternal and Infant Health*, Peadiatric and Perinatal Epidemiology, 2012, 26(Suppl. 1):239–258; Agustin Conde-Agudelo, et al., *Birth Spacing and Risk of Adverse Perinatal Outcomes: a Meta-Analysis*, Journal of the American Medical Association, 2006, 295(15):1809–1823; Jessica Gipson, et al., *The Effects of Unintended Pregnancy on Infant, Child, and Parental Health: a Review of the Literature*, Studies in Family Planning, 2008, 39(1):18–38.

[45] Hal Lawrence, Testimony of American Congress of Obstetricians and Gynecologists, submitted to the Committee on Preventive Services for Women, Institute of Medicine, 2011, http://www.nationalacademies.org/hmd/~/media/8BA65BAF76894E9EB8C768C01C84380E.ashx.

[46] Pamela Herd, et al., *The Implications of Unintended Pregnancies for Mental Health in Later Life*, American Journal of Public Health, 2016, 106(3):421–429; *Screening for Depression in Adults*: Recommendation Statement, American Family Physician, 2016, 94(4):340A–340D, http://www.aafp.org/afp/2016/0815/od1.html.

family planning among the 10 great public health achievements of the twentieth century.[47]

The government implies in the IFRs that contraception may have negative health consequences that outweigh its benefits. That is demonstrably false, and the government itself provides the oversight to ensure that it is false. Notably, the FDA's approval processes require that drugs and devices, including contraceptives, be proven safe through rigorous controlled trials. In addition, the CDC publish extensive recommendations to help clinicians and patients identify potential contraindications and decide which specific contraceptive methods are most appropriate for each patient's needs and health circumstances.[48] Medical experts, such as the American College of Obstetricians and Gynecologists, concur that contraception is safe and has clear health benefits that outweigh any potential risks.[49]

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[47] *Achievements in public health, 1900–1999: family planning*, CDC, Morbidity and Mortality Weekly Report, 1999, 48(47): 1073–1080.

[48] *US Medical Eligibility Criteria for Contraceptive Use*, Centers for Disease Control and Prevention, 2016, https://www.cdc.gov/reproductivehealth/contraception/mmwr/mec/summary.html.

[49] Brief of *Amici Curiae, American College of Obstetricians and Gynecologists, Physicians for Reproductive Health, American Academy of Family Physicians, American Nurses Association, et al., Zubik v. Burwell*, 2016, No. 15-191 (Feb. 17, 2016).

Expanding the exemptions to the contraceptive coverage requirement would also have negative social and economic consequences for women, families, and society. By enabling them to reliably time and space wanted pregnancies, women's ability to obtain and effectively use contraception promotes their continued educational and professional advancement, contributing to the enhanced economic stability of women and their families.[50] Economic analyses have found positive associations between women's ability to obtain and use oral contraceptives and their education, labor force participation, average earnings, and a narrowing of the gender-based wage gap.[51] Moreover, the primary reasons women give for why they use and value contraception are social and economic: In a 2011 study, a majority of women reported that access to contraception had enabled them to take better care of themselves or their families (63%), support themselves financially (56%), stay in school or complete their education (51%), or get or keep a job or pursue a career (50%).[52]

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[50] Adam Sonfield, et al., *The Social and Economic Benefits of Women's Ability to Determine Whether and When to Have Children,*: Guttmacher Institute, 2013, https://www.guttmacher.org/report/social-and-economic-benefits-womens-ability-determine-whether-and-when-have-children.

[51] *Id.*

[52] Jennifer Frost and Laura Duberstein Lindberg, *Reasons for Using Contraception: Perspectives of U.S. Women Seeking Care at Specialized Family Planning Clinics*, 2012, Contraception, http://www.guttmacher.org/pubs/journals/j.contraception.2012.08.012.pdf.

The government contends that expanding the exemption would not impose any real harm, suggesting that the women most at risk for unintended pregnancy are not likely to be covered by employer-based group health plans or by student insurance sponsored by a college or university. That argument is misleading. Low-income women, women of color, and women aged 18–24 are at disproportionately high risk for unintended pregnancy,[53] and millions of these women rely on private insurance coverage—particularly following implementation of the ACA. In fact, from 2013 to 2016, the proportion of women overall and of women below the poverty level who were uninsured dropped by more than one-third nationwide, declines driven by substantial increases in both Medicaid and private insurance coverage.[54] In addition, the ACA specifically expanded coverage for people aged 26 and younger, allowing them to remain covered as dependents on their parents' plans, regardless of whether the young woman is working herself or attending college or university.

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[53] Declines in Unintended Pregnancy in the United States, 2008–2011, *supra*.

[54] *Dramatic Gains in Insurance Coverage for Women of Reproductive Age Are Now in Jeopardy*, Guttmacher Institute, News in Context, Jan. 17, 2018, https://www.guttmacher.org/article/2018/01/dramatic-gains-insurance-coverage-women-reproductive-age-are-now-jeopardy.

VII. Medicaid, Title X, and State Laws Are No Substitute for the Federal Guarantee

The government claims that "[i]ndividuals who are unable to obtain contraception coverage through their employer-sponsored health plans because of the exemptions created in these interim final rules … have other avenues for obtaining contraception…"[55] But the programs and laws the government highlights—the Title X national family planning program, Medicaid, and state contraceptive coverage requirements—simply cannot replicate or replace the gains in access made by the contraceptive coverage guarantee.

Many women who have the benefit of the ACA's contraceptive coverage mandate are not eligible for free or subsidized care under Title X. Title X provides no-cost family planning services to people living at or below 100% of the federal poverty level ($12,060 for a single person in 2017),[56] and provides services on a sliding fee scale between 100% and 250% of poverty; women above 250% of poverty must pay the full cost of care. By contrast, the federal contraceptive

[55] Department of the Treasury, Department of Labor and Department of Health and Human Services, Religious exemptions and accommodations for coverage of certain preventive services under the Affordable Care Act, Federal Register, 82(197):47838–47862, https://www.gpo.gov/fdsys/pkg/FR-2017-10-13/pdf/2017-21852.pdf.

[56] Office of the Assistant Secretary for Planning and Evaluation, U.S. Federal Poverty Guidelines used to Determine Financial Eligibility for Certain Federal Programs, 2017, https://aspe.hhs.gov/poverty-guidelines.

coverage guarantee eliminates out-of-pocket costs for contraception regardless of income.

Funding for Title X has not increased sufficiently for the program even to keep up with the increasing number of women in need of publicly funded care;[57] therefore, Title X cannot sustain additional beneficiaries as a result of the IFRs. From 2010 to 2014, even as the number of women in need of publicly funded contraceptive care grew by 5%, representing an additional one million women in need,[58] Congress cut funding for Title X by 10%.[59] With its current resources, Title X is able to serve only one-fifth of the nationwide need for publicly funded contraceptive care.[60] Still, the government has proposed diverting already insufficient Title X funding to help cover the cost of care for any women

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[57] Women in need of publicly funded contraceptive services are defined as those women who a) are younger than 20 or are poor or low-income (i.e., have a family income less than 250% of the federal poverty level) and b) are sexually active and able to become pregnant but do not want to become pregnant. *See* Jennifer Frost, et al., Contraceptive Needs and Services, 2014 Update, Guttmacher Institute, 2016, https://www.guttmacher.org/sites/default/files/report_pdf/contraceptive-needs-and-services-2014_1.pdf.

[58] *Id.*

[59] *Funding History*, Department of Health and Human Services, Office of Population Affairs, , 2017, https://www.hhs.gov/opa/title-x-family-planning/about-title-x-grants/funding-history/index.html.

[60] *Contraceptive Needs and Services, 2014 Update, supra*.

affected by the IFRs, an action that would inevitably hurt patients who rely on publicly funded services.

Similarly, many women who would lose private insurance coverage of contraception under the federal government's expanded exemption would not be eligible for Medicaid. Eligibility for Medicaid varies widely from state to state. At best, as in Massachusetts, childless adults and parents are eligible for full-benefit Medicaid only if they have incomes at or below 138% of the federal poverty level.[61] Again, by contrast, the federal contraceptive coverage guarantee applies regardless of income. And because the U.S. Supreme Court has ruled that states cannot be compelled by the federal government to expand Medicaid eligibility, the federal government cannot rely on Medicaid to fill in gaps in coverage that would result from expanding the exemption.[62]

The federal government's assertion that Title X and Medicaid can replace or replicate the ACA's contraception coverage guarantee is additionally problematic given that the government itself is at the same time moving to undermine Title X and Medicaid. For example, the government's recent budget

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[61] Kaiser Family Foundation, *Medicaid income eligibility limits for adults as a percent of the federal poverty level*, 2018, State Health Facts, https://www.kff.org/health-reform/state-indicator/medicaid-income-eligibility-limits-for-adults-as-a-percent-of-the-federal-poverty-level.

[62] *See Nat'l Fed'n of Indep. Bus. v. Sebelius*, 567 U.S. 519 (2012)

proposals have sought to exclude Planned Parenthood Federation of America and its affiliates from Title X, Medicaid and other federal programs,[63] and have called for massive cuts to Medicaid.[64] The Department of Health and Human Services has proposed sweeping changes to Title X regulations that would undermine quality of care and access to providers,[65] and it has encouraged states to revamp their Medicaid programs in ways that would restrict program eligibility (*e.g.*, by imposing work requirements) and thereby interfere with coverage and care.[66] The administration has strongly backed similar congressional proposals for cutting and limiting access to Title X and Medicaid. Policymakers in many states have also restricted publicly funded family planning programs and providers, further

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[63] Kinsey Hasstedt, *Beyond the Rhetoric: the Real-World Impact of Attacks on Planned Parenthood and Title X*, *Guttmacher Policy Review,* 2017, 20:86–91, https://www.guttmacher.org/gpr/2017/08/beyond-rhetoric-real-world-impact-attacks-planned-parenthood-and-title-x.

[64] Tami Luhby, Not Even the White House Knows How Much it's Cutting Medicaid, CNN, May 24, 2017, http://money.cnn.com/2017/05/24/news/economy/medicaid-budget-trump/index.html.

[65] Compliance With Statutory Program Integrity Requirements, 83 Fed. Reg. 106 (proposed rule June 1, 2018) (to be codified at 42 CFR pt. 59).

[66] Adam Sonfield, *Efforts to Transform the Nature of Medicaid Could Undermine Access to Reproductive Health Care*, Guttmacher Policy Review, 2017, 20:97–102, https://www.guttmacher.org/gpr/2017/10/efforts-transform-nature-medicaid-could-undermine-access-reproductive-health-care.

undermining the ability of these programs to serve those affected by the expanded exemption.[67]

Neither can state-specific contraceptive coverage laws replicate or replace the increase in access to contraception provided by the ACA's contraceptive coverage guarantee. Twenty-one states have no such laws at all.[68] Of the 29 states and the District of Columbia that do have contraceptive coverage requirements, only nine currently bar copayments and deductibles for contraception (and another two states have new requirements not yet in effect). Additionally, the federal requirement makes it clear that health plans may seek to influence a patient's choice only within a specific contraceptive method category (*e.g.*, to favor one hormonal IUD over another) and not across methods (*e.g.*, to favor the pill over the ring).[69] Few of the state laws include similar protections. Similarly, most of the state requirements do not specifically require coverage of all 18 distinct methods that the federal requirement encompasses (*e.g.*, only seven

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[67] Rachel Benson Gold and Kinsey Hasstedt, *Publicly Funded Family Planning Under Unprecedented Attack*, American Journal of Public Health, 2017, 107(12):1895–1897, http://ajph.aphapublications.org/doi/pdf/10.2105/AJPH.2017.304124.

[68] *Insurance Coverage of Contraceptives*, *supra.*

[69] FAQs about Affordable Care Act implementation (part XXVI), Department of Labor, May 11, 2015, https://www.dol.gov/sites/default/files/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-xxvi.pdf.

states currently require coverage of female sterilization).[70] Finally, state laws cannot regulate self-insured employers at all, and those employers account for 60% of all workers with employer-sponsored health coverage.[71]

VIII. Massachusetts-Specific Impact

If implemented, the interim final rules would have public health and fiscal consequences in Massachusetts, as in other states across the country. Some women impacted by the IFRs would not qualify for Medicaid or Title X because they would not meet the income eligibility requirements for coverage or subsidized care under these programs. As noted above, childless adults and parents in Massachusetts are eligible for full-benefit Medicaid only if they have incomes at or below 138% of the federal poverty level.[72] This means that affected women who lose coverage as a result of the rules may not be eligible. As a result, some women would be at increased risk of unintended pregnancy, either because they are not able to afford the methods that work best for them, or because cost would force them to forego contraception use entirely.

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[70] *Insurance Coverage of Contraceptives*, *supra*.

[71] Kaiser Family Foundation, *Employer Health Benefits: 2017 Annual Survey,* 2017, https://www.kff.org/report-section/ehbs-2017-section-10-plan-funding/.

[72] *Medicaid income eligibility limits for adults as a percent of the federal poverty level*, *supra*.

Other women would be eligible for and rely on publicly funded family planning services through programs such as Medicaid and Title X. The increase in the number of women relying on publicly funded services would increase the strain on the state's family planning programs and providers, making it more difficult for them to meet the existing need for publicly funded care. In 2014, 373,000 women were in need of publicly funded family planning in Massachusetts, and the state's family planning network was able to only meet 25% of this need.[73]

Another indicator of the existing unmet need for contraception in Massachusetts is that substantial numbers of state residents experience unintended pregnancy each year. In 2010, 54,000 unintended pregnancies occurred among Massachusetts residents, a rate of 40 per 1,000 women aged 15–44.[74] Of those unintended pregnancies that ended in birth, 56% were paid for by Medicaid and other public insurance programs.[75] Unintended pregnancies cost the state

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[73] *Contraceptive Needs and Services, 2014 Update, supra*.

[74] Kathryn Kost, *Unintended Pregnancy Rates at the State Level: Estimates for 2010 and Trends Since 2002,* Guttmacher Institute, 2015, https://www.guttmacher.org/report/unintended-pregnancy-rates-state-level-estimates-2010-and-trends-2002.

[75] Adam Sonfield and Kathryn Kost K, *Public Costs from Unintended Pregnancies and the Role of Public Insurance Programs in Paying for Pregnancy-Related Care: National and State Estimates for 2010*, Guttmacher Institute, 2015, https://www.guttmacher.org/report/public-costs-unintended-pregnancies-and-role-public-insurance-programs-paying-pregnancy.

approximately $138 million and the federal government approximately $220 million in 2010. The IFRs are likely to increase the number of unintended pregnancies experienced by state residents, and thus to increase state and federal expenditures.

IX. Conclusion

The Guttmacher Institute respectfully urges the Court to hold that the District Court erred in granting summary judgment in favor of the government, and to reverse and remand.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE WITH FED. R. APP. 32(g)(1)

Pursuant to Federal Rules of Appellate Procedure 29(a)(5) and 32(g), I, M. Duncan Grant, hereby certify that this brief contains 6,263 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(f).

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CERTIFICATE OF SERVICE

I certify that on September 24, 2018, true and correct copies of the foregoing brief were served on all parties to this appeal, via CM/ECF, pursuant to First Circuit Rule 25.0(e)(2), because counsel for all parties are ECF Filers who will be served electronically by the Notice of Docket Activity.

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