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SEX, DRUGS, TRUMP AND BIRTH CONTROL

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INTRODUCTION

In 1959, President Eisenhower declared that the government should not get involved with birth control,¹ but these words were not heeded. On January 21, 2017, millions of people worldwide took part in the Women's March to protest against the government for human rights, inclusive of women's rights and healthcare reform.² With the possible repeal of the Affordable Care Act imminently closing in,³ women are left wondering if a male-dominated government truly understands women's contraceptive needs. Tom Price, the former Secretary of the Department of Health and Human Services, previously showed a lack of financial understanding of birth control coverage when he made statements suggesting that there were not any women incapable of affording birth control.⁴ This is obviously not the case, when the unintended pregnancy rate is at almost fifty percent, and there are masses of women living in poverty.⁵ After Senate Republicans voted against a measure that proposed to pay for birth control and mammograms, required insurance coverage for maternity leave, and prevented insurance companies from charging enlarged rates for preexisting conditions,⁶ it became evident that many politicians just do not get it. Should something as important as birth control be affected every time there is an election or a change of power? It seems that Eisenhower may have had the right idea. The adoption of a permanent resolution that provides stable and accessible birth control options may lessen the volatility of our system. Over-the-Counter (OTC) access to oral contraception (OC) may be the solution and, given that President Trump supports this idea,⁷ could be a viable option.

1. Elaine Tyler May, *How the Catholic Church almost came to accept birth control—in the 1960s*, WASH. POST (Feb. 24, 2012), https://www.washingtonpost.com/opinions/how-the-catholic-church-almost-came-to-accept-birth-control/2012/02/21/gIQAy1JYR_story.html?utm_term=.8c0a74d670d0 [<https://perma.cc/TB6C-AHAN>].

2. See *The March*, WOMEN'S MARCH, <https://www.womensmarch.com/march> [<https://perma.cc/6NHG-ZX6E>].

3. Maggie Haberman & Robert Pear, *Trump Tells Congress to Repeal and Replace Health Care Law 'Very Quickly'*, N.Y. TIMES (Jan. 10, 2017), https://www.nytimes.com/2017/01/10/us/repeal-affordable-care-act-donald-trump.html?_r=0 [<https://perma.cc/9FKX-NE7Y>].

4. Olga Khazan, *Tom Price: 'Not One' Woman Struggled to Afford Birth Control*, THE ATLANTIC (Nov. 29, 2016), <http://www.theatlantic.com/health/archive/2016/11/tom-price-not-one-woman-cant-afford-birth-control/509003> [<https://perma.cc/4AKZ-6Z2Z>].

5. *Fact Sheet: Unintended Pregnancy in the United States*, GUTTMACHER INST. (Sept. 2016), <https://www.guttmacher.org/fact-sheet/unintended-pregnancy-united-states#6> [<https://perma.cc/YB6X-JWL9>] [hereinafter *Unintended Pregnancy*].

6. Becca Andrews, *Republicans Are Coming for Your Free Birth Control*, MOTHER JONES (Jan. 12, 2017, 8:52 PM), <http://www.motherjones.com/politics/2017/01/make-birth-control-expensive-again> [<https://perma.cc/4WJ2-E4A6>].

7. Susan Scutti, *Trump supports birth control without a prescription*, CNN (Sept. 16,

“The most effective way to reduce abortion rates [and] to prevent unintended pregnancy [is] by improving access to consistent, effective, and affordable contraception.”⁸ Currently, oral contraceptives are being held captive by physicians, drug makers, politicians, and the Food and Drug Administration (FDA) because there are incentives that are given more weight than the rights and comfort of women.⁹ Often, unrelated, invasive procedures act as barriers to acquiring the only thing that can prevent unwanted and unplanned pregnancies.¹⁰ While men can walk into publicly funded clinics and acquire contraception or sexual performance-enhancing drugs without undergoing prostate exams, women are mandated to undergo unrelated pelvic examinations and medical services for contraception.¹¹ In both of these cases, the opportunity to impose preventative health-care arises, but only women are subject to these regulations of inequality.¹² Women are left with a conundrum: do they submit to these unethical practices to get their prescription, or do they roll the dice and end up paying dire, lifelong consequences?

The average woman will spend roughly three years attempting to get pregnant, pregnant and postpartum, and “three decades—more than three-quarters of her reproductive life—trying to avoid an unintended pregnancy.”¹³ Unplanned pregnancies have a public health impact that leads to adverse medical outcomes for mothers and children, including premature births, delayed prenatal care, and mental and physical effects in children.¹⁴ Unfortunately, over the last twenty years, the rate of unintended pregnancies has consistently “account[ed] for approximately 50% of all pregnancies.”¹⁵ These rates are significantly greater than those of other developed

2016, 4:10 PM), <http://www.cnn.com/2016/09/15/health/trump-contraceptives-without-prescription> [<https://perma.cc/GE2K-R369>].

8. AM. COLL. OF OBSTETRICIANS & GYNECOLOGISTS, COMMITTEE OPINION: ACCESS TO CONTRACEPTION (2015), <https://www.acog.org/-/media/Committee-Opinions/Committee-on-Health-Care-for-Underserved-Women/co615.pdf?dmc=1&ts=20171107T2231495401> [<https://perma.cc/89DD-U764>] [hereinafter ACCESS TO CONTRACEPTION].

9. See Elizabeth Nolan Brown, *Why Americans Can't Have Over-the-Counter Birth Control Pills*, REASON (Mar. 26, 2014, 4:31 PM), <https://reason.com/archives/2014/03/26/over-the-counter-birth-control-pills-us> [<https://perma.cc/NUA6-93HL>].

10. *Id.*

11. Heather S. Dixon, *Pelvic Exam Prerequisite to Hormonal Contraceptives: Unjustified Infringement on Constitutional Rights, Governmental Coercion, and Bad Public Policy*, 27 HARV. WOMEN'S L.J. 177, 196–97 (2004).

12. *Id.* at 178.

13. *Unintended Pregnancy*, *supra* note 5.

14. *Id.*

15. AM. COLL. OF OBSTETRICIANS & GYNECOLOGISTS, COMMITTEE OPINION: OVER-THE-COUNTER ACCESS TO ORAL CONTRACEPTIVES 1 (2012), <https://www.acog.org/-/media/Committee-Opinions/Committee-on-Gynecologic-Practice/co544.pdf?dmc=1&ts=20160921T1935019227> [<https://perma.cc/6TTJ-V8AG>] [hereinafter OVER-THE-COUNTER ACCESS].

countries,¹⁶ and many of these countries allow access to non-prescription contraception.¹⁷ These staggering numbers emphasize the importance of providing access to much needed birth control. Currently, non-emergent contraception for women in the United States is available only with a prescription and is often accompanied by invasive and unnecessary physical examinations.¹⁸ The American College of Obstetricians and Gynecologists (ACOG) released an opinion supporting OTC contraception because it is low-risk, women can self-screen for contraindications, and cervical screenings are not related to implementation of a contraceptive regimen.¹⁹ Nonuse or gaps in contraceptive use are commonly attributable to deficiencies in access, but offering OTC availability could significantly remediate our unintended pregnancy rates.²⁰

Despite the need for ease of access to birth control, monetary considerations have hindered the progression of OTC contraception. The United States Preventive Services Task Force recommends that women should undergo a cervical cancer screening once every three years,²¹ but many physicians do not comply with this standard.²² The vast majority of doctors automatically test patients even if it is not needed.²³ Ironically, cervical cancer screenings and sexually transmitted infection screenings have nothing to do with birth control other than barricading access to it.²⁴ However, doctors are financially incentivized to continue holding women's prescriptions "hostage" and forcing unnecessary exams.²⁵ Dr. Jeffrey Singer, an

16. *Unintended Pregnancy*, *supra* note 5.

17. Brown, *supra* note 9 (noting that out of 147 countries, 62 percent allowed access to oral birth control without a prescription or screening, and eight percent allowed access without a prescription but with a screening).

18. *Id.* ("A 2010 study found 33 percent of doctors *always* require a pelvic exam and pap smear before prescribing hormonal contraception, and 44 percent regularly do. But there's no medical reason for linking these things. It's like refusing to give someone antibiotics unless they submit to a cholesterol screening.").

19. OVER-THE-COUNTER ACCESS, *supra* note 15, at 3.

20. *Id.* at 1.

21. *Final Update Summary, Cervical Cancer: Screening*, U.S. PREVENTIVE SERVICES TASKFORCE (Mar. 2012), <https://www.uspreventiveservicestaskforce.org/Page/Document/UpdateSummaryFinal/cervical-cancer-screening> [<https://perma.cc/Q7TL-CVMT>].

22. Meredith Melnick, *Are Doctors' Exams a Barrier to Birth Control?*, TIME (Dec. 6, 2010), <http://healthland.time.com/2010/12/06/why-annual-exams-shouldnt-be-required-to-get-birth-control-pills> [<https://perma.cc/H3WS-2BWW>].

23. *Id.* (mentioning a survey from 2010 that showed that about 33 percent of physicians "always" require a pelvic exam before prescribing contraception, and 44 percent "regularly" did).

24. OVER-THE-COUNTER ACCESS, *supra* note 15, at 3 (explaining that pelvic examinations are not a necessity or requirement for prescribing oral contraception and "should not be used as barriers to access.").

25. Brown, *supra* note 9.

Arizona surgeon and adjunct scholar at the Cato Institute, described these practices as “doctors extorting pay for a ‘permission slip’ to get the same medication over and over again.”²⁶ Disturbingly, physicians are not the only parties that are profiting from mandatory prescriptions. Pharmaceutical companies make more from prescription insurance payments than they could if contraception was in a competitive market.²⁷ The FDA regulates prescription drugs, OTC medications, and is responsible for switches from one to the other.²⁸ An FDA prescription drug switch can be initiated by the following parties: (1) the FDA Commissioner; (2) any person who files a citizen petition; or (3) the drug manufacturer.²⁹ However, it is almost impossible for anyone but the drug maker to have adequate funding and access to the data required to implement a change.³⁰ “Unsurprisingly, none of the[se] sponsors who profit from keeping contraceptives Rx-only want to challenge [the] status.”³¹ Money simply outweighs practical application, ethics, and patient care.

The need for change has given rise to trailblazers who are testing alternative methods for OTC access to birth control. Because change through the FDA is cumbersome and nearly impossible, states are beginning to take matters into their own hands.³² Oregon enacted a statute allowing women to receive oral contraception directly through a pharmacy without a doctor’s visit.³³ Although the statute still technically requires a prescription, a pharmacist is able to write the required documentation after the patient has answered a twenty-question self-assessment.³⁴ A few months later, California followed suit by adopting a similar law that offered not only “pills, [but also] patches, injections and vaginal rings.”³⁵ While these laws represent a dynamic change in women’s healthcare rights, they still have issues and do not provide uniform access nationwide.

26. *Id.*

27. *Id.*

28. See *Drugs*, FOOD & DRUG ADMIN., <https://www.fda.gov/Drugs> [<https://perma.cc/LT79-6WCN>].

29. *Tummino v. Torti*, 603 F. Supp. 2d 519, 525 (E.D.N.Y. 2009); see 21 U.S.C.A. §§ 353(b)(3), 355(c)–(d) (Westlaw through Pub. L. No. 115-68).

30. Brown, *supra* note 9.

31. *Id.*

32. Pam Belluck, *Birth Control Without Seeing a Doctor: Oregon Now, More States Later*, N.Y. TIMES (Jan. 4, 2016), http://www.nytimes.com/interactive/2016/01/04/health/birth-control-oregon-contraception.html?_r=0 [<https://perma.cc/4ABD-SV47>].

33. 30 OR. REV. STAT. ANN. § 689.683 (West 2017).

34. See *id.* Belluck, *supra* note 32.

35. Soumya Karlamangla, *What you need to know about California’s new birth control law*, L.A. TIMES (Apr. 8, 2016, 4:19 PM), <http://www.latimes.com/local/lanow/la-me-ln-birth-control-law-20160408-story.html> [<https://perma.cc/7PRN-ZPD2>].

This Article explores both medical and legal reasons as to why OTC access to contraception is needed and justified. It also applies current changes in the government and discusses how the repeal of the Affordable Care Act (ACA) could substantially affect birth control. Alternative and traditional options are presented and analyzed to determine their viability.

Part I walks through the historical background of contraception and the distribution practices over the last century. The history of Plan B is also detailed in depth to offer insight into how the FDA handled contraception switches in the past so that this can later be compared to what may happen in the future.

Part II discusses the current unintentional pregnancy epidemic. Specific data is offered to show why women who are young, minorities, or poor are more susceptible to unintended pregnancies than the rest of the population, and what impact OTC oral contraception can have on these groups.

Part III walks through the requirements for pelvic examinations and oral birth control and discusses why no correlation or dependent relationship exists.

Part IV discusses some of the most prevalent concerns expressed by opponents of over-the-counter oral contraception. Several studies are provided to explain how these concerns are largely baseless.

Part V discusses how some physicians are exploiting requirements for financial benefits. The influence of pharmaceuticals on physicians is also discussed.

Part VI looks at the how the FDA switch process, politics, and religion can influence birth control distribution.

Part VII discusses how actions by the FDA and the prescription requirement present Constitutional issues that impinge on the rights of women.

Part VIII discusses several of the possible solutions that are being proposed or utilized to solve contraception availability issues.

The final section provides a comprehensive conclusion explaining why it is necessary to offer OTC oral contraception and how this can be best accomplished.

I. BACKGROUND

Women's access to oral contraception has faced extreme opposition that has persisted for decades.³⁶ In 1873, Congress passed the

36. See *Margaret Sanger and the Birth Control Movement*, ISSUES & CONTROVERSIES IN AM. HISTORY, http://ndhs.org/s/192/images/editor_documents/library/issues_and_con

Comstock Law, an act labeling contraceptives as “obscene” material, and outlawed the distribution of birth control through the postal service and through interstate commerce.³⁷ Aggressive raids of health-care facilities, confiscation of diaphragms, banning of women’s literature discussing birth control, and formal charges against individuals actively supporting contraception became the enforcement tools for the new legislation.³⁸ Hastily, twenty-four states followed suit and enacted similar regulations that employed devastating penalties, including a year-long imprisonment for any married couple using contraception within the privacy of their own bedrooms.³⁹ Due to these harsh government restrictions, the “*rhythm method*, which involved women having sex only during the *safe days* of their menstrual cycle so that pregnancy would not occur,” was introduced and became the predominant, and sometimes only, birth control option for women.⁴⁰ Unfortunately, the difficulty of correctly utilizing this technique left women with a better chance of winning Russian Roulette than staying off pregnancy.⁴¹ However, despite this high fallibility, the Catholic Church, deviating from its staunch view against contraception, sanctioned the use of this method as a natural form of birth control, further expanding its use.⁴² Without options, women were forced to desperately cling to this primitive and unreliable method for years while contraception remained illegal.⁴³

The next four decades played out like a game of tug-of-war pitting birth control proponents against resistant states adhering to outdated perceptions and ideals. One of the first instances of progression resulted from *United States v. One Package*, which made it legal for physicians to receive contraception and information through the mail unless prohibited by local law.⁴⁴ The rationale was that

troversies_in_american_history_-_margaret_sanger_and_the_birth_control_movement.pdf?sessionId=387b8c12-bcbd-45cb-a397-f95c6203313c&cc=1 [https://perma.cc/5EYS-Y2TY].

37. *Id.*

38. *Id.* (detailing that, in 1914, Margaret Sanger was indicted for nine violations of the Comstock Law after including information about “birth control” in an issue of *The Women Rebel*).

39. Carol Flora Brooks, *The Early History of the Anti-Contraceptive Laws in Massachusetts and Connecticut*, 18 AM. Q. 3, 4 (1966).

40. Roseann B. Termini & Miranda Lee, *Sex, Politics, and Lessons Learned From Plan B: A Review of the FDA’s Actions and Future Direction*, 36 OKLA. CITY U. L. REV. 351, 352 (2011).

41. *Fertility Awareness Methods*, PLANNED PARENTHOOD, <https://www.plannedparenthood.org/learn/birth-control/fertility-awareness> [https://perma.cc/MM7B-XD84] (revealing that 24 out of 100 people using the Rhythm Method incorrectly become pregnant).

42. *See Rhythm Method*, CASE W. RESERVE UNIV., <https://case.edu/affil/skuyhistcontraception/online-2012/Rhythm-method.html> [https://perma.cc/9HJQ-X687] (prior to 1951, the only birth control option approved by Rome was abstinence).

43. *Id.*

44. *United States v. One Package*, 86 F.2d 737, 739–40 (2d Cir. 1936).

physicians who lawfully use contraception to save the health of a patient and not for unlawful abortions should not be held liable.⁴⁵ Despite this minor headway, well into the 1960s, anti-birth control laws preventing the sale and advertisement of contraception were in full effect in nearly thirty states.⁴⁶ In 1960, the FDA approved oral contraception, but hauntingly, the after-effects of the Comstock Law still loomed, leading to continued resistance.⁴⁷ Eight states still prohibited the sale of contraceptives despite FDA approval, widespread acceptance, and mass support of the pill.⁴⁸ Understanding the need to force the hands of these defiant states, “[t]he United States Supreme Court recognized a constitutional right to contraception in 1965 in the controversial *Griswold v. Connecticut* case involving a physician who was arrested and prosecuted for providing birth control to a married couple.”⁴⁹ Seven years later, the Supreme Court widened its stance and extended these constitutional rights to unmarried people, barring states from interfering in the distribution of birth control to single individuals.⁵⁰ The cause gained momentum and garnered widespread support, including endorsements by President Eisenhower, who felt that the government had no place meddling with birth control, and President John F. Kennedy, who supported federal backing of contraception for the poor.⁵¹

The growing acceptance of birth control led to millions of women taking contraception, including almost eighty percent of American Catholic women.⁵² Availability of highly effective contraception made conception a choice rather than chance, made family planning possible, and resulted in sixty percent of women in their reproductive

45. *Id.* at 737.

46. Kirsten M.J. Thompson, *A Brief History of Birth Control in the U.S.*, OUR BODIES OURSELVES (Dec. 14, 2013), <http://ourbodiesourselves.org/health-info/a-brief-history-of-birth-control> [<https://perma.cc/SVX4-BLSB>].

47. Sarah Glazer, *Birth Control Choices: Do American women need better birth control products?*, CQ RESEARCHER, <https://library.cqpress.com/cqresearcher/document.php?id=cqressrre1994072903> [<https://perma.cc/E848-KQSN>] (explaining that, in 1957, the FDA approved the pill for treatment of menstrual disorders. Three years later, the pill was finally approved by the FDA for use as birth control).

48. *Id.*

49. Termini & Lee, *supra* note 40, at 352. *See generally* *Griswold v. Connecticut*, 381 U.S. 479 (1965) (ruling that prohibiting contraception for married couples is a constitutional violation of the right to privacy).

50. *See generally* *Eisenstadt v. Baird*, 405 U.S. 438 (1972) (ruling that it was a constitutional violation of the Equal Protection Clause to criminalize the provision of contraception to unmarried people).

51. May, *supra* note 1 (revealing that President Eisenhower formally declared that the government should not get involved with birth control).

52. Philip Pullella, *U.S. Roman Catholic bishops fully support their church's ban . . .*, UPI ARCHIVES (Oct. 1, 1980), <https://www.upi.com/Archives/1980/10/01/US-Roman-Catholic-bishops-fully-support-their-churchs-ban/1942339220800> [<https://perma.cc/E2YD-6BBJ>].

years being employed.⁵³ These effects were drastic improvements; however, availability and affordability issues were pervasive.⁵⁴ Despite President Eisenhower's warning that government should take its hands off birth control⁵⁵ and the Supreme Court ruling that people have the right "to be free from unwarranted governmental intrusion into matters so fundamentally affecting a person as the decision whether to bear or beget a child,"⁵⁶ the government, influenced by political agendas, and the FDA remained highly involved in restricting access to birth control.⁵⁷

Recently, a clash between the government, religious groups, and women's autonomy came to a head when emergency contraception was introduced.⁵⁸ Many groups were staunchly opposed to Plan B because they viewed the drug as "a pill for early abortion rather than a pill for contraception."⁵⁹ The need to give more expedient access led to a fight for OTC access that was long, arduous, and fraught with corrupt political interference.⁶⁰ Because Plan B is recommended to be taken within twenty-four hours after unprotected intercourse,⁶¹ the prescription requirement was counterproductive and made it impossible for some women to get the drug before this small window closed. Understanding the need to break down this barrier, sixty-six organizations pushed for OTC access to the drug.⁶² The process started in 2001 but was delayed due to unresolved issues in the request.⁶³ The actual manufacturer of the drug stepped in and submitted a Supplemental New Drug Application (SNDA), again requesting OTC authorization.⁶⁴ In response to the SNDA, the FDA put together

53. *Id.*

54. *Griswold v. Connecticut—The Impact of Legal Birth Control and the Challenges that Remain*, PLANNED PARENTHOOD (May 2015), https://plannedparenthood.org/uploads/filer_public/b6/7c/b67c1da4-c40a-4d0f-90af-952fdbf11fbf/factsheet_griswold_may_2015_r2.pdf [<https://perma.cc/EFJ3-ZQ9S>].

55. *See* May, *supra* note 1.

56. *Eisenstadt v. Baird*, 405 U.S. 438, 453 (1972).

57. Philip J. Hiltz, *Birth Control Backlash*, N.Y. TIMES (Dec. 16, 1990), <http://www.nytimes.com/1990/12/16/magazine/birth-control-backlash.html?pagewanted=all&mcubz=0> [<https://perma.cc/H8M2-B475>].

58. *See generally* Alex Kandalaft & Maddie Doucet Vicry, *Seventeenth Annual Review of Gender and Sexuality Law: Annual Review Article: Access to Contraception*, 17 GEO. J. GENDER & L. 55, 56 (2016).

59. Termini & Lee, *supra* note 40, at 355.

60. *Id.* at 352.

61. *Id.* at 353.

62. *Tummino v. Torti*, 603 F. Supp. 2d 519, 526 (E.D.N.Y. 2009) (explaining that 66 organizations of citizens and professionals petitioned the FDA for the OTC switch of Plan B emergency contraception).

63. *Id.*

64. *Id.* at 523 (Women's Capital Corporation would later become Barr Pharmaceuticals, Inc.).

two committees to ensure that the drug's safety and efficacy as an OTC product fulfilled the requirements of 21 U.S.C. § 335.⁶⁵ Evidence suggests that many of the members of the committees "were not qualified for the position and were placed only due to their conservative political views and connections."⁶⁶ Surprisingly, despite the inherent bias that one might suspect from the composition of the advisory board, they "overwhelmingly recommended" approval of Plan B as an OTC product without age restrictions.⁶⁷ "All twenty-eight panel members voted that the drug had been proven to be 'safe enough' for OTC use for all ages."⁶⁸ Despite the extensive data and the recommended approval by the expert panel, the FDA denied the application based on a lack of research regarding adolescents.⁶⁹ In response to the rejection, Barr Pharmaceuticals resubmitted the application restricting access to those under the age of sixteen.⁷⁰ Again, the FDA denied the application, and in response, the drug company filed a third application restricting access to women who were seventeen years of age or older and provided further data every time the FDA requested information.⁷¹ Included in the submitted data were studies of adolescents as young as fourteen, but the FDA still rejected the application, citing that it would be difficult for a pharmacist to determine the age of a purchaser.⁷² Persistently, Barr Pharmaceuticals filed another application which granted access to those eighteen and older.⁷³ On August 24, 2006, the FDA approved the switch of Plan B to OTC for men and women over the age of eighteen.⁷⁴ The FDA based the restriction of access to minors on a lack of evidence, but presumably, "one could assume there was no data or research completed on male patients."⁷⁵ Throughout the process, the FDA thinly veiled their bias and underhanded motives by creating false requirements for Barr Pharmaceuticals.⁷⁶

The denials by the FDA, despite expert recommendations, multiple applications, and extensive supporting data, raised eyebrows and led to an investigation by the U.S. Government Accountability

65. Termini & Lee, *supra* note 40, at 356.

66. *Id.*

67. *Id.*

68. *Id.*

69. *Id.* See also *Tummino v. Torti*, 603 F. Supp. 2d 519, 523–24 (E.D.N.Y. 2009).

70. Termini & Lee, *supra* note 40, at 356–57 (indicating that this change was based on the FDA defining a pediatric-age group as birth to 16 years of age).

71. *Id.* at 357.

72. *Id.*

73. *Id.* See also *Torti*, 603 F. Supp. 2d at 536.

74. Termini & Lee, *supra* note 40, at 357.

75. *Id.*

76. *Id.* at 356–57.

Office (GAO).⁷⁷ The Center for Drug Evaluation and Research (CDER) conducted an extensive review of the Plan B application and concluded that, based on scientific evidence, the product was safe and effective for use by adolescent females and that they understood that the product did not protect against sexually transmitted diseases and was not for routine use.⁷⁸ Commissioner Margaret Hamburg said that:

[S]he had “reviewed and thoughtfully considered the data, clinical information, and analysis provided by CDER,” and she expressly agreed that “there is adequate and reasonable, well-supported, and science-based evidence that Plan B One-Step is safe and effective and should be approved for nonprescription use for all females of child-bearing potential.”⁷⁹

Despite the FDA being on board with Plan B’s approval, Kathleen Sebelius, the Secretary of Health and Human Services, disagreed with the decision and ordered the FDA to deny the application.⁸⁰ “Some have opined that due to political pressure from high-ranking officials, the decision to deny the application was made even before the committees reviewed the research and data.”⁸¹ It was an election year and politicians knew that opposing Plan B would keep them on the good side of religious groups that were opposed to making birth control accessible to adolescents.⁸² Even President Bush endorsed this decision,⁸³ despite the decision’s “departure from agency practice.”⁸⁴ Sebelius argued that girls can reach menarche by age eleven and that there was not enough evidence to prove that these girls could understand how to safely use the product.⁸⁵ Ironically, the FDA had previously waived the requirement that the studies had to include girls between the ages of eleven and thirteen.⁸⁶ Thus, Sebelius made the FDA deny the Plan B application “because it lacked data that the FDA itself had told the sponsor it did not have to provide.”⁸⁷ The Editor-in-Chief of the *New England Journal of Medicine* opined that Sebelius’s decisions were not based on science, but rather were

77. *Id.* at 357.

78. *Tummino v. Hamburg*, 936 F. Supp. 2d 162, 166–67 (E.D.N.Y. 2013).

79. *Id.* at 167.

80. *Id.* (explaining the President endorsed Secretary Sebelius’s denial for Plan B).

81. Termini & Lee, *supra* note 40, at 358.

82. See *Tummino v. Hamburg*, CTR. FOR REPROD. RIGHTS (Aug. 13, 2013), <https://www.reproductiverights.org/case/tummino-v-hamburg> [<https://perma.cc/5XS4-9V4A>].

83. *Hamburg*, 936 F. Supp. 2d at 167.

84. *Id.* at 170.

85. *Id.* at 172.

86. *Id.* at 171.

87. *Id.*

politically motivated.⁸⁸ At the prompting of members of Congress, the Government Accountability Office conducted an investigation and found that the FDA's actions went against their customary practices and that behavior of FDA officials deviated from the norms, even going so far as officials refusing to place their names on the "not approvable letter[s]."⁸⁹

Even after the 100 plus years that the fight over birth control has carried on, ease of access still eludes us. Impediments such as required gynecological examinations and prescription-only access unnecessarily bar some women from obtaining much needed birth control.⁹⁰ Additionally, the volatile state of the government leaves many women concerned about their health and the impacts of a possible Affordable Care Act repeal.⁹¹ "The most vulnerable regulation is the requirement that health insurers cover contraception for all women without a co-payment."⁹² A total repeal would cancel out this privilege and "leave [roughly] 22 million people without coverage, many of them women" from utilizing this benefit specifically for obtaining birth control.⁹³ Offering over-the-counter access would break down barriers and restrict flippant decisions from having devastating consequences on women's health.⁹⁴ However, history has a strange way of repeating itself, and the plight of Plan B shows that a possible FDA switch may be an uphill battle against strong opposition.⁹⁵

II. THE UNINTENDED PREGNANCY EPIDEMIC

Unintended pregnancy is "a major public health problem in the United States" that is perpetuated by the lack of access to contraception.⁹⁶ Nationally, approximately fifty percent of pregnancies are unplanned, of which only five percent are attributable to women who use contraception properly.⁹⁷ These pregnancy rates, along with abortions, are higher in our country than in most other developed

88. *Id.* at 170–71 ("It cannot be based on issues of safety, since a 12-year-old can purchase a lethal dose of acetaminophen in any pharmacy for about \$11," but the only adverse effects of levonorgestrel are nausea and delay of menses).

89. Termini & Lee, *supra* note 40, at 358.

90. *See* Brown, *supra* note 9.

91. *See* Margot Sanger-Katz, *No, Birth Control Coverage Won't Go Away*, N.Y. TIMES (Nov. 11, 2016), https://www.nytimes.com/2016/11/11/upshot/no-birth-control-coverage-wont-go-away.html?_r=0 [<https://perma.cc/H7AN-9498>].

92. *Id.*

93. *Id.*

94. *See* Brown, *supra* note 9.

95. *See* Termini & Lee, *supra* note 40, at 364–66.

96. OVER-THE-COUNTER ACCESS, *supra* note 15, at 1.

97. *Unintended Pregnancy*, *supra* note 5.

countries.⁹⁸ Women who are poor, aged eighteen to twenty-four, or who are minorities, are at a much higher risk of having an unintended pregnancy and account for the majority of the cases each year.⁹⁹ Statistics show that contraception is effective at avoiding these devastating circumstances and that, by creating solutions that are tailored to reach these highly susceptible demographics, this epidemic can be combated.¹⁰⁰ Preventing unintended pregnancies requires getting to the root of the problem and addressing the most common reasons why they occur: access and cost.¹⁰¹ These affected groups often do not have the resources to pay for unnecessary testing, physician visits, or for the extensive medical costs associated with pregnancy and child rearing.¹⁰² The consequence, birth rates increase and the adverse effects of unintended births, such as delayed prenatal care, premature birth, and negative physical and mental health for children, exacerbate our national healthcare costs, resulting in cumulative, yearly government expenditures of over twenty-one billion dollars.¹⁰³ A 2004 survey showed that “47% of uninsured women and 40% of low-income women . . . not using [contraception] . . . would [begin] using [it] if [it] were available from pharmacies without a prescription,”¹⁰⁴ showing that removing costly barriers would have a substantial impact.

Offering OTC access also provides an avenue for young women to acquire much needed protection and prevents lapses in use.¹⁰⁵ Often, young women do not start birth control because they are fearful about disclosing their sexual activity to a parent or guardian.¹⁰⁶ Too much focus is placed on abstinence-only education for young people despite research showing “its ineffectiveness in increasing age of sexual debut and decreasing number of partners and other risky behavior.”¹⁰⁷ Adequate contraception is the only effective way to lower teen pregnancy and allowing discrete OTC access would curb the issue.¹⁰⁸ Additionally, access to multiple packs of oral contraception effectively results in better continuation of preventative regimens.¹⁰⁹

98. See ACCESS TO CONTRACEPTION, *supra* note 8.

99. See *Unintended Pregnancy*, *supra* note 5.

100. See ACCESS TO CONTRACEPTION, *supra* note 8.

101. See OVER-THE-COUNTER ACCESS, *supra* note 15, at 1.

102. See ACCESS TO CONTRACEPTION, *supra* note 8.

103. *Unintended Pregnancy*, *supra* note 5 (detailing that in 2010, total public expenditures for unintentional pregnancies amounted to approximately \$21 billion.)

104. OVER-THE-COUNTER ACCESS, *supra* note 15.

105. *Id.* at 2–3.

106. See Belluck, *infra* note 330.

107. ACCESS TO CONTRACEPTION, *supra* note 8.

108. *Id.* See generally Belluck, *infra* note 330.

109. ACCESS TO CONTRACEPTION, *supra* note 8.

The result is fewer gaps in coverage and lessened failure rates attributable to treatment inconsistency.

III. MISSED CONNECTIONS: WHY PELVIC EXAMS AND CONTRACEPTIVES DO NOT CORRELATE

Preventative gynecological testing and physician check-ups conducted in accordance with recommended standards of care are very important for early detection of serious disorders and disease in women,¹¹⁰ but they should not be a requirement for birth control. Outdated methodology lumps pelvic examinations and birth control together simply because both relate to women's reproductive health, but new developments show that this dependent association is flawed.¹¹¹ Government and expert recommendations, backed by data and research, highlight the lack of correlation between pelvic examinations and the administration of birth control, but thus far have been taken with a grain of salt.¹¹² Perpetuating the issue, physicians are financially incentivized to continue administering needless health-care and are insulated from liability by the prescription requirement and outmoded perceptions about women's health.¹¹³ Requiring yearly pelvic examinations and testing as prerequisites for prescribing birth control is grossly unnecessary and wholly deceitful.

Many physicians, without consideration of an individual patient's medical history, regularly require yearly pap smears and pelvic exams for a hormonal contraception prescription despite the present standards and there being no medical reason for linking the two.¹¹⁴ The government currently recommends that, starting at age twenty-one, women should get a pap smear every three years.¹¹⁵ After the age of thirty, a woman can switch to a combination pap smear and human papillomavirus test that only needs to be administered once every five years.¹¹⁶ The National Ambulatory Medical Care Survey reported that 62.8 million pelvic examinations were administered in 2010, often regardless of whether or not the patient

110. See Melnick, *supra* note 22.

111. *Id.*

112. Brown, *supra* note 9.

113. *Id.*

114. *Id.* ("A 2010 study found 33 percent of doctors *always* require a pelvic exam and pap smear before prescribing hormonal contraception, and 44 percent regularly do. But there's no medical reason for linking these things. It's like refusing to give someone antibiotics unless they submit to a cholesterol screening.").

115. See *Women: Stay Healthy at Any Age*, AGENCY FOR HEALTHCARE RESEARCH & QUALITY (May 2014), <http://www.ahrq.gov/patients-consumers/prevention/lifestyle/healthy-women.html> [<https://perma.cc/8XTY-VC6K>].

116. See *id.*

was asymptomatic.¹¹⁷ The dangers associated with these frivolous practices are not merely that of inconvenience; an expert panel “not only found no benefit from the annual pelvic exam, they found that it often causes discomfort and distress” and can lead to unnecessary surgery.¹¹⁸ An independent government task force reached a similar conclusion, determining that there was not enough scientific evidence to prove that these exams were needed.¹¹⁹ Despite current evidence being “lacking and of poor quality”¹²⁰ and not providing sound medical reasons for these exams, physicians continue to aggressively test asymptomatic patients anyway.¹²¹

IV. CONCERNS ABOUT OTC ACCESS TO THE PILL

Access to contraception is a point of contention that places political, medical, religious and many other views at odds with each other. Motivation aside, there are several primary concerns that opponents of OTC access to birth control often assert: (1) safety; (2) screening for contraindications; (3) adherence and continuation; (4) use of preventative services; and (5) cost.¹²² The ACOG, an organization made up of 58,000 board-certified gynecologists, released an opinion that addressed each of these concerns.¹²³ They concluded that “[w]eighing the risks versus the benefits based on currently available data, OCs should be available over-the-counter.”¹²⁴

A. Safety

Every drug or intervention has some possibility of harm,¹²⁵ but the risk associated with oral contraception is so minuscule that OTC

117. *Draft Recommendation Statement: Gynecological Conditions: Periodic Screening with the Pelvic Examination*, U.S. PREVENTIVE SERVS. TASK FORCE (June 2016), <https://www.uspreventiveservicestaskforce.org/Page/Document/draft-recommendation-statement157/gynecological-conditions-screening-with-the-pelvic-examination> [<https://perma.cc/L2YQ-4MRE>] [hereinafter *Gynecological Conditions*].

118. Howard LeWine, *Expert panel says healthy women don't need yearly pelvic exam*, HARV. HEALTH PUBL'NS (July 2, 2014), <http://www.health.harvard.edu/blog/expert-panel-says-healthy-women-don-t-need-yearly-pelvic-exam-201407027250> [<https://perma.cc/9ENX-6Q5B>].

119. Linda Carroll, *It's unclear whether yearly pelvic exam is necessary, task force says*, TODAY (June 29, 2016, 7:30 AM), <http://www.today.com/health/it-s-unclear-whether-yearly-pelvic-exam-necessary-task-force-t100354> [<https://perma.cc/9ENX-6Q5B>].

120. *Gynecological Conditions*, *supra* note 117.

121. *Id.*

122. See OVER-THE-COUNTER ACCESS, *supra* note 15, at 1–3.

123. See generally OVER-THE-COUNTER ACCESS, *supra* note 15; see also *About Us*, AM. CONG. OF OBSTETRICIANS & GYNECOLOGISTS, <https://www.acog.org/About-ACOG/About-Us> [<https://perma.cc/S9MJ-X3YG>].

124. OVER-THE-COUNTER ACCESS, *supra* note 15, at 3.

125. *Id.* at 1.

access should be approved by the FDA. Everyday drugs such as aspirin have negative effects, including gastrointestinal bleeding, even in small doses.¹²⁶ Another example, Tylenol, the most popular OTC pain reliever in the world, “is the leading cause of acute liver failure in the U.S., and the drug in some cases [leads] to fatalities.”¹²⁷ Each year, acetaminophen, the active ingredient in Tylenol—which sends approximately 60,000 people to the hospital—“accounts for more than 100,000 [visits] to poison [control] centers,” and causes hundreds of deaths.¹²⁸ Despite these effects, the FDA allows OTC access with only a small warning on the package.¹²⁹ In contrast, you cannot overdose on birth control pills, “and you’re very unlikely to experience other serious adverse effects,”¹³⁰ but you cannot acquire contraception without physician visits, invasive testing and a prescription. In an effort to detract from realities such as these, opponents point to a dangerously increased incidence of venous thromboembolism from oral birth control,¹³¹ however, in actuality, the rate of venous thromboembolism for oral birth control users is “extremely low” especially when compared to the greater risk during pregnancy or in the postpartum period.¹³² Because oral contraception is very low-risk, it should be afforded the same OTC classification as other drugs, such as Tylenol, that have far greater adverse effects.

B. Contraindication Screening

Despite the safety of OC use, many opponents are still concerned about potential harm for women with contraindications.¹³³ However, studies have shown that contraindications can be detected by women who self-screen.¹³⁴ In one study, women were asked to do self-assessments of contraindications and the results were then compared to assessments by healthcare providers.¹³⁵ Out of 399 participants, only seven self-screening assessments were not in line with the clinical assessment.¹³⁶ Similar results were found in another

126. *Id.*

127. *Tylenol*, DRUGWATCH (Mar. 7, 2016), <https://www.drugwatch.com/tylenol> [<https://perma.cc/ZE4Z-RNYJ>].

128. *Id.*

129. *Id.*

130. Brown, *supra* note 9.

131. OVER-THE-COUNTER ACCESS, *supra* note 15, at 1.

132. Rates of venous thromboembolism for OC users is (3–10.22/10,000 women-years) while rates are higher during pregnancy (5–20/10,000 women-years) and the postpartum period (40–65/10,000 women-years). *Id.* at 1–2.

133. *Id.* at 2.

134. *Id.*

135. *Id.*

136. *Id.* (showing that agreement on medical eligibility criteria among women and healthcare providers was greater than 90 percent).

study conducted on 1,271 women.¹³⁷ Surprisingly, “[b]oth studies showed that in cases of discrepancy, women were more likely to report contraindications than were health care providers.”¹³⁸ Another study, conducted in the United Kingdom, “replicated the findings that women take a more conservative approach compared with clinicians and also demonstrated that none of the 328 women studied would have incorrectly used OCs based on self-screening.”¹³⁹ Thus, not only is self-screening highly effective at detecting contraindications, but the women who are self-screening are more sensitive to possible issues than their physicians. Overall, the ability of women to accurately self-screen eliminates the need for physician interaction prior to obtaining birth control.

C. Adherence and Continuation

Other concerns include the idea that women might have more issues with continuing to routinely take birth control if they utilize oral contraception instead of long-acting methods such as IUDs.¹⁴⁰ Many women are not currently utilizing birth control at all, which presents a larger problem than there being some compliance issues.¹⁴¹ Whether or not a woman chooses long-term or short-term birth control, at the end of the day, contraception is being taken and unintended pregnancies are being limited. “In one study, 68% of . . . women who might avail themselves to over-the-counter OCs reported not currently using any contraceptive method.”¹⁴² The focus should not be on the method, but rather on how utilization of birth control, in general, can be increased.

Despite concerns, the theory that OTC access results in poor continuation is not supported by recent evidence. A study evaluating 1,000 women showed that there were higher rates of continuation for those who obtained OTC birth control versus in a clinic.¹⁴³ Additionally, data shows that access to multiple pill packs at a time results in better adherence and continuation rates,¹⁴⁴ but insurance

137. OVER-THE-COUNTER ACCESS, *supra* note 15, at 2.

138. *Id.*

139. *Id.*

140. See Amanda MacMillan, *Study: IUDs, Implants vastly more effective than the pill*, CNN (May 23, 2012, 5:21 PM), <http://www.cnn.com/2012/05/23/health/iuds-implants-versus-pill-birth-control/index.html> [<https://perma.cc/DBD8-9TJQ>].

141. See *Fact Sheet: Contraceptive Use in the United States*, GUTTMACHER INST. (Sept. 2016), <https://www.guttmacher.org/fact-sheet/contraceptive-use-united-states> [<https://perma.cc/9795-3UQE>].

142. OVER-THE-COUNTER ACCESS, *supra* note 15, at 2.

143. *Id.*

144. *Id.* at 2–3. See also ACCESS TO CONTRACEPTION, *supra* note 8, at 3.

limits the amount of products that can be dispensed.¹⁴⁵ In fact, seventy-three percent of women cannot get more than one month of birth control at a time, despite there being an issue with women acquiring refills on a timely basis.¹⁴⁶ By offering OTC access, overall usage rates will increase, women will have access to multiple months of products, and continuity will improve.

D. Preventative Services

Another concern is that women will stop going for preventive screenings and services if they can get OTC birth control.¹⁴⁷ Annual health visits are important to a woman's health, but holding birth control hostage to force women into succumbing to unrelated medical care is not an appropriate justification. In accordance, ACOG recognized that "cervical cancer screening or sexually transmitted infection (STI) screening is not required for initiating OC use and should not be used as barriers to access."¹⁴⁸ A study in 2012 showed that there were no significant differences in the screening habits of women who received prescription birth control and women who received OTC oral contraception, showing that birth control does not have a significant effect on the utilization of preventative services.¹⁴⁹

Scheduling issues aside, the actual screenings are unreliable and do not justify the continued push for these services.¹⁵⁰ The regular pelvic examination screenings for Chlamydia, cervical cancer, and early detection of ovarian cancer produce poor results and dissuade some women from seeking treatment.¹⁵¹ New advancements provide more effective screening alternatives that do not require invasive visits.¹⁵² By utilizing these new methods of screening, compliance rates will increase.

1. Chlamydia Screening

Chlamydia is a very common sexually transmitted bacterial infection that, if left untreated, "can cause . . . permanent damage

145. ACCESS TO CONTRACEPTION, *supra* note 8, at 3.

146. *Id.*

147. OVER-THE-COUNTER ACCESS, *supra* note 15, at 3.

148. *Id.*

149. *See id.*

150. Carolyn L. Westhoff, Heidi E. Jones, & Maryam Guiahi, *Do New Guidelines and Technology Make the Routine Pelvic Examination Obsolete?*, 20 J. WOMEN'S HEALTH 5, 6-8 (2011).

151. *Id.* at 5, 7-8.

152. *Id.* at 6-8.

to a woman's reproductive system."¹⁵³ It may be difficult or impossible for women who experience these horrific effects to get pregnant and, if they do, may cause a potentially fatal ectopic pregnancy.¹⁵⁴ Of the estimated three million people who contract Chlamydia each year, the highest incidence of the infection occurs in women under the age of twenty-five.¹⁵⁵ Despite the large concentration within this age bracket, testing rates remain low among young women.¹⁵⁶ Currently, "avoidance of [the pelvic] examination may be a reason that only about 50% of insured women [under 26 years old] undergo recommended annual screening for *Chlamydia*."¹⁵⁷ New advancements permit detection of Chlamydia through urine and self-collected vaginal swabbing.¹⁵⁸ This innovative technology is highly sensitive, obviates the need for pelvic examinations to screen for infection, and is vastly "more cost-effective and cost-saving than clinician-collected specimens during . . . pelvic examination[s]."¹⁵⁹ By supplementing these less expensive and intrusive options for the pelvic examination, more women will engage in early screening that will help prevent infertility and permanent gynecological harm.

2. Cervical Cancer Screening

Abnormal cervical screenings require frequent follow up care, but women with normal results do not need annual testing and can follow the currently recommended three- to five-year protocol.¹⁶⁰ The utilization of a pelvic examination for the detection of cancer has been abandoned because bimanual examinations have poor and ineffective results of early detection and alternative methods are consistent and preferred.¹⁶¹ "Annual pelvic exams for screening purposes (as opposed to diagnostic purposes, as in the case of a patient presenting physical symptoms) carry a high risk of false positives, which can lead to expensive and sometimes risky unnecessary biopsies or surgeries."¹⁶² In essence, over-screening can actually

153. *Chlamydia—CDC Fact Sheet*, CTRS. FOR DISEASE CONTROL (May 19, 2016), <http://www.cdc.gov/std/chlamydia/stdfact-chlamydia.htm> [<https://perma.cc/679F-HKNF>].

154. *Id.*

155. *Chlamydia—CDC Fact Sheet (Detailed)*, CTRS. FOR DISEASE CONTROL, <https://www.cdc.gov/std/chlamydia/stdfact-chlamydia-detailed.htm> [<https://perma.cc/BQ2A-97H3>].

156. *Id.*

157. Westhoff et al., *supra* note 150, at 7.

158. *Id.* at 6.

159. *Id.*

160. *Id.* at 6–7.

161. *Id.* at 7.

162. Christina Cauterucci, *If You're a Healthy Woman, There's No Evidence You Need an Annual Pelvic Exam*, SLATE (June 29, 2016, 1:33 PM), <http://www.slate.com/blogs>

produce more harm than good.¹⁶³ In recognition of evidence such as this, the FDA, World Health Organization (WHO), ACOG, and Planned Parenthood Federation of America (PPFA) explicitly stipulate that a pelvic examination is not required or necessary for the prescription of hormonal contraception.¹⁶⁴ While appropriate and consistent testing for cervical cancer is important, the other “justifications” are largely unfounded and, in the case of birth control, completely unnecessary.¹⁶⁵

3. *Early Detection of Ovarian Cancer*

The bimanual pelvic examination is a poor detector of early stages of ovarian cancer, rendering it an ineffective method for preventative treatment.¹⁶⁶ Studies comparing the United States and the United Kingdom demonstrate that there is no difference in the diagnosis of Stage I ovarian cancer when the bimanual pelvic examination is not performed.¹⁶⁷ The examination has “poor sensitivity and specificity for the detection of ovarian cancer,” rendering it obsolete.¹⁶⁸ Recently, a trial by the National Cancer Institute eliminated these practices after data showed that “no ovarian cancers had been [found by] this modality alone.”¹⁶⁹ Additionally, the U.S. Preventive Services Task Force found that this testing does not result in a decrease in mortality or any preventative benefits,¹⁷⁰ and along with the American Cancer Society and ACOG, recommend forgoing this method.¹⁷¹

E. Cost

Many groups are concerned that offering OTC birth control will drive up prices and affect insurance coverage for certain types of contraception.¹⁷² This is not the case; it will actually provide a more

/xx_factor/2016/06/29/annual_pelvic_exams_are_not_necessary_for_healthy_women_u_s_panel_says.html [https://perma.cc/GN9K-XVFF].

163. Cf. Westhoff et al., *supra* note 150, at 5–8.

164. *Id.* at 7 (confirming that these recommendations are applicable for asymptomatic patients).

165. OVER-THE-COUNTER ACCESS, *supra* note 15, at 3.

166. Westhoff et al., *supra* note 150, at 7.

167. *Id.* (explaining that these recommendations are applicable for asymptomatic patients).

168. *Id.*

169. *Id.*

170. Cauterucci, *supra* note 162.

171. Westhoff et al., *supra* note 150, at 7.

172. Sneha Barot, *Moving Oral Contraceptives to Over-the-Counter Status: Policy*

affordable option for many women.¹⁷³ Currently, birth control is covered fully under the Affordable Care Act and also under Medicaid.¹⁷⁴ However, this is likely to change under President Donald Trump, who has pushed to quickly repeal the Affordable Care Act.¹⁷⁵ Under the ACA, individuals who fall 138% below the national poverty level qualify for Medicaid.¹⁷⁶ Outside of Medicaid, only women who are insured gain access to free birth control, while uninsured women are unaffected.¹⁷⁷ This means that any woman who is not insured or that does not fall 138% below the federal poverty limit is left without access to free care. Because of the prescription requirement, women falling in this gap are not only paying for their birth control, but they are also paying for costly health visits, testing and even unnecessary surgical procedures.¹⁷⁸ “More than twenty percent of public health care providers report that most of their clients seeking contraception have difficulty paying for their visit.”¹⁷⁹ Insured and uninsured low-income women are presented with even more barriers such as transportation difficulties, especially in rural areas where offices can be far away, or the inability to go to appointments “during business hours because of their work schedules.”¹⁸⁰ Therefore, these additional services and barriers are more cost prohibitive than the birth control itself.

Offering OTC oral contraception would foster market competition that would drive down the price of birth control.¹⁸¹ Despite the low manufacturing cost for birth control, drug makers charge astronomical prices because the costs are not shouldered by the consumer, but are instead passed on to insurance companies that are required to foot the bill.¹⁸² There are many pharmaceutical companies producing oral contraception, and in an OTC model, these drug makers

Versus Politics, 18 GUTTMACHER POL'Y REV. 85, 87 (2015), https://www.guttmacher.org/sites/default/files/article_files/gpr1808515.pdf [<https://perma.cc/A9LC-G9HK>].

173. Manning, *infra* note 181.

174. REPRODUCTIVE RIGHTS & HEALTH: THE AFFORDABLE CARE ACT'S BIRTH CONTROL BENEFIT IS WORKING FOR WOMEN, NAT'L WOMEN'S LAW CTR. 1, 1 (Dec. 2016), <https://nwlc.org/resources/the-affordable-care-acts-birth-control-benefit-is-working-for-women> [<https://perma.cc/FX34-JBVD>].

175. Haberman & Pear, *supra* note 3.

176. Kandalaft & Vicry, *supra* note 58, at 79.

177. *Id.* at 78.

178. *Cf.* Westhoff et al., *supra* note 150 and Cauterucci, *supra* note 162.

179. Kandalaft & Vicry, *supra* note 58, at 78.

180. *Id.*

181. Hadley Heath Manning, *Planned Parenthood Misunderstands The Costs Of Birth Control, And The Concept Of Real Choice*, FORBES (Oct. 25, 2014, 9:38 AM), <http://www.forbes.com/sites/theapothecary/2014/10/25/planned-parenthood-misunderstands-the-costs-of-birth-control-and-the-concept-of-real-choice/#292a8cf819fb> [<https://perma.cc/E8BL-6B2P>].

182. *Id.*

would be forced to offer competitive pricing.¹⁸³ “This means that neither women nor insurance policy holders in general would have to pay thousands of dollars each year for what should be an inexpensive product.”¹⁸⁴

V. HEALTH PROVIDER EXPLOITATION

Making unsubstantiated healthcare a contingency for acquiring birth control makes treatment more about money and less about a woman’s autonomy and sound medical practice. If a man were to make an appointment to get his blood pressure medication refilled, and the doctor always conditioned the prescription on the patient undergoing an unneeded rectal exam, this would be considered outrageous. Because the resounding consensus by many groups—such as the FDA, WHO, ACOG, and PPFA—is that a pelvic exam is unnecessary for the prescription of hormonal contraception, this requirement is, in effect, equally nonsensical and should be considered a fraudulent medical practice.¹⁸⁵ Unfortunately, it is too easy for physicians to support these practices because not doing so would chip away at their profits.¹⁸⁶ Allowing OTC access removes the temptation to administer needless healthcare and places a greater emphasis on providing women with treatment that is individualized to their needs.

A. *Third-Party Influence*

Exchanges between physicians, drug makers, and medical device companies raise questions about whether perks and benefits are influencing how doctors are treating patients. Despite the Sunshine Act, companies are shelling out billions of dollars to physicians and hospitals each year.¹⁸⁷ In 2015 alone, 7.52 billion dollars were paid by the industry.¹⁸⁸ Doctors are being remunerated for many things that one might expect, such as meals, travel, and speeches, but they

183. *Id.*

184. *Id.*

185. Westhoff et al., *supra* note 150, at 6.

186. *Is the Routine Pelvic Examination Obsolete?*, COLUM. UNIV. (Feb. 25, 2011), <https://www.mailman.columbia.edu/public-health-now/news/routine-pelvic-examination-obsolete> [<https://perma.cc/UJ2K-2Z33>] [hereinafter *Routine Pelvic Examination*] (explaining that pelvic exams are a large factor in healthcare costs. Thus, eliminating them would cut the amount of money received by doctors).

187. Sy Mukherjee, *Drug and Medical Device Companies Shelled Out \$7.5 Billion to Docs and Hospitals in 2015*, FORTUNE (July 5, 2016), <http://fortune.com/2016/07/05/drug-companies-paid-doctors-billions> [<https://perma.cc/KF5M-X9KB>].

188. *Id.*

are also being compensated with things that you might not expect, such as research and continuing medical education (CME).¹⁸⁹ In order to maintain an active medical license, physicians must complete CMEs that are intended to apprise them of new science.¹⁹⁰ Many CMEs are conducted in desirable locations with lavish accommodations and are funded by drug and medical device companies who reap financial benefits from frivolous medical procedures.¹⁹¹ The result is that doctors are receiving yearly medical education that is biased and developed with the ulterior motive of pushing more unneeded services, and the process is highly successful.¹⁹² For instance, a ProPublica analysis concluded that doctors who were given more money “were also more likely to prescribe brand name, rather than cheaper generic, drugs. And the percentage of brand name prescriptions tends to increase with the amount of money received.”¹⁹³ OTC access would cut down on these practices by reducing the amount of opportunities that physicians have to carry out this unethical behavior.

B. Physician Motivation

Office visits and testing add up to increased profits, and, because pap smears and contraception have been a package deal for so long, they are ritualistic and many physicians do not want to stop administering these tests.¹⁹⁴ Not only are women having to schedule yearly gynecological appointments for the sole purpose of getting a birth control prescription, but, regardless of their personal medical needs or issues, are being forced to undergo too frequent and often unneeded examinations.¹⁹⁵ “A 2010 study found 33 percent of doctors *always* require a pelvic exam and pap smear before prescribing hormonal contraception, and 44 percent regularly do.”¹⁹⁶ While this may seem harmless, these needless pelvic exams consume precious time during wellness visits that could be better utilized, can prevent women from seeking routine care because they are “notoriously uncomfortable and . . . disliked,” and can lead to unnecessary surgeries.¹⁹⁷ For

189. *Id.*

190. Stephanie Mencimer, *Holding Birth Control Hostage*, MOTHER JONES (Apr. 30, 2012, 10:00 AM), <http://www.motherjones.com/politics/2012/04/doctors-holding-birth-control-hostage> [https://perma.cc/9FFM-4M6Z].

191. *AAFP CME by Location*, AAFP, <http://aafp.org/cme/browse/all-locations.html> [https://perma.cc/LV5A-DY75]; Mencimer, *supra* note 190.

192. *See, e.g.*, Mukherjee, *supra* note 187.

193. *Id.*

194. LeWine, *supra* note 118.

195. Brown, *supra* note 9.

196. *Id.*

197. *Routine Pelvic Examination*, *supra* note 186.

example, U.S. rates of hysterectomies and ovarian cystectomies “are more than [double that of] . . . European countries, where . . . pelvic examination is limited to symptomatic [patients].”¹⁹⁸ Increasingly, it is being recognized “that more services do not always lead to improved health outcomes and that often the opposite is true: that more services are associated with worse health [sic] outcomes.”¹⁹⁹ Despite these negative effects, physicians are not willing to discontinue these practices and embrace new procedures because they are being incentivized to not change.²⁰⁰ Medical procedures are lucrative and not testing asymptomatic patients chips away at unnecessary surgeries and, ultimately, extra revenue streams.²⁰¹ Doctors want to keep their offices booming and money in their pockets and can do so by pressing for additional visits, testing, and surgeries.²⁰² At the end of the day, a precarious situation is created where physicians profit at the expense of patients, but OTC access can change this by stopping needless visits.²⁰³

C. Healthcare Fraud

By conducting indiscriminate and unnecessary pelvic screenings, healthcare providers are in direct conflict with the directives of the Department of Justice and Centers for Medicare and Medicaid Services (CMS) and are adding to the fraud epidemic.²⁰⁴ Administering superfluous healthcare is not a small issue, but rather, a problem of epic proportions. It is estimated that unnecessary healthcare totals at least \$158 billion a year.²⁰⁵ Through the False Claims Act, the Justice Department and the CMS recovered over \$16.2 billion dollars in healthcare fraud cases in only six years.²⁰⁶ To compound this rampant exploitation of medical services, the Department of Justice made it their mission to be “committed to ensuring that laboratory tests, including drug and genetic tests, are ordered based on each patient’s medical needs and not just to increase physician and

198. *Id.*

199. *Id.* (quoting Dr. Carolyn Westhoff).

200. *Cf. id.*

201. Brown, *supra* note 9.

202. *Cf. Routine Pelvic Examination, supra* note 186.

203. *Cf.* Brown, *supra* note 9.

204. Millennium Health, *infra* note 206.

205. *Health Policy Brief*, HEALTHAFFAIRS (Dec. 13, 2012), http://healthaffairs.org/healthpolicybriefs/brief_pdfs/healthpolicybrief [<https://perma.cc/9YJQ-NF3W>].

206. Press Release, Dep’t of Justice, Millennium Health Agrees to Pay \$256 Million to Resolve Allegations of Unnecessary Drug and Genetic Testing and Illegal Remuneration to Physicians (Oct. 19, 2015), <https://www.justice.gov/opa/pr/millennium-health-agrees-pay-256-million-resolve-allegations-unnecessary-drug-and-genetic> [<https://perma.cc/E2TF-H3KB>] [hereinafter Millennium Health]. See generally 31 U.S.C.A. §§ 3729–3733 (2009).

laboratory profits.”²⁰⁷ Additionally, the head of the Justice Department’s Civil Division, Principal Deputy Assistant Attorney General Benjamin C. Mizer, stated that the Department “will not tolerate practices such as the ordering of excessive, non-patient specific tests and the provision of inducements to physicians that lead to unnecessary costs being imposed upon our nation’s health care programs.”²⁰⁸ Despite this stance, this is precisely what the prescription requirement encourages. When physicians conduct pelvic examinations and screenings on asymptomatic patients against government and medical recommendations, they are administering fraudulent medical care that is in violation of the False Claims Act.²⁰⁹

VI. OTHER HINDRANCES STALLING THE PROGRESSION OF BIRTH CONTROL

Safety, efficiency, reasonable access, objectivity, and public welfare are all elements that should be paramount when evaluating and determining the status of readily used drugs,²¹⁰ but these are not considerations that are driving the availability of birth control. Political, religious, and monetary motives are at the forefront of a divisive movement restricting OTC access to contraception, and the FDA does not have the ability to combat the problem.²¹¹ This is mostly attributable to the prescription-to-OTC switch process which is fatally flawed, allowing self-interested parties to block access to OTC oral contraception.²¹²

Political intrusion into contraception matters has slowed and, at times, halted the switch process.²¹³ “When Plan B emergency contraception was being considered for [OTC] sale, politicians of both parties intervened in the process, slowing it down and imposing an unreasonable age restriction, one that was lifted only after a 10-year legal battle.”²¹⁴ History often repeats itself, and companies may hesitate to push for OTC oral contraception because of the potential for

207. Millennium Health, *supra* note 206.

208. *Id.*

209. See 31 U.S.C.A. § 3729 (2009).

210. Cf. Daniel Grossman, *Birth control pills should not be prescription-only*, L.A. TIMES (June 19, 2015, 5:00 AM), <http://www.latimes.com/opinion/op-ed/la-oe-grossman-otc-birth-control-pills-20150619-story.html> [<https://perma.cc/B273-UE7E>].

211. Tasha M. LaSpina et al., *Eleventh Annual Review of Gender and Sexuality Law: Health Care Law Chapter: Access to Contraception*, 11 GEO. J. GENDER & L. 371, 404–06 (2010). See generally Grossman, *supra* note 210; Mencimer, *supra* note 190.

212. LaSpina et al., *supra* note 211, at 405–06. See generally Grossman, *supra* note 210; Mencimer, *supra* note 190.

213. LaSpina et al., *supra* note 211, at 395.

214. Grossman, *supra* note 210.

political interference that could result in exorbitant costs and uncertainties during the FDA approval process.²¹⁵

Many religious organizations vehemently oppose contraception and do not want to expand availability.²¹⁶ Refusal clauses allow drug distributors, such as pharmacists, to refuse to dispense birth control, even if a valid prescription is provided.²¹⁷ While these clauses were originally created to ensure that a healthcare provider “was not forced” to perform an abortion,²¹⁸ they are now being directed at emergency and oral contraceptives.²¹⁹ This is attributable to extremist groups that believe “that even basic oral and implant contraceptives act as abortifacients.”²²⁰ By granting OTC access, the right to restrict access to contraception through refusal will be removed.

A. *The FDA Switch Process*

The FDA regulates prescription drugs, OTC medications, and is responsible for switches from one to the other.²²¹ To change the classification of a drug from prescription to OTC, the FDA protocol must be followed, large fees must be paid, and heaps of evidence about safety and efficacy must be provided.²²² An FDA prescription drug switch can be initiated by the following parties: (1) the FDA Commissioner; (2) any person who files a citizen petition; or (3) the drug manufacturer.²²³ The petitioning party must pay a roughly one-million dollar filing fee to start the process and must submit extensive research about the drug.²²⁴ Although the Commissioner or a citizen is technically allowed to petition for a drug switch, pharmaceutical manufacturers are often the only party who can provide detailed safety information and afford the steep fees.²²⁵ However, pharmaceutical companies have no incentive to request a change because they make more from prescription insurance payments than they would if contraception was in the competitive market.²²⁶

215. *Id.*

216. LaSpina et al., *supra* note 211, at 404–05.

217. *Id.* at 391–92.

218. *Id.* at 389.

219. *Id.*

220. *Id.* at 390.

221. *Drugs*, FOOD & DRUG ADMIN., <http://www.fda.gov/aboutFDA/transparency/Basics/UCM192696.htm> [<https://perma.cc/QUB2-WJP5>].

222. *Tummino v. Torti*, 603 F. Supp. 2d 519, 525 (E.D.N.Y. 2009); Grossman, *supra* note 210.

223. *Tummino*, 603 F. Supp. 2d at 525; *see* 21 U.S.C.A. §§ 353(b)(3), 355(c)–(d) (2006).

224. Grossman, *supra* note 210.

225. Brown, *supra* note 9.

226. *Id.*

“Unsurprisingly, none of the[se] sponsors who profit from keeping contraceptives Rx-only want to challenge [the] status.”²²⁷ The FDA switch process creates a deadlock that gives drug companies the power to dictate the status of contraception based on ulterior motives.

B. Plan B and Politics

The ineffective and corrupt practices involved in the OTC switch of Plan B serve as a warning of the possible difficulties that regular oral contraception may face.²²⁸ The political schemes that were evidenced by the egregious and unfounded determinations for Plan B demonstrate that women’s health and autonomy is not the driving motivation behind OTC contraception access.²²⁹ Given the tumultuous political climate, it is highly probable that political agendas will make the OTC switch difficult.²³⁰ Debates over contraception coverage already bog down the process, “with both Democrats and Republicans hoping to score some political points with their own proposals rather than working together.”²³¹ The current dissonance between Republicans and Democrats may only increase the tension. If drug makers do petition and the FDA requirements are met, history has shown that there is still no guarantee that a fair ruling will be rendered.²³² After assessing the plight of Plan B and considering the unsteady state of politics, companies will be hesitant to cough up the one million dollar filing fee knowing that they may face an uphill battle.

C. Refusal Clauses Are Legal Loopholes for Discrimination

Refusal clauses allow religious organizations to place barriers between women and much needed contraception. By approving OTC access to the pill, the FDA can remove the leverage that these clauses hold. *Roe v. Wade*²³³ set off a “political firestorm” that led to the creation of “refusal clause” statutes.²³⁴ Insurers, healthcare

227. *Id.*

228. See Kandalajt & Vicry, *supra* note 58, at 56.

229. LaSpina et al., *supra* note 211, at 404–06. See generally Grossman, *supra* note 210; Mencimer, *supra* note 190.

230. See generally Charlotte Alter, *Why Over-the-Counter Birth Control Is Stalled*, TIME (Dec. 23, 2015), <http://time.com/4132835/why-over-the-counter-birth-control-is-stalled> [<https://perma.cc/CL9F-D3SN>].

231. *Id.*

232. There is much evidence that financial, religious, and political factors take precedence over women’s health. LaSpina et al., *supra* note 211, at 404–06; Grossman, *supra* note 210; Mencimer, *supra* note 190.

233. *Roe v. Wade*, 410 U.S. 113 (1973).

234. LaSpina et al., *supra* note 211, at 388.

providers, employers, hospitals and many other institutions and individuals were allowed to refuse to have anything to do with medical treatment that went against the “individual’s or institution’s moral, ethical, or religious beliefs.”²³⁵ While these statutes were originally targeted at abortions, they are now broadly interpreted to encompass contraception.²³⁶ “[E]arlier concern over access to contraception has re-emerged, pitting professional autonomy and individual religious freedom against a woman’s right to reproductive health care and right to autonomy in family planning.”²³⁷ “Although states may not constitutionally deprive women of access to contraception,” providers and pharmacists are using refusal clauses as a “legal loophole” to refuse to perform procedures, prescribe medication, or fill prescriptions.²³⁸ By allowing OTC access to oral birth control, physicians and pharmacists that are utilizing these backdoor policies will largely be taken out of the equation. Thus, women will be left with more freedom to make personal choices about family planning without undue restrictions.

VII. CONSTITUTIONAL ISSUES

Both denial of OTC access to oral contraception and the mandating of pelvic examinations in order to disperse oral contraception raise constitutional issues regarding the Fifth Amendment’s Due Process guarantee and the Fourteenth Amendment’s Equal Protection Clause.

A. Contraception and Case Law

The Supreme Court decisions in *Griswold v. Connecticut*,²³⁹ *Eisenstadt v. Baird*,²⁴⁰ and *Carey v. Population Services International*²⁴¹ support that access to contraception is a fundamental right. In *Griswold*, restricting a married couple’s access to contraceptives was deemed a violation of the right to privacy.²⁴² The right to use contraception was expanded to unmarried people in *Eisenstadt*.²⁴³ The

235. *Id.*

236. *Id.* at 389 (elaborating on how refusal clauses were enacted to protect healthcare providers from being forced into performing abortions but now are being used against family planning devices).

237. *Id.*

238. *Id.* at 390.

239. *Griswold v. Connecticut*, 381 U.S. 479 (1965).

240. *Eisenstadt v. Baird*, 405 U.S. 438 (1972).

241. *Carey v. Population Servs. Int’l*, 431 U.S. 678 (1977).

242. *Griswold*, 381 U.S. at 485.

243. *Eisenstadt*, 405 U.S. at 453.

Court stated that “[i]f the right [to] privacy means anything, it is the right of the individual, married or single, to be free [of] unwarranted governmental intrusion into matters so fundamentally affecting a person as the decision whether to bear or beget a child.”²⁴⁴ Thus, the fundamental right was extended to a “right to procreative privacy.”²⁴⁵ The right was implicitly extended to distribution of contraception in *Carey*.²⁴⁶ The Court found “that a law [restricting] the display, advertisement, and distribution of [birth control] was unconstitutional and [specified] that government restrictions on contraceptive access must meet strict scrutiny.”²⁴⁷ The Court reasoned that access to contraception is an integral part of the constitutional right to make childbearing decisions and that it should be free from “unjustified intrusion by the [s]tate.”²⁴⁸

It is established that women have a strong right to a “dignity interest in bodily integrity.”²⁴⁹ *Roe v. Wade*²⁵⁰ and *Planned Parenthood v. Casey*²⁵¹ are landmark decisions that weighed a woman’s right to bodily integrity against the government’s interests in guarding life and health.²⁵² *Roe* made it clear that the right to privacy protected a woman’s decision of whether to terminate a pregnancy.²⁵³ This leads to an inference that deciding to prevent pregnancy “is also a fundamental right [included] in the right to privacy.”²⁵⁴ *Casey* established that dignity and autonomy are protected by the Constitution and that “[a]t the heart of liberty is the right to define one’s own concept of existence, of meaning, of the universe, and of the mystery of human life.”²⁵⁵ While these cases addressed abortion rights specifically, more recently *Tummino v. Hamburg* built upon these foundations and granted OTC access to Plan B without age restrictions.²⁵⁶ Many argue that *Tummino* was also only applicable in an

244. *Id.*

245. Scout Richters, *The Moral Interception of Oral Contraception: Potential Constitutional Claims Against the FDA’s Prescription Requirement for a Progestin-Only Birth Control Pill*, 22 J.L. & POL’Y 393, 417 (2013). See also *Carey*, 431 U.S. at 687 (stating “the Constitution protects individual decisions in matters of childbearing from unjustified intrusion by the State. Restrictions on the distribution of contraceptives clearly burden the freedom to make such decisions.”).

246. *Carey*, 431 U.S. at 700–02.

247. Richters, *supra* note 245, at 417.

248. *Carey*, 431 U.S. at 687.

249. Dixon, *supra* note 11, at 183.

250. *Roe v. Wade*, 410 U.S. 113 (1973).

251. *Planned Parenthood of Se. Pa. v. Casey*, 505 U.S. 833 (1992).

252. Dixon, *supra* note 11, at 184.

253. Richters, *supra* note 245, at 418.

254. *Id.*

255. *Planned Parenthood*, 505 U.S. at 851.

256. See generally *Tummino v. Hamburg*, 936 F. Supp. 2d 162 (E.D.N.Y. 2013).

abortion context, but it has never been established that Plan B has any effect after an egg has been fertilized.²⁵⁷ Further, the U.S. Government Accountability Office actually stated that these contraceptives “have not been shown to cause a postfertilization event—a change in the uterus that could interfere with implantation of a fertilized egg.”²⁵⁸ Thus, it can be inferred that the constitutionally protected right extends past abortion to non-emergent oral contraception.

B. Fifth Amendment Substantive Due Process Violations

If an FDA application for OTC oral birth control was denied, the reasoning would most likely be that the “prescription requirement serves the government’s compelling interest in protecting women’s health,”²⁵⁹ but this claim cannot be substantiated. To disprove a Due Process claim, the FDA would be required to show that the prescription requirement was narrowly tailored to serve this governmental interest.²⁶⁰ The government would not be able to show that women’s health is the reason for the denial because overwhelming evidence proves otherwise.²⁶¹

Determining whether or not the FDA should make a drug available OTC hinges on its safety and efficacy,²⁶² and there are numerous reasons why OC fulfills the requirements. First, there are very few women that have contraindications for oral contraception use, but the prescription requirement is overly inclusive because it is applied to all women.²⁶³ The FDA routinely allows dangerous, even lethal, drugs to be distributed with the caveat that they have a label specifying the contraindications.²⁶⁴ Oral contraceptives are among some of safest drugs that could be sold OTC,²⁶⁵ and labeling is adequate to alert the small number of women that may experience issues.²⁶⁶ Additionally, studies have shown that women can effectively self-screen for contraindications²⁶⁷ and can make an accurate assessment

257. *Id.* at 165 (citing the U.S. Government Accountability Office (GAO)).

258. *Id.* (quoting the GAO).

259. Richters, *supra* note 245, at 419.

260. *See id.* at 416.

261. *Id.* at 421.

262. Theresa M. Michele, *Regulatory Approaches for Prescription to OTC Switch*, FOOD & DRUG ADMIN. (July 2, 2015), <http://www.fda.gov/downloads/drugs/newsevents/ucm454815.pdf> [<https://perma.cc/5CL9-QQLF>].

263. Richters, *supra* note 245, at 419.

264. *Id.* at 419–20.

265. *Cf. Tummino v. Torti*, 603 F. Supp. 2d 519, 523 (E.D.N.Y. 2009).

266. Richters, *supra* note 245, at 424.

267. Daniel Grossman et al., *Accuracy of Self-Screening for Contraindications to Combined Oral Contraceptive Use*, 112 OBSTETRICS & GYNECOLOGY 572, 572 (2008).

of their risk after reading a label. Most healthcare providers determine whether to prescribe birth control “almost entirely by hearing a recitation of the woman’s medical history.”²⁶⁸ Consultation with a pharmacist or with alternate methods, such as information kiosks, can provide the same level of guidance and consideration given by a healthcare provider.²⁶⁹ Most importantly, a visit to a healthcare provider has actually been shown to result in “[higher] health risks and poorer health outcomes” due to additional procedures that are unnecessarily performed.²⁷⁰ Lastly, prescription requirements deter and restrict many women from getting access to birth control, leading to an increase in unintended pregnancies.²⁷¹ “Aborti[ons] . . . or carrying a pregnancy to full term both [result in] higher risks” than those associated with oral contraception.²⁷² Therefore, there is a much greater risk to women’s health by retaining the prescription requirement.

The pelvic examination requirement is also unconstitutional because the government cannot establish that the requirement is narrowly tailored to protecting women’s health from the adverse effects of oral contraception. “[T]he pelvic exami[nation] does not serve its stated purpose, it is not necessary, and it is overly broad.”²⁷³ The purpose of the exam is to identify women who are susceptible to the side effects of oral contraception and to restrict them from receiving a prescription.²⁷⁴ The exam does not accomplish this goal because oral contraception is not definitively linked to cervical cancer, the exam is inadequate at detecting problems, alternative methods are just as reliable and less invasive, “and the requirement [can] actually *increase*[] risks” to women.²⁷⁵ “Under strict scrutiny review, a legislative rationale based on a mere associat[ed] correlation is insufficient justification for restricting a constitutional right.”²⁷⁶

Because it is claimed that the pelvic exam screens for cancer, the government has to show that oral birth control causes cervical cancer.²⁷⁷ Initially, family planning clinics required annual pelvic exams because they had a hunch that oral contraception may cause cervical cancer, but a causal connection between the two has never

268. Richters, *supra* note 245, at 420.

269. *Id.* at 420–21.

270. *Id.* at 421.

271. *Id.* at 398.

272. *Id.* at 421.

273. Dixon, *supra* note 11, at 184.

274. *Id.*

275. *Id.* at 185.

276. *Id.*

277. *Id.*

been found.²⁷⁸ Ironically, not only is oral contraception not linked to cervical cancer, but it “may actually *protect against* these [types of] cancers.”²⁷⁹ Women on the birth control pill are approximately half as likely to develop “ovarian and endometrial cancer as do nonusers.”²⁸⁰ Furthermore, pelvic examinations do not effectively screen for ovarian cancer because they do not indicate women who have precancerous lesions or human papillomavirus (HPV).²⁸¹ Fifteen to thirty percent of women with lesions will receive a negative result from a pap smear, despite the test being correctly administered and interpreted.²⁸² While pelvic examinations can detect HPV, “[out] of the millions of [cases], only a few [women] will . . . develop cervical cancer.”²⁸³ These tests are too broad and cannot accurately predict who will actually develop cervical cancer.²⁸⁴ In addition to the testing inconsistencies, over-screening causes harm because it leads to false positives, which in turn requires additional testing or surgery that causes discomfort, added costs, and risks.²⁸⁵ Women who are denied oral contraception because of contraindications, inability to afford the office visit, or because of refusal to submit to this exam are left with less reliable birth control methods, resulting in an increase in pregnancies.²⁸⁶ Full-term pregnancy and abortions have substantially greater risks than utilization of oral contraception.²⁸⁷ Therefore, oral contraception poses lower risks, is more effective than other birth control methods, and can help women avoid risks associated with unplanned pregnancies and abortions.²⁸⁸ The negative effects of requiring a pelvic exam greatly outweigh any benefit that it may provide.²⁸⁹

Pelvic examinations are not needed to prescribe hormonal contraception because the results do not have any bearing on whether a patient receives a prescription.²⁹⁰ Most physicians prescribe based only on verbal information provided by the patient.²⁹¹ European physicians have found that pelvic exams are “irrelevant and unnecessary

278. *Cf. id.* at 85 n.49.

279. *See* Dixon, *supra* note 11, at 185–86.

280. *Id.* at 188.

281. *Id.* at 186.

282. *Id.*

283. *Id.*

284. *See id.*

285. *See* Westhoff et al., *supra* note 150, at 7.

286. *See* Dixon, *supra* note 11, at 187.

287. *Id.*

288. *See id.* at 185–87.

289. *See id.* at 188–89.

290. *Id.* at 189.

291. *See* Richters, *supra* note 245, at 420.

barriers to contraception accessibility.”²⁹² The FDA, Planned Parenthood, and other family planning organizations allow women to delay the pelvic exam for up to three months after administering hormonal contraception.²⁹³ This demonstrates that the exam is not necessary to safely administer oral contraception. ACOG stated that “cervical cancer screening or sexually transmitted infection (STI) screening is not required for initiating OC use and should not be used as barriers to access.”²⁹⁴ Alternate testing that is less invasive has been found to produce better detection results of cervical cancer, HPV, and Chlamydia than a pelvic exam.²⁹⁵ Thus, pelvic exams are not needed to determine whether or not oral contraception can be safely administered.

Because pelvic examinations can increase risks to women’s health and the requirement of this testing is unnecessary, pelvic examinations are not narrowly tailored to protect women’s health from the side effects of oral contraception. Women have a constitutionally protected right to dignity and bodily integrity, and the weak reasoning provided by the government does not justify violating these rights. This is a violation of the Due Process Clause, and women should not be forced to adhere to unconstitutional barriers that prevent access to oral contraception.

C. Fourteenth Amendment Equal Protection Violations

The prescription requirement for oral contraception violates the Equal Protection Clause because it has both a disparate impact on women and a discriminatory purpose behind the requirement.²⁹⁶ “The disparate impact of the prescription requirement is evident: only women use oral contraception and therefore are the only sex subjected to the prescription requirement.”²⁹⁷ According to *Village of Arlington Heights v. Metropolitan Housing Development Corp.*, courts must look at circumstantial and direct evidence of intent inclusive of the historical background, the legislative history and “[d]epartures from the normal procedural sequence.”²⁹⁸ The obvious suppression

292. See Dixon, *supra* note 11, at 189.

293. *Id.* at 189–90 n.79.

294. OVER-THE-COUNTER ACCESS, *supra* note 15, at 3.

295. See Dixon, *supra* note 11, at 190–91 (concluding that DNA tests not conducted in conjunction with pelvic exams, are better at detecting cervical abnormalities that indicate a risk of cervical cancer development). Self-collected vaginal swabs accurately detect abnormalities and can serve as a substitute for pap screening. *Id.* at 191.

296. See Richters, *supra* note 245, at 423.

297. See *id.*

298. *Village of Arlington Heights v. Metro. Hous. Dev. Corp.*, 429 U.S. 252, 266–68 (1977).

of the pill and women's rights, including the criminalization of contraception distribution, provides glaring evidence of discrimination.²⁹⁹ Starting in 1873, Congress passed the Comstock Law, which labeled birth control as an obscenity and outlawed its distribution.³⁰⁰ Then in the early 1900s, women were encouraged by society and religious organizations to engage in highly risky birth control procedures such as the Rhythm Method.³⁰¹ It was not until the 1960s that the pill was offered as a contraceptive method, but the Vatican would not support the drug and some states still had laws making birth control use a crime.³⁰² It was not until *Eisenstadt v. Baird* in 1972, that the Supreme Court stopped states from standing in the way of birth control distribution to single individuals.³⁰³ While birth control has evolved over the last fifty years, *Tummino v. Hamburg* demonstrates that discrimination and biased government involvement is not a thing of the past.³⁰⁴ The government openly recognizes that the FDA alone is the only party with the "necessary information and scientific expertise to assess the data and information required to make a determination that a drug is safe and effective."³⁰⁵ In *Tummino*, the court highlighted the egregious deviation from this principal and stated:

This salutary principle was flagrantly violated by Secretary Sebelius, who completely lacks the "necessary information and scientific expertise to assess the data and information required to make a determination that a drug is safe and effective," and

299. See, e.g., *A Brief History of Birth Control: From early contraception to the birth of the Pill*, TIME (May 3, 2010), <https://content.time.com/time/magazine/article/0,9171,1983970,00.html> [<https://perma.cc/LAQ8-GEUY>].

300. Megan Gibson, *The Long, Strange History of Birth Control*, TIME (Feb. 2, 2015), <http://time.com/3692001/birth-control-history-djerassi> [<https://perma.cc/2PCP-R94P>].

301. *Rhythm Method*, *supra* note 42. The Rhythm Method is a method of birth control that required women to abstain from sex halfway through their menstrual cycle when she was most fertile. *Id.*

302. Frances Kissling, *How the Vatican Almost Embraced Birth Control*, MOTHER JONES (May/June 2010), <http://www.motherjones.com/politics/2010/04/catholic-church-vatican-bishops-birthcontrol> [<https://perma.cc/LWC6-D3EU>]; *100 Years of Birth Control: How access to contraception revolutionized women's lives, from 1914 to today*, PLANNED PARENTHOOD, https://plannedparenthoodaction.org/uploads/filer_public/ed/78/ed78a43a-e466-4194-870c-251794d9d22b/7-16-14-birth-control-timeline-final.pdf [<https://perma.cc/D452-DT7Y>]. In 1961, it was a crime to use birth control in Connecticut despite the FDA approving a pill for contraceptive use. See *Time line of birth control*, YEAPeOPLE.COM, <http://www.yeapeople.com/BirthCtrl.html> [<https://perma.cc/R6PP-LABD>].

303. See *Eisenstadt v. Baird*, 405 U.S. 438, 447 (1972) (concluding that a state statute barring unmarried people from obtaining contraception violated the Equal Protection Clause because there was no rational basis for treating similarly situated married and unmarried people differently).

304. See generally *Tummino v. Hamburg*, 936 F. Supp. 2d 162 (E.D.N.Y. 2013).

305. *Tummino v. Hamburg*, 936 F. Supp. 2d 198, 201 (E.D.N.Y. 2013) (internal citations omitted).

whose role in the process has been circumscribed by Congress as well as by the delegation to the Commissioner of any authority that the Secretary may have—a clear recognition by Congress and the Secretary of her lack of competence in this area. Yet, in something out of an alternate reality, the defendants seek a stay to pursue an appeal that would vindicate the Secretary’s disregard of the very principle they advocate.³⁰⁶

The continued, meritless reasoning behind the government’s actions have no explanation other than flagrant discrimination, perpetuating unequal medical standards for women.

Pelvic examination mandates are unsubstantiated healthcare burdens that unequally effect women and minorities.³⁰⁷ The Equal Protection Clause “[requires] that a state must treat similarly situated” people in the same manner.³⁰⁸ Publicly funded family planning services require pelvic exams for the purposes of “detecting sexually transmitted diseases, pelvic inflammatory disease, or cancer.”³⁰⁹ There is a lack of evidence showing any connection between oral contraceptive use and the factors detected by the exam, showing that there is an “illegitimate purpose behind the requirement.”³¹⁰ While women are required to undergo this invasive procedure to acquire birth control, men can readily get condoms and prescription enhancement drugs without undergoing STD or prostate screenings, despite both situations presenting the same opportunity to impose preventative testing.³¹¹ Additionally, racial groups are also disparately impacted by the prescription birth control requirements.³¹² Income status and race are closely linked in the United States, and racial and ethnic minorities utilize publicly funded health clinics at a disproportionately high rate.³¹³ Title X clinics (publicly funded clinics) mandate a pelvic examination for contraceptive access, and any woman who declines to consent to this testing is denied a prescription.³¹⁴ “Relegating women who refuse pelvic exams and cannot afford private physicians to contraceptive methods with significantly lower efficacy rates will result in many more unintended pregnancies for minority women than for nonminority women.”³¹⁵ This result

306. *Id.* (internal citations omitted).

307. *See* Dixon, *supra* note 11, at 198.

308. *Id.* at 196.

309. *Id.* (internal citations omitted).

310. *Id.* at 202.

311. *Id.* at 196–97.

312. *See id.* at 200 n.153.

313. *See* Dixon, *supra* note 11, at 200.

314. *Id.* at 201.

315. *Id.*

creates an even larger disparate impact on minorities who are already at high risk.³¹⁶ Women and minorities are placed in a compromising and unjust position. The obvious disparate impact coupled with ongoing discrimination substantiates an Equal Protection violation.

VIII. POSSIBLE SOLUTIONS

A. Pharmacy Distribution

States have begun to take responsive measures to the prescription drug deadlock, but they may prove to be an inefficient overall solution. Both Oregon and California passed legislation allowing contraception to be dispensed with the approval of a pharmacist.³¹⁷ After answering a short twenty-question self-assessment and paying roughly twenty-five dollars, women can walk away with birth control.³¹⁸ Seemingly, this is a straightforward and effective remedy to improve contraception access, but there are still barriers and discrepancies that could render these programs partially ineffective.

In *Carey v. Population Services International*, the Supreme Court declared that a law making it criminal to advertise, display, or distribute contraception to a person under sixteen, or for anyone other than a pharmacist to distribute contraceptives to people over fifteen was unconstitutional.³¹⁹ The Court found that restricting distribution of birth control to pharmacists “unduly restricted access to birth control (unjustifiably infringing the right to control procreation) and that the law violated the rights of those under sixteen to have access to contraceptives.”³²⁰ A case could be made that allowing pharmacists to be the gatekeepers for birth control distribution could create a similar situation.

Another issue is availability. Eighteen months after California’s governor signed the law allowing pharmacists to dispense birth control without a physician prescription, only a handful of pharmacies were participating.³²¹ The new regulations require state-mandated training prior to distribution, and many of the big box pharmacies, such as Walgreens and Rite Aid, are simply hesitant to undergo training

316. *Id.*

317. See Belluck, *supra* note 32.

318. *Id.*

319. Dixon, *supra* note 11, at 183.

320. *Id.*

321. Kelly O’Mara, *Law Allows Women to Obtain Birth Control Without Prescription, But Few Pharmacies Offer Service*, KQED NEWS (May 19, 2016), <https://ww2.kqed.org/stateofhealth/2016/05/19/law-allows-women-to-obtain-birth-control-without-prescription-but-few-pharmacies-offer-service> [<https://perma.cc/6FP3-LU9Q>].

and implement formalities without knowing the financial impact.³²² In May of 2016, it is estimated that only 100 out of 7,000 pharmacies were participating.³²³ Hurdles such as having to provide extra staff to answer incoming doctor calls while another pharmacist conducts a consultation—or having to provide a private consultation room—increase resistance.³²⁴ At the end of the day, the regulations are not mandatory and pharmacies are leery of taking part without a financial incentive.³²⁵ Further, even if the pharmacy does take part, refusal clauses still allow employees to refuse to dispense birth control if they feel that it conflicts with their personal beliefs.³²⁶

Distribution aside, there are continuity issues that could impact both pharmacies and consumers. In Oregon, “[o]nly self-administered oral or transdermal products” are dispensed³²⁷ while California offers self-administered hormonal birth control, including “pills, patches, injections and vaginal rings.”³²⁸ Authorizing different products per state creates consumer and pharmacist confusion. Big pharmacies that seek to implement programs across all of their locations will not be able to create a standardized system because of the differing legislation.³²⁹ This difficulty could lead to further resistance. From a consumer perspective, women who are regularly taking one type of birth control may be forced to change their treatment regimen because of availability.

The continuity issue is further problematic when examining the nation as a whole. Highly conservative states may refuse to adopt similar legislation. When originally passed, the Affordable Care Act’s requirement that all health plans pay for prescription birth control was highly controversial and was “met with emotional[,] political[,] and religious opposition.”³³⁰ Undoubtedly, the same backlash will befall this type of legislation in conservative states and could block the passage of the regulations. While these state initiatives are a step in the right direction, the potential loopholes, lack of consistency,

322. See, e.g., *id.*

323. *Id.*

324. *Id.*

325. *Id.*

326. *Pharmacist Conscience Clauses: Laws and Information*, NAT’L CONFERENCE OF STATE LEGISLATURES (last updated May 2012), <http://www.ncsl.org/research/health/pharmacist-conscience-clauses-laws-and-information.aspx> [<https://perma.cc/BM3T-N9L4>].

327. *Frequently Asked Questions*, OR. STATE PHARMACY ASSOC., <http://www.oregonpharmacy.org/hb2879---hormonal-birth-control-faqs> [<https://perma.cc/C65C-P2T9>].

328. Karlamangla, *supra* note 35.

329. O’Mara, *supra* note 321.

330. Pam Belluck, *Birth Control via App Finds Footing Under Political Radar*, N.Y. TIMES (June 19, 2016), <https://www.nytimes.com/2016/06/20/health/birth-control-options-websites.html> [<https://perma.cc/QY3X-TZ6H>].

and strong opposition may greatly impinge on the applicability of these programs.

B. Online Options

New grassroots efforts to combat availability issues have given way to a new supply method: online birth control providers.³³¹ Companies such as Nurx, Maven, Lemonaid and Planned Parenthood Care allow patients to get a prescription and order pills through a website without a physical visit to a physician.³³² Some of the online services even offer video conferencing and messaging with nurse practitioners.³³³ “Providers recommend a medication on the spot and order it to be sent to a pharmacy near the patient.”³³⁴ Women who have difficulty getting off work for an office visit or who cannot afford extenuating medical costs can easily procure the medication that they need. Luckily, these applications have managed to fly under the radar and have encountered little opposition thus far.³³⁵ By circumventing doctor’s visits and unnecessary testing, the patient will incur less cost, see faster service, and achieve easier access to much needed contraception.³³⁶ Insurance can be used for the service, and affordable options are available for those without coverage, as well.³³⁷ These companies sound like the perfect answer for accessibility, but there are a few snags.

First, the biggest issue is that this method suffers from the same distribution issues as the pharmacy option. These sites can only service an extremely limited amount of states and may not be able to expand to cover the entire nation.³³⁸ Second, shipping delays could potentially cause issues with the timing of OC. If the prescription arrives late or a person waits until the last minute to order, they may fall behind on their schedule, leaving them unprotected for a small period of time. Lastly, indigent women without access to a computer or the Internet would not be able to take advantage of these services. This would effectively create a discriminatory effect and ignore one of the largest groups that experiences unintended

331. *Id.*

332. Stephanie M. Lee, *Now You Can Get Birth Control Through These Apps*, BUZZFEED (Jan. 11, 2016, 6:38 PM), https://www.buzzfeed.com/stephaniemlee/these-apps-deliver-birth-control-to-your-door?utm_term=.td7637NNJ#.qx1PbXRRO [https://perma.cc/8HKL-2U75].

333. *Id.*

334. *Id.*

335. *Id.*

336. *Id.*

337. *Id.*

338. Belluck, *supra* note 330.

pregnancies. While this is a positive option, there must be larger expansion to make this a viable option for women in every state.

C. Can Acts Produce Action?

In an effort to combat the fatal flaw of the FDA switch process, the Allowing Greater Access to Safe and Effective Contraception Act was introduced.³³⁹ This bill proposed to incentivize drug companies if they sought FDA approval of OTC contraception.³⁴⁰ Unfortunately, this Act was met with disapproval because it did not address insurance coverage for OTC contraception and without a solution, many feared that costs would skyrocket.³⁴¹ A second Act, the Affordability Is Access Act, was later proposed to provide answers for the deficiencies in the previous initiative.³⁴²

The purpose of this Act is to ensure timely access to affordable birth control by requiring coverage without cost-sharing for oral birth control for routine, daily use that is approved by, or otherwise legally marketed under regulation by, the Food and Drug Administration for use by women without a prescription.³⁴³

The Act specifically references that more than 55,000,000 women benefitted from cost-free benefits that amounted to a savings of more than \$483,000,000 in “out-of-pocket costs.”³⁴⁴ While this Act proposed an appropriate solution for access and cost, the bill was not passed.³⁴⁵ The success of future attempts to enact this Act may have an even lower success rate if the ACA is repealed and the birth control mandate ends. Politicians may support OTC access but will be reluctant to vote for an act that reinstates the birth control mandate.

CONCLUSION

After over a decade, birth control is still being shackled by outdated perceptions, corruption, and unnecessary government control.

339. Kimberly Leonard, *On Capitol Hill, a Push to Make the Pill Over the Counter*, U.S. NEWS (June 9, 2015, 7:11 PM), <https://www.usnews.com/news/articles/2015/06/09/on-capitol-hill-a-push-to-get-the-birth-control-pill-over-the-counter> [<https://perma.cc/4NE2-9AS2>].

340. *Id.*

341. *Id.*

342. *Id.*

343. Affordability Is Access Act, S.1532, 114th Cong. § 2 (2015), <http://www.help.senate.gov/imo/media/doc/TAM15414.pdf> [<https://perma.cc/2E36-VPJZ>].

344. *Id.* § 3(7).

345. *S. 1532 (114th): Affordability Is Access Act*, GOVTRACK (Dec. 8, 2016), <https://www.govtrack.us/congress/bills/114/s1532> [<https://perma.cc/Z9ZH-R4ZK>].

The new administration's proposed repeal of the ACA creates an expedient need to find a permanent solution offering accessible and affordable birth control. Unplanned pregnancies are on the rise due to prohibitive costs and poor access, but technological advances and legislation could potentially remedy these problems. Having an unplanned pregnancy rate of fifty percent indicates that prescription-only OC distribution is inadequate and that there are too many barriers blocking women from acquiring contraception. Offering OTC access will remedy this situation and lower the unplanned pregnancy rates.³⁴⁶ In turn, the government will save billions of dollars that can be utilized to lower or fully cover the cost of OC.³⁴⁷

The requirement of yearly pelvic examinations as a prerequisite for an OC prescription is outdated and ineffective. Unrelated testing only serves to alienate women by raising costs, causing undue embarrassment, disproportionately affecting minorities, and by disregarding a woman's autonomy.³⁴⁸ Innovative testing for sexually transmitted diseases, HPV, and cancer offer effective alternatives to these exams and should be utilized. Additionally, gynecological experts and authorities, such as the ACOG, recognize the lack of connection between making OC dependent on unnecessary gynecological services and recommend breaking down these unnecessary barriers.³⁴⁹ The lack of correlation between pelvic examinations and oral birth control, coupled with the availability of effective, substitute testing, demonstrates that these archaic practices should not continue.

Physicians continue to support prescription birth control requirements because of financial incentives.³⁵⁰ The result is that they conduct unnecessary testing, pelvic examinations, and procedures, often disregarding an individual patient's needs.³⁵¹ Pharmaceutical companies are similarly situated because they also gain financially by keeping oral birth control prescription only.³⁵² It is unrealistic to expect biased physicians and drug makers to objectively make determinations regarding OC. The obvious solution is to offer OTC OC to take the power out of the hands of the physicians and place it in those of the patients. This in turn will remove the opportunity to exploit patient care and will lower the incidence of false medical claims.³⁵³

346. ACCESS TO CONTRACEPTION, *supra* note 8, at 2.

347. *Id.*

348. *See, e.g., id.* at 3.

349. OVER-THE-COUNTER ACCESS, *supra* note 15, at 3.

350. Brown, *supra* note 9.

351. *Id.*

352. *Id.*

353. Mencimer, *supra* note 190.

There are too many outside influences that restrict access to birth control. First, the FDA switch process is a broken mechanism that invites corrupt parties and politicians to justify unsubstantiated blocking of OTC access. The FDA switch process cannot be directed by pharmaceutical companies that profit more from keeping drugs out of the competitive market. This is counterintuitive because it stops women from gaining easier access to much needed drugs and does not allow the open market to drive down costs. Second, politicians cannot constantly dictate the fate of birth control. Their continuous meddling only serves to deter possible companies from petitioning for an OTC drug switch. Additionally, constant strife between Democrats and Republicans makes coming to an amicable solution almost impossible. Lastly, refusal clauses provide legal loopholes for religious organizations. Religious beliefs should not dictate whether a woman has access to birth control, and these clauses must be circumvented to ensure that this does not happen.

The barriers to obtaining contraception are infringements on women's rights and are about more than autonomy; they are outright constitutional violations. Sadly, a cause of action challenging constitutionality cannot be brought until the FDA denies a switch application, and a switch application will not be filed because drug makers have no desire to make birth control OTC. This is a purposely constructed self-defeating process. Women are being strong-armed into complying with unconstitutional practices without being offered proper protection. Thus, other alternatives must be utilized to bypass the FDA and stop these egregious violations.

A solution will not be effective enough unless it can permanently secure OTC access to oral contraception nationwide. State initiatives that offer access through pharmacists and online retailers are steps in a positive direction, but they do not offer protection for all women and they have serious application issues. There are too many loopholes and inconsistencies for this to be the most effective solution. Providing permanent legislation that grants OTC contraception access and mandates that the government will substantially or fully pay for OC is the best solution. The Affordability Is Access Act proposes these elements and addresses both cost and access, but the bill died in a 2015 congressional session. In lieu of the ACA repeal, a new Act that omits the coverage requirements has a better chance of approval, but there must be a strong push from Donald Trump and politicians to build the necessary momentum required. Ultimately, online- and pharmacy-prescribed contraception provide an adequate interim option while legislation is being developed, but an Act will be the only means to provide a permanent solution.

