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THE MORAL INTERCEPTION OF ORAL CONTRACEPTION: POTENTIAL CONSTITUTIONAL CLAIMS AGAINST THE FDA'S PRESCRIPTION REQUIREMENT FOR A PROGESTIN-ONLY BIRTH CONTROL PILL

*Scout Richters**

INTRODUCTION

In its July/August 2012 issue, *The Atlantic* magazine named an over-the-counter birth control pill one of the “Biggest Ideas of the Year.”¹ In actuality, the idea of making an oral contraceptive available over the counter is far from novel.² In 1993, *The American Journal of Public Health* published an editorial asserting “safety and compliance concerns are no longer sufficient to justify maintaining the current clinical control over a woman’s contraceptive selection.”³ The editorial went on to declare that “[a] national dialogue on [the issue of over-the-counter oral contraceptives] is overdue.”⁴ Twenty years later, the unavailability of a daily over-the-counter oral contraceptive has the growing

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¹ *The Ideas Report*, ATLANTIC (July 2012), <http://www.theatlantic.com/special-report/ideas-2012/>; Nicole Allan, *Sell the Pill Over the Counter*, ATLANTIC (June 13, 2012), <http://www.theatlantic.com/magazine/archive/2012/07/sell-the-pill-over-the-counter/308997/>.

² See, e.g., James Trussell et al., *Should Oral Contraceptives Be Available Without Prescription?*, 83 AM. J. PUB. HEALTH 1094 (1993).

³ *Id.*

⁴ *Id.*

potential to generate a meritorious constitutional claim implicating the right to privacy and embedded right to use contraception.

While the idea of an over-the-counter birth control pill is not new, there has undoubtedly been a recent resurgence in the movement for such a contraceptive option.⁵ For example, in a 2012 Committee Opinion, the American College of Obstetricians and Gynecologists (ACOG), the largest association of OB/GYNs in the country, announced its support for the sale of over-the-counter oral contraceptives.⁶ The American Medical Association (AMA) followed suit.⁷ During its 2013 annual meeting, the AMA adopted a resolution recommending “that manufacturers of oral contraceptives be encouraged to submit the required application and supporting evidence for the [Food and Drug Administration (FDA)] to consider approving a switch in status from prescription to over-the-counter for such products”⁸

Additionally, recent cases such as *Tummino v. Von*

⁵ See, e.g., Margaret Wentz, *Drop the Paternalism and Sell the Pill over the Counter*, GLOBE & MAIL (Mar. 20, 2012, 2:00 AM), <http://www.theglobeandmail.com/commentary/drop-the-paternalism-and-sell-the-pill-over-the-counter/article536144/>. FDA-approved birth control methods can be divided into several classes. FDA, OFFICE OF WOMEN’S HEALTH, *Birth Control Guide*, available at <http://www.fda.gov/downloads/ForConsumers/ByAudience/ForWomen/FreePublications/UCM356451.pdf> (listing various kinds of oral contraception and how they are used). These classes include “Barrier Methods,” “Hormonal Methods,” “Emergency Contraception,” “Implanted Devices,” and “Permanent Methods.” A daily birth control pill is a hormonal method of contraception. Both the estrogen-progestin combination oral contraceptive as well as the progestin-only variety are currently FDA-approved but are available only with a doctor’s prescription. *Id.*

⁶ AM. COLL. OF OBSTETRICIANS & GYNECOLOGISTS, COMM. ON GYNECOLOGIC PRACTICE, COMM. OP. NO. 544, OVER-THE-COUNTER ACCESS TO ORAL CONTRACEPTIVES 1–3 (2012), available at <http://www.acog.org/~media/Committee%20Opinions/Committee%20on%20Gynecologic%20Practice/co544.pdf>. See also Abby Ohlheiser, *OB/GYNs Back Over-The-Counter Birth Control*, SLATE (Nov. 21, 2012, 11:00 AM), http://www.slate.com/blogs/the_slatest/2012/11/21/over_the_counter_birth_control_backed_by_largest_ob_gyn_group_in_the_country.html.

⁷ Annual Meeting Memorial Resolutions, Am. Med. Ass’n (June 2013), at 464 [hereinafter AMA Resolutions], available at <http://www.ama-assn.org/assets/meeting/2013a/a13-resolutions.pdf>.

⁸ *Id.*

*Eschenbach*⁹ and *Tummino v. Hamburg*¹⁰ suggest that the current movement for expanded contraceptive access has made its way to the courts. In *Hamburg*, plaintiffs initially brought action in 2005 challenging the FDA's decision to deny a citizen petition¹¹ requesting that all women, regardless of age, have over-the-counter access to emergency contraception.¹² Judge Edward R. Korman presided over the *Hamburg* case. He found that the FDA's denial of the citizen petition for over-the-counter emergency contraception rested on unusual actions, deviations from policy, and the unprecedented involvement of the Health and Human Services (HHS) Secretary Kathleen Sebelius.¹³

Judge Korman ultimately instructed the FDA to "make levonorgestrel-based emergency contraceptives¹⁴ available [to

⁹ *Tummino v. Von Eschenbach*, 427 F. Supp. 2d 212 (E.D.N.Y. 2006).

¹⁰ *Tummino v. Hamburg*, 936 F. Supp. 2d 162 (E.D.N.Y. 2013).

¹¹ A citizen petition can be filed with the FDA requesting that the Agency "issue, amend, or revoke a regulation or order or take or refrain from taking any other form of administrative action." 21 C.F.R. § 10.25 (2010). "A Citizen Petition may be filed at anytime" and "must contain certain things such as clearly stating what the Petitioner is asking the FDA to do and a statement of grounds for the request. After the Petition is filed, anyone can file comments about it, and the Dockets Management Branch will then send the Petition and any comments to the appropriate divisions within FDA for resolution." *The Petition Process*, FDA PETITIONS, <http://www.fdapetitions.com/process.html> (last visited Nov. 2, 2013).

¹² *Hamburg*, 936 F. Supp. 2d at 165. See also 21 C.F.R. § 310.200(b) (2010) ("A proposal to exempt a drug from the prescription-dispensing requirement of section 503(b)(1)(C) of the act may be initiated by the Commissioner or by any interested person. Any interested person may file a [Citizen] [P]etition seeking such exemption . . ."). "Emergency contraception, or emergency birth control, is used to help keep a woman from getting pregnant *after* she has had sex without using birth control or if the birth control method failed." *Emergency Contraception (Emergency Birth Control) Fact Sheet*, OFFICE ON WOMEN'S HEALTH, <http://www.womenshealth.gov/publications/our-publications/fact-sheet/emergency-contraception.cfm#a> (last updated Nov. 2, 2011).

¹³ *Hamburg*, 936 F. Supp. 2d at 169–71.

¹⁴ Levonorgestrel "is a progestin hormone that prevents pregnancy by preventing the release of an egg (ovulation) and changing the womb and cervical mucus to make it more difficult for an egg to meet sperm (fertilization) or attach to the wall of the womb (implantation)." *Levonorgestrel Oral*, WEBMD, <http://www.webmd.com/drugs/drug-17833-levonorgestrel+oral.aspx> (last visited

women of all ages] without a prescription”¹⁵ Judge Korman further stated that the FDA did not have the authority to require that Plan B¹⁶ “be sold only at pharmacies and health clinics and that it be kept behind the counter” as had been its practice.¹⁷ This, he held, constituted an impermissible point-of-sale restriction on the distribution of emergency contraception.¹⁸ Though the decision to ban age and point-of-sale restrictions on the sale of Plan B concerned emergency contraception rather than a daily birth control pill (“the pill” or “birth control pill”), it indicates the potential for judicial involvement in the FDA’s future decisions concerning contraceptive access.

While there is strong support for expanded access to contraception, there are staunch opponents to an over-the-counter daily birth control pill.¹⁹ The Catholic Medical Association, for example, ardently opposes the ACOG’s recommendation to make birth control pills available over the counter.²⁰ Catholic obstetricians and gynecologists (OB/GYNs) largely cite safety concerns as their reason for opposition, although one St. Louis OB/GYN, Dr. Richard Brennan, reasoned that “[e]asier access to the pill means more people taking the pill, and in turn, a higher number of contraceptive failure. As we know, greater than [fifty] percent of abortions today are a result of contraceptive failures.”²¹ Opponents also have financial reasons to oppose an over-the-counter birth control pill.²² For example, since pap smears are now

Nov. 2, 2013).

¹⁵ *Hamburg*, 936 F. Supp. 2d at 197.

¹⁶ Plan B is a brand of emergency contraception. *About*, PLAN B ONE-STEP, <http://www.planbonestep.com/about-plan-b-one-step.aspx> (last visited Nov. 3, 2013).

¹⁷ *Hamburg*, 936 F. Supp. 2d at 180, 183.

¹⁸ *Id.* at 183.

¹⁹ *See, e.g.*, Jennifer Brinker, *Easier Access? Statement Pushing Over-the-Counter Access to the Pill Leaves Some Wondering How it Truly Benefits Women*, ST. LOUIS REV. (Dec. 19, 2012), <http://stlouisreview.com/article/2012-12-19/easier-access>.

²⁰ *Id.*

²¹ *Id.*

²² *See* Elisabeth Rosenthal, *Is It Time for Off-the-Shelf Birth-Control Pills?*, N.Y. TIMES (Apr. 20, 2013), <http://www.nytimes.com/2013/04/21/sunday-review/is-it-time-for-off-the-shelf-birth-control-pills.html> (discussing arguments

recommended once every three years, many young women see their gynecologists every year just to obtain birth-control prescriptions.²³ Therefore, if women could obtain the pill over the counter, they would visit their gynecologists less frequently, resulting in a financial loss for the gynecologist.²⁴ Moreover, whether it be to curry favor with constituents like the religious groups and medical professionals described above, or to simply make their own views public, some politicians have recently expressed opposition to expanded access to birth control.²⁵ Therefore, certain medical professionals, religious groups, and politicians oppose an over-the-counter pill for a myriad of reasons.

Though reproductive rights advocates or other interested parties have not yet submitted a citizen petition requesting that a daily birth control pill be switched from prescription to over-the-counter status,²⁶ proponents of such a switch have initiated a dialogue with the FDA.²⁷ For example, on March 23, 2012, the FDA held a public hearing entitled, *Using Innovative Technologies and other Conditions of Safe Use to Expand Which Drug Products Can Be Considered Nonprescription*.²⁸ At the hearing, several presenters urged FDA panelists to consider making a daily hormonal birth control pill available without a prescription.²⁹ Daniel Grossman, Assistant Clinical Professor of Obstetrics and Gynecology at the University of California at San Francisco,

that drug companies and gynecologists could lose business as a result of women gaining easier access to birth-control pills).

²³ *Id.*

²⁴ *Id.*

²⁵ See, e.g., Nick Baumann, *The Republican War on Contraception*, MOTHER JONES (Feb. 9, 2012), <http://www.motherjones.com/politics/2012/02/republican-war-birth-control-contraception>.

²⁶ See, e.g., AMA Resolutions, *supra* note 7, at 464 (recommending that an equivalent manufacturer's application be filed).

²⁷ See FOOD & DRUG ADMIN., CTR. FOR DRUG EVALUATION & RES., FDA-2012-N-0171, USING INNOVATIVE TECHNOLOGIES AND OTHER CONDITIONS OF SAFE USE TO EXPAND WHICH DRUG PRODUCTS CAN BE CONSIDERED NONPRESCRIPTION 7, 37 (2012) [hereinafter FDA Public Hearing 2012], available at <http://www.fda.gov/downloads/Drugs/NewsEvents/UCM301940.pdf>.

²⁸ *Id.* at 1.

²⁹ See *id.* at 38–52.

presented at the hearing.³⁰ During his presentation, Grossman told panelists that despite the safety and popularity of oral contraceptives, the high rate of unintended pregnancies indicates that the prescription requirement may impose a significant barrier to access for some women.³¹

According to Grossman and other proponents of an over-the-counter birth control pill, a progestin-only³² oral contraceptive would be the most likely candidate for initial over-the-counter availability.³³ Because progestin-only oral contraceptives do not contain estrogen, these birth control pills have fewer contraindications than their estrogen-progestin combination counterparts.³⁴ Despite the safety of progestin-only oral contraceptives, the FDA, as evidenced by its treatment of emergency contraception, is unlikely to hurry to make a daily hormonal birth control pill available over the counter. Deviations from policy, including “intolerable delays,” surrounded the FDA’s actions with respect to the petition for unrestricted access to over-

³⁰ *Id.* at 41. Grossman also serves as the coordinator of the Oral Contraceptives Over-the-Counter Working Group, a privately funded coalition of scientists, doctors, and reproductive justice advocates who are currently in the process of evaluating the viability of an over-the-counter oral contraceptive. *Id.* at 41–42.

³¹ *Id.*

³² A progestin-only oral contraceptive is sometimes called the “mini-pill” because, unlike combination pills that contain estrogen and progestin, the mini-pill contains only progestin. *Progestin-Only Contraceptives*, FAMILY DOCTOR, <http://familydoctor.org/familydoctor/en/prevention-wellness/sex-birth-control/birth-control/progestin-only-contraceptives.html> (last visited Oct. 18, 2013). “The Mini-Pill affects the mucus around the cervix and makes it harder for sperm to enter the uterus. It also affects the transport of the egg through the fallopian tubes. In these ways, the Mini-Pill prevents fertilization.” *Mini-Pills*, FEMINIST WOMEN’S HEALTH CTR., <http://www.feministcenter.org/health-wellness-services/comprehensive-gyn/birth-control-options/birth-control-information/101-mini-pills> (last visited Oct. 17, 2013).

³³ See *Progestin-Only Pill Eyed as OTC OC Candidate*, 33 CONTRACEPTIVE TECH. UPDATE 52, 52 (2012).

³⁴ *Progestin-Only Contraceptives*, *supra* note 32. A contraindication is a patient condition that makes a medication unadvisable for use. *Definition of Contraindication*, MEDTERMS, <http://www.medterms.com/script/main/art.asp?articlekey=17824> (last visited Oct. 18, 2013).

the-counter emergency contraception.³⁵ Further, there was unprecedented involvement by the Secretary of Health and Human Services that marked the “first time a cabinet member had ever publicly countermanded a determination by the F.D.A. . . .”³⁶ After the FDA initially agreed to approve an application from Plan B’s manufacturer to make the product available over the counter without age restrictions, the HHS Secretary ordered the FDA Commissioner to deny the application.³⁷ Though the Secretary’s “political interference”³⁸ applied to the manufacturer’s application and not the pending citizen petition, her directive “made it impossible as a practical matter for the FDA to approve the Citizen Petition” that relied on the same data as the manufacturer’s application.³⁹ Though the FDA won’t likely replicate these deviations from policy to delay a hypothetical citizen petition for a daily over-the-counter oral contraceptive, given its history with emergency contraception, it is unlikely that the FDA will decide to initiate actions to make a daily birth control pill available over the counter.

The FDA has not yet been compelled to make a decision or take action with regard to an over-the-counter daily birth control pill because advocates have yet to submit a petition or application. Without a final agency action sufficient to subject the decision to judicial review, plaintiffs are unable to bring a constitutional claim. However, should the FDA take official action and deny an over-the-counter daily birth control pill, then a substantive due process or equal protection claim challenging the constitutionality of the prescription requirement would be possible. The constitutionally recognized right to contraception and the value placed on gender equality in American society bolster the viability of such a claim. Additionally, the safety of the progestin-only pill, the availability of new technology to dispense medicines over the counter, and mounting public policy considerations serve as practical justifications for the elimination of the prescription requirement.

³⁵ *Tummino v. Hamburg*, 936 F. Supp. 2d 162, 198 (E.D.N.Y. 2013).

³⁶ *Id.* at 170.

³⁷ *Id.* at 167.

³⁸ *Id.* at 170.

³⁹ *Id.* at 169.

The FDA's maintenance of the prescription requirement for a progestin-only birth control pill has the potential to generate a meritorious substantive due process or equal protection violation claim. Part I of this Note examines the prevalence of unintended pregnancies in the United States, discusses the ways in which the prescription requirement acts as a barrier to contraceptive access for some women, and finally suggests that, based on the availability of new technology, a progestin-only pill is safe for over-the-counter sale. Part II discusses the FDA and the criteria the Agency uses to switch a medication from prescription to over-the-counter status. Part III assumes *arguendo* that the FDA's maintenance of the prescription requirement would be subject to judicial review and assesses the viability of a substantive due process violation claim and an equal protection violation claim challenging the prescription requirement for a progestin-only pill.

I. UNINTENDED PREGNANCY, BARRIERS TO ACCESS, AND THE SAFETY OF THE PILL

A. Prevalence of Unintended Pregnancies in the United States

Nearly half of all pregnancies in the United States are unintended.⁴⁰ Whether unwanted or mistimed, minority women, young women, and low-income women have the highest rates of these unintended pregnancies.⁴¹ While a significant number of unintended pregnancies end in abortion, many do not.⁴² Births from unwanted pregnancies can be problematic for the child, the

⁴⁰ *Facts on Unintended Pregnancy in the United States*, FACT SHEET (Guttmacher Inst., New York, N.Y.), Oct. 2013, at 1, 1–2 [hereinafter *Facts on Unintended Pregnancy*], available at <http://www.guttmacher.org/pubs/FB-Unintended-Pregnancy-US.pdf>.

⁴¹ *Id.* at 1.

⁴² *Facts on Induced Abortion in the United States*, IN BRIEF (Guttmacher Inst., New York, N.Y.), Oct. 2013, at 1, 1 [hereinafter *Facts on Induced Abortion*], available at http://www.guttmacher.org/pubs/fb_induced_abortion.pdf (“[A]bout four in [ten]” unintended pregnancies “are terminated by abortion Twenty-two percent of all pregnancies (excluding miscarriages) end in abortion.”).

mother, and society at large.⁴³

Unintended pregnancies often produce negative consequences for both the mother and the child. Women who experience unintended pregnancies and choose to give birth are less likely to breastfeed, less likely to receive timely prenatal care, and are more likely to smoke during their pregnancies.⁴⁴ Substantial research indicates that women who experience unplanned pregnancies are more likely than women who planned their pregnancies to experience depression and other mental health problems both during their pregnancies and after giving birth.⁴⁵ In addition, “unintended births have implications for the child that last from early childhood through adolescence and even into adulthood.”⁴⁶ For example, children born as a result of an unintended pregnancy “have poorer physical health than those whose births were intended,” may be “less successful in school,” and, according to one study, are at an increased risk of child abuse.⁴⁷ Studies also indicate that the majority of teen pregnancies are unintended.⁴⁸ “Daughters of teen mothers are three times more likely to become teen parents themselves than girls born to older moms.”⁴⁹ Moreover, “sons born to young teens are significantly more likely to be incarcerated.”⁵⁰

⁴³ See Jennifer McIntosh et al., *Changing Oral Contraceptives from Prescription to Over-the-Counter Status: An Opinion Statement of the Women’s Health Practice and Research Network of the American College of Clinical Pharmacy*, 31 PHARMACOTHERAPY 424, 424 (2011).

⁴⁴ William D. Mosher et al., *Intended and Unintended Births in the United States: 1982–2010*, NAT’L HEALTH STATS. REPS., no. 55, July 24, 2012, at 1, 13.

⁴⁵ Cassandra Logan et al., *The Consequences of Unintended Childbearing: A White Paper*, CHILD TRENDS, INC., May 2007, at 8, available at <http://www.thenationalcampaign.org/resources/pdf/consequences.pdf>.

⁴⁶ *Id.* at 5.

⁴⁷ *Id.* at 6, 7.

⁴⁸ See Lawrence B. Finer & Mia R. Zolna, *Unintended Pregnancy in the United States: Incidence and Disparities, 2006*, 84 CONTRACEPTION 478, 481 (2011).

⁴⁹ Kari Huus, *A Baby Changes Everything: The True Cost of Teen Pregnancy’s Uptick*, NBC NEWS (Feb. 19, 2010), http://www.nbcnews.com/id/35448556/ns/us_news-the_elkhart_project/t/baby-changes-everything-true-cost-teen-pregnancys-uptick.

⁵⁰ *Id.*

Apart from the negative consequences for mothers and children, unplanned pregnancies result in economic costs to the public.⁵¹ In 2006, public funds totaling more than \$11 billion paid the medical expenses for more than two-thirds of the births resulting from unintended pregnancies.⁵² In 2008, the cost of each birth paid for by Medicaid averaged \$12,613, while the contraceptive costs for each patient would have averaged only \$257.⁵³ Therefore, every dollar invested in contraceptives saves \$3.74 in Medicaid expenses.⁵⁴ One study evaluated the short-term monetary public savings of unintended pregnancy prevention through California's Medicaid family planning project.⁵⁵ The authors estimated that by averting approximately 205,000 unintended pregnancies, the public saved more than \$1 billion within the two years following the prevented pregnancies.⁵⁶

Additionally, eliminating the prescription requirement for oral contraceptives would save money on unnecessary medical care. The IMS Institute for Healthcare Informatics estimates that more than \$200 billion was spent on unnecessary health services in 2009.⁵⁷ Incidentally, a blood pressure screening and a breast exam are the "only physical examination steps pertinent to contraindications of oral contraceptives."⁵⁸ Because high blood pressure is only a contraindication for the estrogen-progestin

⁵¹ McIntosh et al., *supra* note 43.

⁵² See Adam Sonfield et al., *The Public Costs of Births Resulting from Unintended Pregnancies: National and State-Level Estimates*, 43 PERSP. SEXUAL & REPROD. HEALTH 94, 98–99 (2011).

⁵³ *Policy Brief: Key Points about Contraception*, BRIEFLY (Nat'l Campaign to Prevent Teen & Unplanned Pregnancy, Washington, D.C.), Sept. 2012, at 1, 2, available at http://www.thenationalcampaign.org/resources/pdf/Briefly_PolicyBrief_FactsAboutContraception.pdf.

⁵⁴ *Id.*

⁵⁵ See Gorette Amaral et al., *Public Savings from the Prevention of Unintended Pregnancy: A Cost Analysis of Family Planning Services in California*, 42 HEALTH SERVICES RES. 1960 (2007).

⁵⁶ *Id.* at 1962, 1970.

⁵⁷ Tara Parker-Pope, *Too Much Medical Care?*, N.Y. TIMES WELL BLOG (July 25, 2012, 12:20 PM), <http://well.blogs.nytimes.com/2012/07/25/too-much-medical-care>.

⁵⁸ Trussell et al., *supra* note 2, at 1095.

combination pill and not a progestin-only pill,⁵⁹ a breast exam would be the sole physical examination relevant to contraindications of progestin-only pills.⁶⁰ The American Cancer Society recommends that the average woman under forty years old have a clinical breast exam only every three years.⁶¹ Additionally, pap smears are now recommended only every three years by the American Congress of Obstetricians and Gynecologists.⁶² Therefore, some women may be forced to undergo unnecessary screenings during at least some of their annual exams simply to obtain a prescription for a birth control pill. Allowing women to forgo unnecessary doctor's appointments, pelvic exams, and other screenings that are conducted before a woman can obtain a prescription for birth control would significantly reduce medical costs.⁶³ Eliminating the prescription requirement for at least some types of oral contraceptives, such as a progestin-only pill, could reduce total expenditures related to unnecessary medical care.⁶⁴

Nonuse and gaps in contraceptive use, particularly those gaps resulting from lapses in birth control prescriptions, are among the primary causes of unintended pregnancies.⁶⁵ Indeed, though only

⁵⁹ Daniel Grossman, *Oral Contraceptives and Conditions of Safe Over-the-Counter Use*, OCS OTC WORKING GRP. (Mar. 23, 2012) [hereinafter Grossman, *Oral Contraceptives*], available at <http://ocsotc.org/wp-content/uploads/2012/03/Grossman-OTC-public-hearing-presentation-23-Mar-12.pdf>.

⁶⁰ See Trussell et al., *supra* note 2, at 1095.

⁶¹ American Cancer Society Guidelines for the Early Detection of Cancer, AM. CANCER SOC'Y, <http://www.cancer.org/healthy/findcancerearly/cancerscreeningguidelines/american-cancer-society-guidelines-for-the-early-detection-of-cancer> (last modified May 3, 2013).

⁶² Announcement, New Cervical Cancer Screening Recommendations from the U.S. Preventative Services Task Force and the American Cancer Society/American Society for Colposcopy and Cervical Pathology/American Society for Clinical Pathology, Am. Cong. of Obstetricians & Gynecologists (Mar. 14, 2012), http://www.acog.org/About_ACOG/Announcements/New_Cervical_Cancer_Screening_Recommendations.aspx [hereinafter New Cervical Cancer Screening Recommendations].

⁶³ See Stephanie Mencimer, *Holding Birth Control Hostage*, MOTHER JONES (Apr. 30, 2012), <http://www.motherjones.com/politics/2012/04/doctors-holding-birth-control-hostage>.

⁶⁴ *Id.*

⁶⁵ See FDA Public Hearing 2012, *supra* note 27, at 47.

sixteen percent of women who are at risk of experiencing an unintended pregnancy do not use any form of contraception for a month or more during the year, these women account for fifty-two percent of all unintended pregnancies.⁶⁶

B. Prescription Requirement as a Barrier to Access

The birth control pill is the most popular method of hormonal contraception.⁶⁷ However, there are barriers that prevent many women, especially minority, young, and low-income women—groups with the highest rates of unplanned pregnancies—from obtaining the pill.⁶⁸ A number of women report difficulty accessing or using methods of birth control as a reason for their nonuse.⁶⁹

Access issues vary greatly among women.⁷⁰ For example, uninsured and low-income women may find it difficult to afford a visit to a primary care physician and in turn, be unable to obtain a prescription for a birth control pill.⁷¹ In one national survey, women who used or wanted to use a prescription contraceptive cited the long wait to get a doctor's appointment, inconvenient office hours, the high cost of seeing a physician, and the pelvic exam requirement—which incidentally does not screen for contraindications to the pill⁷²—as top obstacles in accessing

⁶⁶ *Facts on Unintended Pregnancy*, *supra* note 40, at 4.

⁶⁷ Daniel Grossman, *Should the Contraceptive Pill Be Available Without Prescription?*, 338 BRIT. MED. J., Jan. 24, 2009, at 202, 202 [hereinafter Grossman, *Contraceptive Pill*].

⁶⁸ See FDA Public Hearing 2012, *supra* note 27, at 41–42; *Barriers to Contraceptive Access for Low-Income Women*, QUICK SHEET (Nat'l Inst. for Reprod. Health, New York, N.Y.) [hereinafter *Barriers to Contraceptive Access*], available at <http://www.nirhealth.org/sections/publications/documents/contraceptiveaccessquicksheetFINAL.pdf>.

⁶⁹ Jennifer J. Frost et al., *Improving Contraceptive Use in the United States*, IN BRIEF (Guttmacher Inst., New York, N.Y.), Apr. 2008, at 3, available at <http://www.guttmacher.org/pubs/2008/05/09/ImprovingContraceptiveUse.pdf>.

⁷⁰ See *Barriers to Contraceptive Access*, *supra* note 68.

⁷¹ *Id.*

⁷² Felicia H. Stewart et al., *Clinical Breast and Pelvic Examination Requirements for Hormonal Contraception: Current Practice vs. Evidence*, 285 J. AM. MED. ASSOC. 2232, 2232 (2001).

prescription oral contraceptives.⁷³ In the same survey, forty-one percent of nonusers indicated that they would be more likely to use a patch, vaginal insert, or the pill if it were available without a prescription.⁷⁴ One reason for this may be that young women are concerned about their parents becoming aware of their use of contraception through the insurers' billing practices.⁷⁵ This concern may affect not only teens, but also young adult women given that individuals up to age twenty-six may remain on their parents' insurance plans.⁷⁶ Based on the plethora of barriers to contraceptive access and the privacy issues involved, it is not surprising that young women, uninsured women, and current oral contraceptive users alike have a strong interest in an over-the-counter oral contraceptive.⁷⁷

Federally mandated contraceptive coverage without co-payments through the Patient Protection and Affordable Care Act (PPACA) fails to address all the barriers to access that women may face. Many barriers, as discussed above, are not directly associated with cost.⁷⁸ Moreover, some women will not be covered under the PPACA, including those women who are undocumented immigrants, and women whose insurance plans will be grandfathered into the new system and will be exempt from the contraceptive coverage mandate.⁷⁹ Moreover, churches and places of worship with religious objections are exempt from the contraceptive mandate and are thus not required to pay for their

⁷³ FDA Public Hearing 2012, *supra* note 27, at 42.

⁷⁴ *Id.*

⁷⁵ Michelle Andrews, *How Some Parents Could Learn Adult Daughters' Birth Control Habits*, NPR (Oct. 2, 2012, 10:54 AM), <http://www.npr.org/blogs/health/2012/10/02/162145030/how-some-parents-could-learn-adult-daughters-birth-control-habits>.

⁷⁶ *Id.*

⁷⁷ The Oral Contraceptives Over-the-Counter Working Group conducted a survey and found that young women, uninsured women, and current contraceptive users were interested in an over-the-counter pill. *See* FDA Public Hearing 2012, *supra* note 27, at 42.

⁷⁸ *See* Amanda Dennis et al., *Moving Oral Contraceptives Over-the-Counter: Frequently Asked Questions about What We Know and What We Still Need to Know*, OCS OTC WORKING GRP., http://ocsotc.org/?page_id=7 (last updated Aug. 2013).

⁷⁹ *See id.*

female employees' birth control prescriptions.⁸⁰

Because PPACA eliminates the cost barrier for a significant number of women, ensuring that oral contraceptive costs are kept low if they are indeed switched to over-the-counter status is extremely important to ensure increased access to the pill.⁸¹ Though PPACA only requires coverage for prescription contraceptives, eliminating the prescription requirement would save women the cost of doctor's visits, save time, and increase convenience in obtaining oral contraceptives.⁸² Additionally, commentators have argued that insurance companies should be required to provide coverage for Plan B, over-the-counter emergency contraception.⁸³ This coverage, they argue, would allow women who are unable to afford the over-the-counter retail price of Plan B to obtain the time-sensitive emergency contraceptive sooner because they would no longer need a prescription simply to get insurance coverage.⁸⁴ Similar requests for insurance coverage would likely be made when a daily birth control pill is available over the counter. Even if insurance is not required to cover an over-the-counter pill, the elimination of the prescription requirement allows women to choose to pay for the pill out-of-pocket in order to save the time and expense associated with a doctor's visit.⁸⁵ Thus, although PPACA lowers the cost of contraceptives for a significant number of American women, eliminating the prescription requirement for progestin-only pills is necessary to give women more options for obtaining birth control. Further, an over-the-counter option for birth control pills would address the non-monetary barriers associated with oral

⁸⁰ See Abigail Rubenstein, *Obama Announces Compromise on Birth Control Rule*, LAW360 (Feb. 10, 2012), <http://www.law360.com/articles/308543/obama-announces-compromise-on-birth-control-rule>.

⁸¹ See Dennis et al., *supra* note 78.

⁸² *Id.*

⁸³ Britt Wahlin, *Viewpoint: Why Birth Control Needs to Be Both Over the Counter and on Your Insurance Plan*, THINKPROGRESS (Apr. 30, 2013, 12:00 PM), <http://thinkprogress.org/health/2013/04/30/1934631/viewpoint-birth-control-otc/>.

⁸⁴ *Id.*

⁸⁵ See *Barriers to Contraceptive Access*, *supra* note 68.

contraceptive access.⁸⁶

C. *A Progestin-Only Pill Could Be Safely Dispensed Over the Counter Using New Technology*

In 1960, the FDA approved the birth control pill for contraceptive use.⁸⁷ Since then, it has generally been regarded as very safe.⁸⁸ Based on its lower prevalence of contraindications, a progestin-only pill, as opposed to an estrogen-progestin combination pill, is the most likely candidate for initial over-the-counter approval.⁸⁹ Progestin-only oral contraceptives are ninety-six percent effective at preventing pregnancy and work by thickening the mucus around a woman's womb while simultaneously thinning the womb's lining.⁹⁰ This makes it difficult for sperm to enter and for an egg to attach to the lining.⁹¹ Progestin-only pills sometimes prevent the release of an egg altogether, much like an estrogen-progestin combination oral contraceptive.⁹² Though perhaps slightly less effective at preventing pregnancy than estrogen-progestin combination pills, progestin-only pills are safer for smokers, individuals with high blood pressure, those prone to clotting abnormalities, and women who have a family history of heart attack or stroke.⁹³ Indeed, *Hamburg* approved an emergency contraceptive pill containing the progestin levonorgestrel for over-the-counter sale without age or

⁸⁶ See Dennis et al., *supra* note 78.

⁸⁷ Alexander Nikolchev, *A Brief History of the Birth Control Pill*, PBS (May 7, 2010), <http://www.pbs.org/wnet/need-to-know/health/a-brief-history-of-the-birth-control-pill/480/>.

⁸⁸ See, e.g., Grossman, *Contraceptive Pill*, *supra* note 67, at 202; Trussell et al., *supra* note 2, at 1095.

⁸⁹ See *Progestin-Only Pill Eyed as OTC OC Candidate*, *supra* note 33. The progestin-only pill "very slightly increases the risk of ectopic pregnancy" and users may experience irregular bleeding. *Mini-Pills*, *supra* note 32.

⁹⁰ *Progestin-Only Contraceptives*, *supra* note 32; *Understanding the Minipill*, BIRTH, [http://www.birth.com.au/Sex-and-contraception/Minipill?](http://www.birth.com.au/Sex-and-contraception/Minipill?p=1) p=1 (last updated Dec. 28, 2012).

⁹¹ *Progestin-Only Contraceptives*, *supra* note 32.

⁹² See *id.*

⁹³ *Understanding the Minipill*, *supra* note 90.

point of sale restrictions.⁹⁴ Levonorgestrel is also used in many daily progestin-only oral contraceptives.⁹⁵

Besides preventing pregnancy, progestin-only birth control pills also have health benefits.⁹⁶ Extensive research indicates that the progestin-only birth control pill regulates the menstrual cycle, lowers the risk of anemia, and decreases the “risk of endometrial cancer and pelvic inflammatory disease.”⁹⁷ In addition to improved physical health, women may benefit from using birth control in other ways.⁹⁸ A University of Michigan study, though not specific to progestin-only pills, found that women who begin taking hormonal birth control pills at an early age are more likely to have higher paying careers later in their lives than women who begin taking the pill at an older age.⁹⁹ The reason, according to the study, is that “[a]s the Pill provided women with cheaper and more effective control over childbearing in late adolescence, they invested more in their human capital and careers.”¹⁰⁰

Several studies have shown that women are able to take a daily birth control pill safely without physician involvement.¹⁰¹ In determining whether to write a prescription for an oral contraceptive, a physician relies mostly on a patient’s medical history.¹⁰² Unsurprisingly, research shows that women who obtained oral contraception after a doctor’s visit were no less likely to have contraindications to the pill than those women who obtained the pill directly from a pharmacy.¹⁰³ In a study examining

⁹⁴ See *Tummino v. Hamburg*, 936 F. Supp. 2d 162, 197 (E.D.N.Y. 2013).

⁹⁵ FDA Public Hearing 2012, *supra* note 27, at 39, 41.

⁹⁶ See *Mini-Pills*, *supra* note 32.

⁹⁷ *Id.*

⁹⁸ See *Birth Control Access Boosts Women’s Wages, Study Finds*, HUFFINGTON POST (Mar. 26, 2012, 2:07 PM), http://www.huffingtonpost.com/2012/03/26/birth-control-access-womens-wages_n_1380250.html.

⁹⁹ *Id.*

¹⁰⁰ Martha J. Bailey et al., *The Opt-in Revolution? Contraception and the Gender Gap in Wages* 26 (Nat’l Bureau of Econ. Research, Working Paper No. 17922, 2012), available at http://www.nber.org/papers/w17922.pdf?new_window=1.

¹⁰¹ See, e.g., Grossman, *Contraceptive Pill*, *supra* note 67, at 202–03.

¹⁰² Trussell et al., *supra* note 2, at 1095.

¹⁰³ Grossman, *Contraceptive Pill*, *supra* note 67, at 202–03. In Mexico, where women can obtain oral contraceptives over-the-counter, women who get

women's continued use of oral contraceptives, discontinuing the pill was more common among women who obtained the contraceptive via a doctor's prescription than those who acquired the pill over the counter.¹⁰⁴ The findings, the researchers suggest, indicate that "removing the prescription requirement for [oral contraceptive pills (OCPs)], in addition to making it easier for women to initiate OCP use, would not have an adverse impact on continuation and might well improve it."¹⁰⁵

Emerging technology could be used to increase access to the pill and improve efficiency in dispensing an oral contraceptive over the counter.¹⁰⁶ At the FDA's 2012 public hearing, Elizabeth Dawes, a senior associate with the non-profit Reproductive Health Technologies Project, explained that technology could improve the distribution of oral contraceptives.¹⁰⁷ According to Dawes, the improved efficiency will be necessary given that more individuals will likely seek medical care after receiving insurance coverage through PPACA.¹⁰⁸ During her presentation, Dawes described new technology such as "electronic kiosks, retail clinics, and self-dispensing machines" that are currently being developed to dispense contraceptives.¹⁰⁹ She explained that research shows these methods of access "to be acceptable and appropriate for clients willing to forego an in-person consultation with the clinical provider."¹¹⁰ Dawes even said that for patients who would like professional guidance in their decision to use oral contraceptives, technology could be used to increase convenience.¹¹¹ As Dawes

the pill over-the-counter are no more likely to experience side effects than women who had a doctor's appointment before using the pill. *Id.* at 202.

¹⁰⁴ Joseph E. Potter et al., *Continuation of Prescribed Compared With Over-the-Counter Oral Contraceptives*, 117 *OBSTETRICS & GYNECOLOGY* 551, 551 (2011). The study compared 514 women who obtained over-the-counter pills in Mexico and 532 women who obtained prescription birth control pills in El Paso, Texas. *Id.*

¹⁰⁵ *Id.* at 556.

¹⁰⁶ FDA Public Hearing 2012, *supra* note 27, at 39.

¹⁰⁷ *See id.* at 38–39.

¹⁰⁸ *Id.* at 38.

¹⁰⁹ *See id.* at 39.

¹¹⁰ *Id.*

¹¹¹ *Id.*

asserted, the “expanded use of telephone or provider-to-patient video interface” has been shown to be effective at producing both patient satisfaction and positive health outcomes while simultaneously lowering the cost of health care.¹¹²

This type of technology could improve the safe distribution of an over-the-counter birth control pill.¹¹³ Dr. Eleanor Schwarz, the Director of Women’s Health Research for the Center for Research on Health Care at the University of Pittsburgh, presented at the same hearing.¹¹⁴ Schwarz described a study in which computerized kiosks were programmed to screen for all of the World Health Organization’s identified contraindications to birth control pills containing estrogen.¹¹⁵ The kiosk featured text in both English and Spanish and provided an audio option for individuals with restricted literacy.¹¹⁶ The kiosk provided information about seven methods of contraception and women, after learning about these methods, had the option to request a prescription.¹¹⁷ Upon this request, the kiosk asked women questions designed to screen them for contraindications to the method they had selected.¹¹⁸ If the kiosk determined that the method was safe for the particular woman, it printed a prescription, which also included the screening information.¹¹⁹ The patient then gave this information to a health care provider who would fill the prescription after checking the patient’s blood pressure.¹²⁰

Most women who used the kiosk had a positive experience with the system.¹²¹ Women who used the kiosk reported that it provided them with trustworthy information and was easy to

¹¹² *Id.*

¹¹³ *See id.* at 47.

¹¹⁴ *Id.*

¹¹⁵ *Id.* at 48.

¹¹⁶ *Id.*

¹¹⁷ *Id.*

¹¹⁸ *Id.*

¹¹⁹ *Id.*

¹²⁰ *Id.* The blood pressure screening was done because hypertension is a contraindication to the estrogen-progestin combination pill. Hypertension is not a contraindication to a progestin-only oral contraceptive. *See Grossman, Oral Contraceptives, supra* note 59.

¹²¹ *See* FDA Public Hearing 2012, *supra* note 27, at 48.

understand and use.¹²² The success of the kiosk system led Schwarz and her team to conduct additional research.¹²³ Using a sample of more than 800 women in four different health care settings, half were randomly assigned to the contraceptive kiosk.¹²⁴ Minority women, women with low levels of education, and women who hadn't used a method of contraception during their last intercourse—groups with high rates of unintended pregnancies—were especially likely to seek prescriptions after using the kiosks.¹²⁵

As indicated by extensive research and the low prevalence of contraindications, progestin-only oral contraceptives are generally accepted as safe.¹²⁶ Indeed, as discussed above, a progestin-only pill, albeit an emergency contraceptive variety, is already available over the counter.¹²⁷ Further, because physicians heavily rely on the medical history provided by the patient herself in determining whether or not to prescribe a progestin-only birth control pill, a doctor's involvement in a woman's decision to use this method of oral contraception is generally unnecessary.¹²⁸ Technology that is in development or already available could be used to aid in the efficient and safe distribution of a daily progestin-only pill.¹²⁹ Though the kiosk system described above would be expensive to install widely, it provides an example of how emerging technology could work to carefully dispense an already safe drug to those who need it. The FDA typically uses labeling to safely distribute over-the-counter drugs,¹³⁰ and the same would certainly be done for a

¹²² *Id.*

¹²³ *Id.*

¹²⁴ *Id.* at 48–49.

¹²⁵ *Id.* For example, “fifty-seven percent of women who requested contraceptive prescriptions reported they'd had one or more episode of unprotected sex in the last month.” *Id.* at 49.

¹²⁶ See Trussell et al., *supra* note 2, at 1095.

¹²⁷ *Tummino v. Hamburg*, 936 F. Supp. 2d 162, 197 (E.D.N.Y. 2013).

¹²⁸ Trussell et al., *supra* note 2, at 1095.

¹²⁹ See FDA Public Hearing 2012, *supra* note 27, at 39, 48.

¹³⁰ See *Hamburg*, 936 F. Supp. 2d at 180. (“The FDA’s willingness to rely on labeling to make [‘Alli, a weight-loss drug that is likely to attract teenage purchasers’ and ‘cough syrup containing dextromethorphan, which is regularly abused by teenagers,’ for example] available for sale over-the-counter without

birth control pill when it is made available over the counter. Therefore, whether it be through a high-tech kiosk or the FDA's more traditional labeling approach, a progestin-only oral contraceptive could be safely dispensed over the counter.

II. THE FDA AND CRITERIA FOR A PRESCRIPTION TO OVER-THE-COUNTER SWITCH

On June 30, 1906, Congress passed the Food and Drug Act.¹³¹ Approved by President Theodore Roosevelt, the Act banned states from buying or selling mislabeled or tainted drugs, food, and drinks.¹³² The Federal Food, Drug, and Cosmetic Act (FDCA), passed in 1938, required that new drugs meet a threshold level of safety before they were approved by the FDA.¹³³ In 1951, the Durham-Humphrey Amendment to the FDCA required that any "habit-forming or potentially harmful [drug] . . . be dispensed under the supervision of a health practitioner as a prescription drug."¹³⁴

The FDA is permitted to exempt drugs from the prescription requirement when the Agency determines that such a requirement is "not necessary for the protection of the public health."¹³⁵ Drugs can be fully or partially switched from prescription to over the counter status or a new drug can be directly classified as over the counter.¹³⁶ Because the FDA has not set forth a rigid test to

any age or point-of-sale restrictions, even though they are unsafe for unsupervised use by young adolescents, stands in stark contrast to its refusal to make equally available concededly safe and time-sensitive levonorgestrel-based emergency contraceptives.").

¹³¹ *History of the FDA and Drug Regulation in the United States*, FDA, at 1, available at <http://www.fda.gov/downloads/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/UnderstandingOver-the-CounterMedicines/ucm093550.pdf>.

¹³² *Id.*

¹³³ *Id.* at 2.

¹³⁴ *This Week in FDA History - Oct. 26, 1951*, FDA, <http://www.fda.gov/AboutFDA/WhatWeDo/History/ThisWeek/ucm117875.htm> (last updated May 20, 2009).

¹³⁵ 21 U.S.C. § 353 (2012).

¹³⁶ *Regulation of Nonprescription Drug Products*, FDA, available at <http://www.fda.gov/downloads/AboutFDA/CentersOffices/CDER/UCM148055>.

determine whether a prescription drug should be made available over the counter, drugs are made available without a prescription on an ad hoc basis.¹³⁷ There are, however, several criteria that are traditionally applied in making such a determination.¹³⁸ Factors used in the FDA's determination include: (1) whether or not the drug has significant toxicity in the event of an overdose, (2) whether the drug is addictive, (3) whether users are able to "self-diagnose conditions for appropriate use," (4) whether users are able to take the medication safely without a medical professional's screening, and (5) whether users are able to take the drug as directed without the explanation of a healthcare provider.¹³⁹

Progestin-only birth control pills easily satisfy the first three factors. Birth control pills are not significantly toxic in the event of an overdose, are not addictive,¹⁴⁰ and, as previously discussed, women are able to self-diagnose their own need to use oral contraception.¹⁴¹ Research indicates that the remaining two factors could also be satisfied.¹⁴² Recent studies and events illustrate that women can safely use progestin-only contraceptives without a doctor's screening. This is evidenced by the availability of technology that could be used to screen for contraindications and studies that reveal that women obtaining progestin-only pills over the counter are no more likely to experience adverse reactions than women who obtained the contraceptive with a prescription.¹⁴³ The final factor, the ability to take medicine without the explanation of a healthcare provider, could be met with clear and informative labeling as well as with new technology such as the kiosks discussed above.¹⁴⁴ Therefore, a progestin-only birth control pill can effectively meet each of the factors the FDA considers in

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¹³⁷ See, e.g., Lars Noah, *Treat Yourself: Is Self-Medication the Prescription for what Ails American Health Care?*, 19 HARV. J.L. & TECH. 359, 366–67 (2006).

¹³⁸ Grossman, *Oral Contraceptives*, *supra* note 59.

¹³⁹ *Id.*

¹⁴⁰ FDA Public Hearing 2012, *supra* note 27, at 42.

¹⁴¹ *Id.*

¹⁴² See *id.* at 43.

¹⁴³ See *id.* at 43, 48.

¹⁴⁴ See McIntosh et al., *supra* note 43, at 433.

determining whether a drug should be made available over the counter.

III. POTENTIAL CONSTITUTIONAL CHALLENGES TO THE PRESCRIPTION REQUIREMENT FOR A PROGESTIN-ONLY BIRTH CONTROL PILL

In order to consider potential constitutional claims, several requirements with regard to procedure must first be met. The first requirement is that the FDA Commissioner puts forth an exemption proposal, a drug sponsor files the requisite supplemental drug application, or a citizen group submits a petition to switch a progestin-only oral contraceptive from prescription to over-the-counter status.¹⁴⁵ Second, the FDA's decision to deny such a proposal or application must constitute a final agency action.¹⁴⁶ If these requirements were met, the FDA action would be subject to judicial review. The plaintiffs' hypothetical constitutional claim would not be reviewed under the same standard used in *Hamburg*, the arbitrary and capricious standard.¹⁴⁷ Because the claim would be a constitutional one, not merely one challenging an agency action as was the case in *Hamburg*, the less agency-deferential de novo review would be applicable to plaintiffs' claim.¹⁴⁸

The FDA's decision to reject a petition allowing over-the-counter emergency contraception, as discussed in *Hamburg*, may forecast its future actions with respect to a daily birth control pill.¹⁴⁹ The FDA may again deviate from policy to deny a petition

¹⁴⁵ 21 U.S.C. § 353(b)(3) (2012); 21 C.F.R. § 10.25(a) (2009); 21 C.F.R. § 310.200(b) (2009).

¹⁴⁶ 5 U.S.C. § 704 (2012).

¹⁴⁷ *Id.* § 706 (2012). *See also* Tummino v. Hamburg, 936 F. Supp. 2d 162, 184 (E.D.N.Y. 2013).

¹⁴⁸ 5 U.S.C.A. § 706 (2012); George v. United States, 901 F. Supp. 2d 1179, 1184 (N.D. Cal. 2012) (stating that “[i]t matters not whether the claim is styled under the [Administrative Procedure Act] or the Constitution itself,” the same standard of review applies in both cases).

¹⁴⁹ *See Hamburg*, 936 F. Supp. 2d at 170 (“The denial of the [Supplemental New Drug Application] and Citizen Petition was accomplished by unexplained departures from a number of established policies and practices followed by the

as it did for emergency contraception. Such actions by the FDA would be highly scrutinized in a hypothetical case.¹⁵⁰ In *Hamburg*, Judge Korman mentioned that because “the constitutional right to obtain and use contraceptives” was implicated by the restriction on the sale of Plan B, “an even more careful examination of [the unprecedented intervention of the HHS Secretary]” was justified.¹⁵¹ Indeed, a constitutional claim invoking the right to contraception would be a next logical step for reproductive rights advocates in light of *Hamburg*. In *Hamburg*, plaintiffs were successful because the FDA’s actions were deemed arbitrary and capricious.¹⁵² In the context of a daily pill, plaintiffs alleging a constitutional claim would enjoy a stricter standard, though any similar arbitrary and capricious FDA actions would lend support to the constitutional claim.¹⁵³ Assuming the above procedural requirements were satisfied, any decision by the FDA to deny a petition or application for an over-the-counter daily birth control pill, particularly after *Hamburg*, has the potential to generate a viable constitutional claim.

A. Fifth Amendment Substantive Due Process

Advocates for an over-the-counter progestin-only birth control pill may choose to allege a government violation of the Fifth Amendment’s substantive due process guarantee. Under this framework, plaintiffs would need to first assert government infringement on a fundamental right.¹⁵⁴ If the right is deemed fundamental, the government then bears the burden to show that the prescription requirement for a progestin-only oral contraceptive is supported by a compelling interest.¹⁵⁵ Additionally, the

FDA.”).

¹⁵⁰ *See id.*

¹⁵¹ *Id.* at 186.

¹⁵² *Id.* at 184.

¹⁵³ *Id.* In *Hamburg*, section 706(2)(A) applied. This section permits a district court to set aside agency actions that are “arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.” 5 U.S.C. § 706(2)(A).

¹⁵⁴ ERWIN CHERMERINSKY, CONSTITUTIONAL LAW PRINCIPLES AND POLICIES 814 (Vicki Been et al. eds., 4th ed. 2011).

¹⁵⁵ *Id.*

government must show that the prescription requirement for a progestin-only oral contraceptive is narrowly tailored to serve that articulated compelling interest.¹⁵⁶

Plaintiffs could argue that the fundamental right to privacy is implicated in the prescription requirement for a daily progestin-only birth control pill. The U.S. Supreme Court's decisions in *Griswold v. Connecticut*,¹⁵⁷ *Eisenstadt v. Baird*,¹⁵⁸ and *Carey v. Population Services International*¹⁵⁹ support the assertion that a fundamental right is at issue.¹⁶⁰ *Griswold* classified the right to contraception as a right imbedded in the right to privacy by reasoning that, among married couples, the decision to use contraceptives fell within a zone of privacy.¹⁶¹ Afterwards, *Eisenstadt* and *Carey* expanded and clarified the right to contraception.¹⁶² In *Eisenstadt*, the Court extended the right to use contraception, encompassed in the right to privacy, to unmarried people using an equal protection analysis.¹⁶³ In doing so, the Court re-characterized the right to contraception as a right to procreative privacy, rather than simply a right to marital privacy as described in *Griswold*.¹⁶⁴ In *Eisenstadt*, the Court reasoned 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."¹⁶⁵ Though it could be argued that the right to contraception imbedded in the fundamental right to privacy does not necessarily indicate that there is a right to access

¹⁵⁶ *Id.* at 817.

¹⁵⁷ *Griswold v. Connecticut*, 381 U.S. 479 (1965).

¹⁵⁸ *Eisenstadt v. Baird*, 405 U.S. 438 (1972).

¹⁵⁹ *Carey v. Population Servs. Int'l*, 431 U.S. 678 (1977).

¹⁶⁰ These cases have been read to imply that the fundamental right to privacy includes the right to use contraception. See CHEMERINSKY *supra* note 154, at 837–38 (“[A] basic right, such as the ability to control procreation, is constitutionally protected . . .”).

¹⁶¹ *Griswold*, 381 U.S. at 485.

¹⁶² See *Carey*, 431 U.S. at 701; *Eisenstadt*, 405 U.S. at 453–55.

¹⁶³ *Eisenstadt*, 405 U.S. at 453.

¹⁶⁴ *Id.*

¹⁶⁵ *Id.*

contraception, the Court's decision in *Carey* is telling.¹⁶⁶ There, the Court decided that a law limiting the display, advertisement, and distribution of contraceptives was unconstitutional and held that government restrictions on contraceptive access must meet strict scrutiny.¹⁶⁷ The Court reasoned that "[t]his is so not because there is an independent fundamental 'right of access to contraceptives,' but because such access is essential to exercise of the constitutionally protected right of decision in matters of childbearing."¹⁶⁸ Following this line of cases, the Court appears willing to include the right to use contraception "free from 'unjustified intrusion by the state'"¹⁶⁹ as part of the right to privacy.

*Roe v. Wade*¹⁷⁰ and *Planned Parenthood v. Casey*¹⁷¹ also provide guidance in this analysis and suggest that a fundamental right is implicated in the prescription requirement for a progestin-only birth control pill. Both cases, though relating to abortion rights, suggest that women have fundamental rights concerning their reproductive decisions.¹⁷² In *Roe*, the Court determined that the "right of privacy . . . is broad enough to encompass a woman's decision whether or not to terminate her pregnancy."¹⁷³ It follows that a woman's decision whether or not to prevent pregnancy in the first place is also a fundamental right encompassed in the right to privacy.¹⁷⁴ In *Casey*, the Court recognized that "choices central to dignity and autonomy are central to the liberty [protected by the Constitution]" and asserted that, "[a]t the heart of liberty is the right to define one's own concept of existence, of meaning, of the

¹⁶⁶ See *Carey*, 431 U.S. at 697–98.

¹⁶⁷ *Id.* at 700–02. Strict scrutiny is "the most intensive type of judicial review." CHEMERINSKY, *supra* note 154, at 554. Under this standard, "the court must regard the government's purpose as vital" and the law must be "the least restrictive or least discriminatory alternative" in order for it to be upheld. Strict scrutiny is used in cases of "discrimination based on race or national origin," for example, as well as when there is an "interference with fundamental rights." *Id.*

¹⁶⁸ *Carey*, 431 U.S. at 688.

¹⁶⁹ *Id.* at 687.

¹⁷⁰ *Roe v. Wade*, 410 U.S. 113 (1973).

¹⁷¹ *Planned Parenthood of Southeastern Pa. v. Casey*, 505 U.S. 833 (1992).

¹⁷² See *Casey*, 505 U.S. at 833; *Roe*, 410 U.S. at 113.

¹⁷³ *Roe*, 410 U.S. at 153.

¹⁷⁴ See *id.*

universe, and of the mystery of human life.”¹⁷⁵ Though *Roe* and *Casey* concern abortion rights, the reasoning used in both cases is applicable to the right to contraception as fundamental under the right to privacy: women have the right to control their reproduction and make autonomous decisions in these matters.¹⁷⁶

The rights to contraceptive access, autonomy, and personal dignity have been expressly articulated by the Court.¹⁷⁷ Plaintiffs challenging the prescription requirement using the Fifth Amendment’s substantive due process guarantee should be able to articulate a fundamental right at issue. After plaintiffs assert that the prescription requirement for a progestin-only oral contraceptive implicates the fundamental right to privacy and imbedded right to contraception, the burden would then shift to the government.¹⁷⁸ The government must show a compelling interest behind the prescription requirement and subsequently show that the regulation was narrowly tailored to serve that compelling interest.¹⁷⁹

The FDA would most likely assert that the prescription requirement serves the government’s compelling interest in protecting women’s health.¹⁸⁰ *Roe* established that “the State [has] an important and legitimate interest in preserving and protecting the health of the pregnant woman . . . and that it has still another important and legitimate interest in protecting the potentiality of human life.”¹⁸¹ It is likely that the government’s interest in protecting women’s health would be found to be sufficiently compelling and would thus satisfy the first prong.¹⁸²

¹⁷⁵ *Casey*, 505 U.S. at 851.

¹⁷⁶ *See id.* at 833; *Roe*, 410 U.S. at 113.

¹⁷⁷ *See, e.g., Casey*, 505 U.S. at 833; *Eisenstadt v. Baird*, 405 U.S. 438 (1972).

¹⁷⁸ *See* CHEMERINSKY, *supra* note 154, at 817.

¹⁷⁹ *See id.*

¹⁸⁰ *Roe*, 410 U.S. at 162.

¹⁸¹ *Id.*

¹⁸² The Court in *Roe* also mentioned a government interest in “maintaining medical standards.” *Roe*, 410 U.S. at 154–55. It stated, “[t]he State has a legitimate interest in seeing to it that abortion, like any other medical procedure, is performed under circumstances that insure maximum safety for the patient. This interest obviously extends at least to the performing physician and his staff, to the facilities involved, to the availability of after-care, and to adequate provision for any complication or emergency that might arise.” *Id.* at 149–50.

If a court determined that the government had a compelling interest in women's health, the FDA would have the burden to show that the prescription requirement for progestin-only oral contraceptives was narrowly tailored to serve that interest.¹⁸³ The government would be unable to show that the prescription requirement is narrowly tailored to serve its compelling interest. The prescription requirement is over-inclusive in that it applies to all women, rather than exclusively to the small percentage of women with contraindications to a progestin-only pill.¹⁸⁴ For other drugs, the FDA addresses similar concerns about contraindications in a small subset of the population through labeling, not by excluding these drugs from over-the-counter distribution.¹⁸⁵ Although women who obtain a prescription for a progestin-only oral contraceptive would be afforded the opportunity to consult with their healthcare provider regarding their decision to use this method of contraception, evidence shows that technology within pharmacies could provide the same level of guidance.¹⁸⁶ Women are able to assess their own need to use oral contraceptives and regardless of whether women consult with a physician, the daily administration of the pill is left in their hands. Healthcare providers determine whether a woman should be prescribed birth control, especially a progestin-only pill, almost entirely by hearing a recitation of the woman's medical history. Women could just as easily read labels that explain contraindications, as they are asked to do with other FDA-approved over-the-counter products, and then make an informed decision about whether or not to take the

The government could use this line of reasoning to argue that the prescription requirement serves its interest of maintaining such standards by ensuring that doctors act as gatekeepers to oral contraception that could be dangerous for some women.

¹⁸³ See CHEMERINSKY, *supra* note 154, at 817.

¹⁸⁴ “[A] classification that is substantially overinclusive or underinclusive tends to undercut the governmental claim that the classification serves legitimate” purposes. *Bernal v. Fainter*, 467 U.S. 216, 221 (1984) (citation omitted).

¹⁸⁵ See *Tummino v. Hamburg*, 936 F. Supp. 2d 162, 180 (E.D.N.Y. 2013). For example, the FDA relies on labeling, rather than point-of-sale or age restrictions, for certain drugs that may be dangerous for younger users, in order to allow these products to be available over the counter. *Id.*

¹⁸⁶ FDA Public Hearing 2012, *supra* note 27, at 39.

pill.¹⁸⁷

In addition, emerging technology could improve the safe distribution of an over-the-counter pill, further undermining the government's argument that the prescription requirement is narrowly tailored to protect women's health. One example is that women could use the kiosk system, discussed above in Part I.C., to input their health histories and undergo screenings for contraindications as well as subsequently consult with a pharmacist in the same location where they would obtain the pill. Regarding these kiosks, clearly and carefully worded questions, a private comfortable setting, as well as features for non-English speakers and individuals with limited literacy have the potential to not only meet, but improve the accuracy and thoroughness of the medical history information given by a woman seeking oral contraception. In this manner, emerging technology could be used to provide convenient and safe access to oral contraceptives.

The prescription requirement for birth control pills ultimately results in more health risks and poorer health outcomes for women than they would face in the absence of such a requirement.¹⁸⁸ This is perhaps the strongest argument as to why the prescription requirement for a progestin-only birth control pill is not narrowly tailored to serve the government's interest in protecting women's health. As suggested above, there is also substantial evidence to suggest that oral contraceptives actually improve a woman's health by, for example, lowering her risk of contracting endometrial cancer and pelvic inflammatory disease.¹⁸⁹

Aborting a pregnancy or carrying a pregnancy to full term both pose higher risks for a woman's health than using oral contraception.¹⁹⁰ Unintended pregnancies, many of which could be

¹⁸⁷ The FDA has established the practice of relying on labeling to inform consumers and allow drugs to be sold over-the-counter. *Hamburg*, 936 F. Supp. 2d at 173.

¹⁸⁸ See, e.g., Logan et al., *supra* note 45, at 1, 5, 7.

¹⁸⁹ See, e.g., *Mini-Pills*, *supra* note 32; *Oral Contraceptives and Cancer Risk*, NAT'L CANCER INST., <http://www.cancer.gov/cancertopics/factsheet/Risks/oral-contraceptives> (last visited Oct. 18, 2013).

¹⁹⁰ See Genevra Pittman, *Abortion Safer than Giving Birth: Study*, REUTERS (Jan. 23, 2012), <http://www.reuters.com/article/2012/01/23/us-abortion-idUSTRE80M2BS20120123>; *Facts on Induced Abortion*, *supra* note 42, at 2.

prevented with greater availability of oral contraceptives, are especially risky for a woman's health because women experiencing an unplanned pregnancy are less likely to seek appropriate prenatal care.¹⁹¹ Also, "[w]omen with unwanted, mistimed, or unplanned births demonstrate lower levels of general psychological well-being during pregnancy and following the birth, and a higher risk of depression"¹⁹² For children born as a result of these pregnancies, "unintendedness seems to be most closely associated with poor physical health, poor mental health, a less close mother-child relationship, and poor educational outcomes."¹⁹³ Moreover, unintended pregnancies resulting in births produce high costs to society as a whole.¹⁹⁴ Considering the possible health benefits of birth control, the dangers of unplanned pregnancies, and the emergence of technology to provide safeguards to over-the-counter distribution, the prescription requirement is not narrowly tailored to serve the government's interest in protecting women's health.

The hypothetical plaintiffs would likely be able to show that the prescription requirement infringes on the fundamental right to privacy under the substantive due process guarantee.¹⁹⁵ While the government would plausibly be able to show a compelling interest in maintaining the prescription requirement for progestin-only oral contraceptives, the government could not demonstrate how the requirement was narrowly tailored to protect women's health. Plaintiffs would thus have a viable chance of success in alleging a Fifth Amendment substantive due process violation present in the prescription requirement for a progestin-only pill.

B. Classification-Based Equal Protection

A challenge to the prescription requirement for a progestin-only oral contraceptive could also be brought under the equal

Though first trimester abortions pose minimal risks, "[t]he risk of death associated with abortion increases with the length of pregnancy" *Id.*

¹⁹¹ Logan et al., *supra* note 45, at 1, 3.

¹⁹² *Id.* at 8.

¹⁹³ *Id.* at 5–6.

¹⁹⁴ *Id.* at 1, 6, 8; McIntosh et al., *supra* note 43, at 424.

¹⁹⁵ See *Carey v. Population Servs. Int'l*, 431 U.S. 678 (1977); *Eisenstadt v. Baird*, 405 U.S. 438 (1972); *Griswold v. Connecticut*, 381 U.S. 479 (1965).

protection clause of the Fourteenth Amendment.¹⁹⁶ Unlike the substantive due process clause, the equal protection clause does not create substantive individual rights.¹⁹⁷ Rather, the equal protection clause asks whether the government has a sufficient purpose in imposing a law that classifies and distinguishes between groups of people.¹⁹⁸ When regulations are facially neutral, as is the case with the prescription requirement for a progestin-only pill, the plaintiff must show that the law has both a disparate impact and a discriminatory purpose.¹⁹⁹

1. Gender Classification Claim

In equal protection cases alleging classification based on gender, intermediate scrutiny²⁰⁰ is used.²⁰¹ Under intermediate scrutiny, if the law at issue is facially neutral as is the prescription requirement, the plaintiffs must articulate that the law is purposively discriminatory and that the law has a discriminatory effect on males or females.²⁰² Then, the burden shifts to the government to show that the regulation at issue is “substantially related to serving an important government purpose.”²⁰³

The prescription requirement is facially neutral because it does not explicitly classify men and women. Therefore, plaintiffs have the burden of showing both that the prescription requirement has a disparate impact on women, and there is a discriminatory purpose

¹⁹⁶ See *Bolling v. Sharpe*, 347 U.S. 497, 498–99 (1954). The Court reads the Fifth Amendment due process clause to include the equal protection guarantee of the Fourteenth Amendment. *Id.*

¹⁹⁷ See CHEMERINSKY, *supra* note 154, at 685.

¹⁹⁸ See *id.*

¹⁹⁹ See *id.* at 777.

²⁰⁰ Intermediate scrutiny, as its name suggests, is “the middle tier of review.” CHEMERINSKY, *supra* note 154, at 553. Under intermediate scrutiny, “the government’s objective must be more than just a legitimate goal for the government to pursue.” *Id.* Also, “the means chosen” to achieve the objective “must be more than a reasonable way of attaining the end[.]” *Id.*

²⁰¹ See, e.g., *United States v. Virginia*, 518 U.S. 515 (1996); *Craig v. Boren*, 429 U.S. 190 (1976).

²⁰² CHEMERINSKY, *supra* note 154, at 777.

²⁰³ *Id.* at 553.

behind it.²⁰⁴ 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.

Plaintiffs also have a strong argument that there is a discriminatory purpose behind the prescription requirement. In *Village of Arlington Heights v. Metropolitan Housing Development Corp.*,²⁰⁵ the Court identified different ways plaintiffs could demonstrate a discriminatory purpose.²⁰⁶ A discriminatory purpose can be shown by a historical pattern of discrimination, statistical patterns that can only be explained by discrimination, and legislative or administrative history that points toward discrimination.²⁰⁷ Here, plaintiffs have a number of arguments at their disposal. First, plaintiffs could point to the historical discrimination of women in general. Additionally, plaintiffs could cite reports showing that virtually every part of the required doctor's visit in order to obtain a prescription is unnecessary to determine whether a progestin-only birth control pill would be safe for use.²⁰⁸ Plaintiffs could also reference statistics that women could easily use available technology and informative labeling to safely take a progestin-only oral contraceptive.²⁰⁹

In proving a discriminatory purpose, plaintiffs can also rely on evidence that the FDA has a history of discriminating against women's rights to access contraception.²¹⁰ Plaintiffs could specifically point to the FDA's unusual action to delay, and eventually deny, over-the-counter emergency contraception for females of all ages as evidence of the FDA's discriminatory motivation in thwarting attempts to expand the availability of oral

²⁰⁴ *Id.* at 777.

²⁰⁵ *Vill. of Arlington Heights v. Metro. Hous. Dev. Corp.*, 429 U.S. 252, 266–68 (1977).

²⁰⁶ Though the case involved a claim of racial discrimination, the same indicia of discriminatory purpose could be applied to a gender discrimination claim.

²⁰⁷ *Arlington Heights*, 429 U.S. at 266–68.

²⁰⁸ See Trussell et al., *supra* note 2, at 1095–96.

²⁰⁹ FDA Public Hearing 2012, *supra* note 27, at 48–49. See also McIntosh et al., *supra* note 43, at 430.

²¹⁰ See *Tummino v. Hamburg*, 936 F. Supp. 2d 162, 168 (E.D.N.Y. 2013); *Tummino v. Von Eschenbach*, 427 F. Supp. 2d 212, 228–29 (E.D.N.Y. 2006).

contraceptives.²¹¹ In fact, the FDA has a long history of taking unusual actions to delay and prevent expanded access to oral contraceptives for women.²¹² For example, the initial Plan B prescription to over-the-counter switch application was the only one of sixty-seven applications filed between 1994 and 2004 not to be approved after advisory committees recommended approval.²¹³

In *Hamburg*, Judge Korman identified a plethora of features of the FDA's decision-making process that rendered the denial of the citizen petition unprecedented.²¹⁴ For example, HHS Secretary Sebelius cited "cognitive and behavioral differences between older adolescent girls and the youngest girls of reproductive age" as a reason to direct the FDA to deny the petition for over-the-counter access for females of all ages.²¹⁵ However, normally the FDA does not rest its decisions about whether to switch a drug from prescription to over-the-counter on "theoretical abuse by a very small segment of the population."²¹⁶ If the FDA did, then it would be required to stop selling any "drugs with known abuses" over the counter, including "laxatives because of abuse by people suffering from bulimia" and "acetaminophen because of its use in

²¹¹ See *Hamburg*, 936 F. Supp. 2d at 168; *Von Eschenbach*, 427 F. Supp. 2d at 228–29.

²¹² See *Hamburg*, 936 F. Supp. 2d at 168; *Von Eschenbach*, 427 F. Supp. 2d at 228–29.

²¹³ U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-06-109, FOOD AND DRUG ADMINISTRATION DECISION PROCESS TO DENY INITIAL APPLICATION FOR OVER-THE-COUNTER MARKETING OF THE EMERGENCY CONTRACEPTIVE DRUG PLAN B WAS UNUSUAL 5 (2005). The Government Accountability Office (GAO) found other aspects of the FDA's review of the Plan B application to be "unusual." For example, "high-level management was more involved in the review of Plan B than in those of other OTC switch applications" and "there are conflicting accounts of whether the decision to not approve the application [on May 6, 2004] was made before the reviews were completed." *Id.*

²¹⁴ See *Hamburg*, 936 F. Supp. 2d at 170.

²¹⁵ *Id.* at 167 (citing Memorandum from Kathleen Sebelius, Sec'y Health & Human Servs., to Margaret Hamburg, Comm'r of Food & Drugs Admin. (Dec. 7, 2011), *Tummino v. Torti*, 603 F. Supp. 2d 519 (E.D.N.Y. 2009) (No. 05-cv-366)).

²¹⁶ *Id.* at 174 (citing Internal Memorandum from Dr. Curtis Rosebraugh, FDA Deputy Dir. of the Div. of OTC Drugs, Exhibit A to Plaintiff's 2007 Motion for Summary Judgment at T-30757–58, *Tummino v. Torti*, 603 F. Supp. 2d 519 (E.D.N.Y. 2009) (No. 05-cv-366), 2007 WL 1143253).

suicides.”²¹⁷ Hypothetical plaintiffs could use this kind of evidence to show that a discriminatory purpose underlies the prescription requirement for progestin-only pills. The plaintiffs have support that the FDA’s “administrative history [is] highly relevant” to a determination of discriminatory purpose.²¹⁸

If plaintiffs are successful in proving disparate impact and purposeful discrimination, then the government must make two showings. First, the government must show that the prescription requirement serves an important objective.²¹⁹ Second, the government must show that the means of the classification are substantially related to the achievement of that important governmental objective.²²⁰

The Court’s decision in *Cleveland Board of Education v. LaFleur* may be instructive to plaintiffs challenging the prescription requirement for a progestin-only birth control pill. In *LaFleur*, the Court declared that a school board requirement that pregnant employees take maternity leave at a fixed time in their pregnancies was unconstitutional.²²¹ The Court reasoned that the regulation amounted “to a conclusive presumption that every pregnant teacher who reaches the fifth or sixth month of pregnancy is physically incapable of continuing” to teach.²²² Plaintiffs challenging the prescription requirement for a progestin-only birth control pill could make a similar argument that the prescription requirement does not serve an important governmental interest. Just as the Cleveland Board of Education’s maternity leave requirement did not substantially serve its articulated interest, promoting educator continuity in instruction,²²³ the prescription requirement for a progestin-only birth control pill does not substantially serve the government’s alleged interest in protecting women’s health. In *LaFleur*, the Court assumed that all pregnant teachers are unable to continue working at a board-determined

²¹⁷ *Id.*

²¹⁸ *Vill. of Arlington Heights v. Metro. Hous. Dev. Corp.*, 429 U.S. 252, 266–68 (1977).

²¹⁹ *See Craig v. Boren*, 429 U.S. 190, 197 (1976).

²²⁰ *Id.*

²²¹ *Cleveland Bd. of Educ. v. LaFleur*, 414 U.S. 632, 643–44 (1974).

²²² *Id.* at 644.

²²³ *See id.* at 643.

time in their pregnancy.²²⁴ Here, the prescription requirement rests on an agency-determined assumption that women need an incentive, in this case a birth control prescription, to seek preventative medical care.²²⁵ Both the requirement in *LaFleur* and the prescription requirement for a progestin-only birth control pill seem to further the belief that agencies and boards understand the needs and psyche of all women better than an individual woman can make autonomous decisions in her own health-related matters.

In later cases, the Court clarified its holding in *LaFleur*. The Court explained that the government's "justification must be genuine, not hypothesized or invented post hoc in response to litigation. And it must not rely on overbroad generalizations about the different talents, capacities, or preferences of males and females."²²⁶ The Court further declared that in classifying on the basis of sex, the government must demonstrate an "exceedingly persuasive" justification for the action.²²⁷ Even if the government can pass the high hurdle in asserting an important interest behind the requirement, the government must still show that the means of the requirement are substantially related to the achievement of that interest.²²⁸

Using this framework, hypothetical plaintiffs could challenge the government's asserted interest in women's health. Protecting the health of women was likely the government's actual objective in requiring a prescription for progestin-only oral contraception. However, a mounting body of evidence suggests that a progestin-only pill could be safely dispensed over the counter.²²⁹ This evidence, plaintiffs could assert, suggests that the women's health objective may indeed be a post hoc rationalization for maintaining the prescription requirement when the progestin-only pill has been considered safe for quite some time.

The government may choose to supplement its articulated purpose of protecting women's health. It could assert that the

²²⁴ *See id.*

²²⁵ *See* Trussell et al., *supra* note 2, at 1095.

²²⁶ *United States v. Virginia*, 518 U.S. 515, 533 (1996) (citation omitted).

²²⁷ *Id.*

²²⁸ *Craig v. Boren*, 429 U.S. 190, 197 (1976).

²²⁹ *See* FDA Public Hearing 2012, *supra* note 27, at 38.

prescription requirement gives women a needed incentive to have regular annual exams, even though these exams have little to do with a doctor's determination that a patient can safely take a progestin-only pill.²³⁰ However, the U.S. Preventative Services Task Force and the American Cancer Society now discourage annual pap tests in favor of less frequent tests depending on a woman's age, risk factors, and prior screening results.²³¹ Though it might in fact be the case that women who would otherwise forgo annual exams submit to them in order to obtain a birth control prescription, this paternalistic rationalization cannot meet the government's burden.

The government may also rely on an "overbroad generalization" by assuming that all women desire direct communication with their doctor, a physical examination, and prescription before choosing to use oral contraception.²³² Evidence suggests that given the inconvenience and expense of doctor's visits, coupled with women's ability to use emerging technology to safely make a decision, many women would prefer an over-the-counter birth control pill.²³³ Thus, though the government's objective of protecting women's health is indeed important, the government would likely be unable to provide the required "exceedingly persuasive justification"²³⁴ for the prescription requirement.

Even if the government did have a sufficiently important interest in protecting women's health, its means are not substantially related to that interest. As discussed above, the barriers the prescription requirement generates actually pose health risks to women.²³⁵ Oral contraceptives have numerous health benefits and unintended pregnancies can pose serious health risks for both the mother and child.²³⁶ There is indeed an alternative to the current oral contraceptive prescription regime that would

²³⁰ See *id.* at 1095.

²³¹ New Cervical Cancer Screening Recommendations, *supra* note 62.

²³² See *Weinberger v. Wiesenfeld*, 420 U.S. 636, 643 (1975).

²³³ FDA Public Hearing 2012, *supra* note 27, at 42.

²³⁴ *United States v. Virginia*, 518 U.S. 515, 533 (1996).

²³⁵ See Logan et al., *supra* note 45, at 1, 8.

²³⁶ *Id.* at 1, 5–8.

enable greater access to birth control for women while ensuring their safety.²³⁷ As explained above, estrogen-progestin combination pills have more contraindications than progestin-only contraceptives.²³⁸ By maintaining the prescription requirement for estrogen-progestin pills while making a progestin-only pill available over the counter, women would no longer be subjected to unnecessary paternalistic barriers hindering access to oral contraception.

Thus, plaintiffs would likely be able to show that the facially neutral prescription requirement has both a discriminatory impact on women and is purposively discriminatory. The government may have difficulty showing that its interest in women's health is not a *post hoc* rationalization for the maintenance of the prescription requirement and that the requirement is not based on overbroad generalizations. However, the government may be able to meet the first of its burdens to show that there is an important interest—the protection of women's health—behind the prescription requirement. However, the government would likely be unable to show that the prescription requirement substantially serves its interest in women's health. Plaintiffs may therefore have success in pursuing a gender classification-based equal protection violation claim.

2. Other Classification-Based Equal Protection Claims

As discussed above, access issues imposed by the prescription requirement for progestin-only oral contraceptives disproportionately affect minority women, young women, and low-income women as evidenced by the high instances of unintended pregnancies among these groups.²³⁹ Plaintiffs may therefore choose to challenge other classifications imposed by the prescription requirement. Because the prescription requirement is facially neutral, to allege an impermissible classification based on race or national origin, plaintiffs would have to make two

²³⁷ *See id.*

²³⁸ *Progestin-Only Contraceptives*, *supra* note 32.

²³⁹ *Facts on Unintended Pregnancy*, *supra* note 40.

showings to subject the classification to heightened scrutiny.²⁴⁰ First, they would need to show that the prescription requirement has a disproportionate impact on a racial or ethnic group. Second, plaintiffs would need to show there is a discriminatory purpose underlying the prescription requirement.²⁴¹ Any wealth and age classification claims brought by the plaintiffs challenging the prescription requirement would be subject only to rational basis review.²⁴²

In regards to race, national origin, and alienage, plaintiffs could likely show the disparate impact of the prescription requirement. They could assert, for example, that African-American women experience significantly more unintended pregnancies than any other racial group in the country and are more likely than white women to have gaps in contraceptive use.²⁴³ Though they may meet the requirements for disparate impact, plaintiffs would be challenged to show that there is a racially discriminatory purpose behind the prescription requirement. In *Washington v. Davis*,²⁴⁴ the Court upheld a police officer promotion test that had a higher passage rate among white employees than black employees. The Court reasoned that without evidence of a discriminatory purpose, a regulation that disparately impacts a racial group will be subject only to rational basis review.²⁴⁵ Unlike a potential gender classification claim where the requirement applied only to women,

²⁴⁰ *Washington v. Davis*, 426 U.S. 229, 242 (1976). Heightened scrutiny is a standard of review greater than rational basis review. Heightened scrutiny includes intermediate and strict scrutiny.

²⁴¹ *Id.*

²⁴² See *Massachusetts Bd. of Ret. v. Murgia*, 427 U.S. 307, 312–314 (1976) (declaring that age classifications are subject only to rational basis review); *Dandridge v. Williams*, 397 U.S. 471, 485–87 (1970) (declaring that wealth classifications are subject only to rational basis review). Under rational basis review, “the government’s objective only need be a goal that is legitimate for government to pursue. In fact, the goal need not be the actual purpose of the litigation but rather, any conceivable legitimate purpose is sufficient. The means chosen need be only a reasonable way to accomplish the objective.” CHEMERINSKY, *supra* note 154, at 552.

²⁴³ *Facts on Unintended Pregnancy*, *supra* note 40; Frost et al., *supra* note 69.

²⁴⁴ *Davis*, 426 U.S. at 232, 235.

²⁴⁵ See *id.* at 239, 242.

and not men, the prescription requirement applies to women of all races. Therefore, the government would be able to show that it would have imposed the same requirement without the alleged impermissible racial purpose.²⁴⁶

Because plaintiffs could not produce sufficient evidence of a discriminatory purpose related to race or national origin and the Court has expressly articulated that wealth and age classifications are subject only to rational basis review, claims based on race, national origin, alienage, wealth, or age would not be subject to heightened scrutiny.²⁴⁷ The prescription requirement would be upheld under rational basis review since the government would be able to show that protecting women's health is, in fact, a legitimate purpose and that the requirements had a rational relation to that legitimate government purpose.²⁴⁸ Because the prescription requirement allows doctors to make the determination about whether an oral contraceptive would be safe for an individual patient, a court would likely hold that the prescription requirement for a progestin-only birth control pill is rationally related to protecting women's health. Such a holding would occur despite the fact that the prescription requirement is over-inclusive and that the women's health objective may not be the actual purpose in the long-time maintenance of the prescription requirement for progestin-only oral contraceptives. Therefore, in bringing an equal protection violation claim, plaintiffs would only have a viable chance of success in asserting an impermissible classification on the basis of gender.

CONCLUSION

The prevalence of unintended pregnancies and the negative consequences that accompany these pregnancies necessitates efforts to reduce barriers to contraceptive access.²⁴⁹ Though oral

²⁴⁶ See *Vill. of Arlington Heights v. Metro. Hous. Dev. Corp.*, 429 U.S. 252, 269–70 (1977). Like the regulation at issue in *Arlington Heights*, there is no evidence that race was a motivating factor in establishing and maintaining the prescription requirement for birth control pills.

²⁴⁷ See *Murgia*, 427 U.S. at 307; *Dandridge*, 397 U.S. at 471.

²⁴⁸ See CHEMERINSKY, *supra* note 154, at 688.

²⁴⁹ See McIntosh et al., *supra* note 43 at 424–25; *Facts on Unintended*

contraceptives are one of the most effective and widely used contraceptive methods, the prescription requirement makes the process of obtaining birth control pills unnecessarily difficult.²⁵⁰ As evidenced by the over-the-counter approval process the FDA employed for Plan B emergency contraception, the FDA will likely continue its practices of delaying and denying expanded access to oral contraception.²⁵¹ Indeed, the politics surrounding birth control, rather than the health risks associated with such drugs, prevents women from exercising their full constitutional right to use contraception.

Thus, plaintiffs would be able to make a strong showing that the prescription requirement for progestin-only oral contraceptives is in fact unconstitutional. Though the right to contraception has been recognized since the 1960s, increased safety, improved technology, and the known health benefits of oral contraceptives have not been adequately considered to fully realize the benefits of contraceptive use in today's society.²⁵² The prescription requirement for a progestin-only oral contraceptive indicates that our nation's long history of female subordination and paternalism of women has not been wholly abolished.²⁵³ The elimination of the prescription requirement would therefore serve the goals of gender equality and a full recognition of the modern right to contraception. It would also address the prevalence of unintended pregnancies and the negative implications of these pregnancies on women, children, and society as a whole.²⁵⁴ Safety concerns, politics, and paternalistic rationales supporting the maintenance of the prescription requirement for the pill are facing ever-growing scrutiny by the courts, medical associations, and by the public at large. Eliminating the prescription requirement for a progestin-only oral contraceptive would give women the ability to more fully

Pregnancy, *supra* note 40.

²⁵⁰ See FDA Public Hearing 2012, *supra* note 27, at 41–42.

²⁵¹ See *Tummino v. Hamburg*, 936 F. Supp. 2d 162, 166–68 (E.D.N.Y. 2013); *Tummino v. Von Eschenbach*, 427 F. Supp. 2d 212, 228–29 (E.D.N.Y. 2006).

²⁵² See *Griswold v. Connecticut*, 381 U.S. 479, 485–86 (1965).

²⁵³ See *Trussell et al.*, *supra* note 2, at 1094–96.

²⁵⁴ See *McIntosh et al.*, *supra* note 43.

control their own birth control decisions.