

## OVER-THE-COUNTER ACCESS TO ORAL CONTRACEPTION: REPRODUCTIVE AUTONOMY ON PHARMACY SHELVES OR A POLITICAL TROJAN HORSE?

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### *Abstract*

*During the fall of 2014, in what seemed like a change of heart, Republican congressional candidates began calling for a policy that reproductive rights advocates have supported for years. Over-the-counter (“OTC”) oral contraception (“OC”) became these candidates’ way to connect with the women alienated by the Republican Party in recent elections. They emphasized how OTC access would allow women themselves, not employers or the government, to have control over contraceptive decisions. Liberals responded that this new effort was just a Trojan horse—legalizing OTC access would not only increase the actual price tag on OC, but it would also remove OC from the Patient Protection and Affordable Care Act’s extended insurance coverage of contraception. Additionally, reproductive rights advocates noted that it is the Food and Drug Administration (“FDA”), not Congress, that legalizes OTC drugs, and the FDA has not received any applications from drug manufacturers who want to sell OC OTC.*

*In reality, both sides have something of a valid argument. OTC OC would be an important step toward reproductive autonomy for American women. It is also correct, however, that an immediate liberalization of OTC presents several issues, economically, politically, and culturally. Despite these valid critiques, OTC access for OC is a change that is worth the time and effort to move past politics and get it right, for many reasons. Requiring insurance companies and Medicaid to reimburse women for OTC OC purchases is a step toward establishing an accessible market and ensuring corresponding reproductive autonomy for women in the United States, which should accompany legalization of OTC OC.*

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\* I would like to thank Professor Carol Sanger, for all of her helpful advice and critiques. I would also like to thank Professor Scott Hemphill for consulting on economic theory, and Sharon Hickey for her feedback and comments. Thanks also to Emma Kaplan, Esi Agbemenu, Kate Gadsden, and Jacqueline Ma for their outstanding and essential editing.

## INTRODUCTION

In 2014, Americans spent a lot of time, energy, and money arguing about oral contraception (“OC” or “birth control pills”)—specifically, who should pay for it. Yet, the public debate surrounding whether employer-sponsored insurance plans should cover OC was mostly unproductive as far as advancing women’s reproductive autonomy is concerned. That is because the current United States prescription-only access system for birth control pills fails to serve the needs of the women who stand to gain the most from access to OC. The employer mandate debate only took us further away from realizing a system that would promote access for all women—that is, legalizing an over-the-counter (“OTC”) Food and Drug Administration (“FDA”) designation for OC instead of limiting it to prescription-only status.

Despite the seemingly groundbreaking contraceptive mandate in the Patient Protection and Affordable Care Act of 2010 (“ACA”), which transferred responsibility for the monetary cost of OC from women to their insurance companies,<sup>1</sup> all women’s access to OC did not improve, nor was the controversy surrounding it reduced. The ACA’s provision that insurers have to now pay for OC was intensely contentious among the American public, and the Supreme Court ruled in 2014 that employers with a religious objection to contraception do not have to comply with the ACA’s employer mandate.<sup>2</sup> This controversy took attention away from the fact that, notwithstanding the obvious benefits of reducing the price of reproductive planning for women with employer insurance plans, the contraceptive mandate fails to help large segments of women, some of whom stand to benefit most from increased access to OC—specifically women who are unemployed, work part time, are undocumented, or are still on their parents’ health insurance<sup>3</sup>—and fails to address the problematic nonmonetary costs of the prescription access system. OTC access would address these issues. With the approval of the American College of Obstetricians

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1 42 U.S.C. § 300gg-13(a)(4) (2012).

2 *Burwell v. Hobby Lobby Stores, Inc.*, 134 S. Ct. 2751, 2751 (2014).

3 See, e.g., ADAM SONFIELD ET AL., GUTTMACHER INST., *THE SOCIAL AND ECONOMIC BENEFITS OF WOMEN’S ABILITY TO DETERMINE WHETHER AND WHEN TO HAVE CHILDREN* (2013), <http://www.guttmacherinstitute.com/pubs/social-economic-benefits.pdf> [<http://perma.cc/HXY2-PVFZ>] ; Nicole M. Hartz, Note, *Adequate Assurance or Medical Mediocrity: An Analysis of the Limits on the Affordable Care Act’s Application to Women’s Health*, 20 WM. & MARY J. WOMEN & L. 245, 257 (2013); Phyllis M. McCandless, Note, *The Fallacy of Mandating Contraceptive Equity: Why Laws That Protect Women with Health Insurance Deepen Institutional Discrimination*, 42 U.S.F. L. REV. 1115, 1116–17 (2008).

and Gynecologists,<sup>4</sup> OTC access is a safe proposal from a public health perspective and one that women want.<sup>5</sup>

This Note argues that legalizing OTC access is safe, desirable, and furthers women's autonomy over reproductive decisions. It also cautions that certain economic, political, and cultural issues might impede immediate implementation. In Part I, I analyze which categories of women benefit from access to OC and how they benefit. I look at the empirically demonstrated advantages of OC and reasons women give for seeking to use OC. I also examine the effect of cost (both the monetary and the nonmonetary costs associated with prescription access) on OC usage. Part II addresses the ways in which the ACA falls short of fully ensuring access to oral contraceptives and protecting reproductive autonomy. It analyzes how the ACA's contraceptive benefits do not extend fully to multiply-marginalized<sup>6</sup> women and how continued reliance on employer-sponsored health plans impairs overall ability to obtain OC. Part III details how OTC access would address these deficiencies and promote access. These reasons include women's own preference for OTC access, the medical safety of OTC access, the successful examples of OTC emergency contraception in the United States and OTC OC in other countries, and OTC's protection of autonomous reproductive decisions. Part IV examines the economic, political, and cultural reasons why immediate implementation could be problematic, even though OTC

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4 AM. COLLEGE OF OBSTETRICIANS & GYNECOLOGISTS, COMMITTEE OPINION No. 544: OVER-THE-COUNTER ACCESS TO ORAL CONTRACEPTION (2012), <http://www.acog.org/Resources-And-Publications/Committee-Opinions/Committee-on-Gynecologic-Practice/Over-the-Counter-Access-to-Oral-Contraceptives> [<http://perma.cc/QVY6-EX88>] [hereinafter COMMITTEE OPINION No. 544: OTC ACCESS].

5 See, e.g., Sharon Cohen Landau, *Birth Control Within Reach: A National Survey on Women's Attitudes Toward and Interest in Pharmacy Access to Hormonal Contraception*, 74 *CONTRACEPTION* 463 (2006); Kate Grindlay et al., *Attitudes Toward Over-the-Counter Access to Oral Contraceptives Among a Sample of Abortion Clients in the United States*, 46 *PERSP. ON SEXUAL & REPRODUCTIVE HEALTH* 83 (2014) [hereinafter Grindlay et al., *Attitudes Toward OTC Access*].

6 Multiply-marginalized individuals are those who identify with more than one group or characteristic against which society discriminates. See CATHERINE E. HARNOIS, *FEMINIST MEASURES IN SURVEY RESEARCH* 128 (2013):

Systems of race, gender, class, and sexuality intersect at the individual level, the institutional level, and every level in between. It is not simply that multiply marginalized individuals experience multiple forms of discrimination (e.g., racial discrimination, gender discrimination, and class-based discrimination). Nor is it simply that multiply marginalized individuals experience discrimination based on multiply marginalized statuses (e.g., racialized gender-discrimination and gendered class-discrimination). Rather, socially-constructed notions of race, class, gender, sexuality, age, physical ability, and ethnicity are all built into and maintained by our political, economic, and cultural institutions[.]

is a good idea overall. In particular, a dual OTC and prescription system could skew an OTC market for OC, if insurers fear losing their market power with drug companies and continue requiring prescriptions for OC coverage. I then propose ways the United States could overcome these obstacles. Specifically, I suggest that the FDA should approve any citizen petition it receives requesting OTC status for OC, and, concurrently, the Department of Health and Human Services (“HHS”) should update their regulations to require insurers and Medicaid to reimburse women for OTC OC purchases. This change would, in effect, create an incentive for insurance companies and the federal government to have a stake in the competitiveness of the OTC OC market.

### I. Who Benefits From Access to Oral Contraception and How So?

OC was approved for sale in the United States on May 11, 1960.<sup>7</sup> Since then, millions of American women have relied on it to prevent pregnancy, among other uses like controlling menstruation or acne treatment. While OC generally provides more control over reproductive decisions for women, that ability itself produces spillover benefits too that affect individual women in varying ways. Women cite a wide range of reasons for utilizing contraception, and they derive many distinct benefits from it.<sup>8</sup> This is partially due to the intersection of factors that affect women’s access to, usage of, and benefits derived from OC. Cost, in particular, does not affect women’s usage of OC uniformly.<sup>9</sup> Understanding these differences is important for analyzing how a particular access system either promotes or impairs women’s usage.

#### A. What are the Benefits of Oral Contraception?

When first introduced in 1960, OC was the first contraceptive to afford women themselves full control over reproductive decisions. OC’s main benefits flow from the basic improvement of allowing women to better plan whether and when they want to be

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7 That is, sale for contraceptive usage. The first OC, the Enovid pill, had been previously approved for sale for the purpose of regulating periods. When this happened in 1959, a huge increase in women reporting irregular periods to their doctors occurred. *Timeline: the Pill*, PBS AM. EXPERIENCE, <http://www.pbs.org/wgbh/amex/pill/timeline/timeline2.html> [<http://perma.cc/32YS-4EKU>] (last visited Jan. 27, 2015). Even after OC was legalized for contraceptive use, it was not legal for unmarried women to use it for that reason until 1972. *Eisenstadt v. Baird*, 405 U.S. 438, 438 (1972).

8 Jennifer J. Frost & Laura Duberstein Lindberg, *Reasons for Using Contraception: Perspectives of US Women Seeking Care at Specialized Family Planning Clinics*, 87 *CONTRACEPTION* 465, 465 (2013).

9 Emily Gray Collins & Brad Hershbein, *The Impact of Subsidized Birth Control for College Women: Evidence from the Deficit Reduction Act (2013)* (unpublished manuscript) (on file with authors).

pregnant.<sup>10</sup> The choice over this fundamental reproductive decision allowed, and continues to allow, women to have more control over their careers, as well as their personal lives.

Economic studies have explored what kinds of benefits are associated with women's increased ability to plan their pregnancies. The liberalization of OC in the late 1960s and early 1970s helped isolate the link between increasing access to OC and multiple important economic indicators of an individual's well-being. Martha Bailey, a labor economist at the University of Michigan, has conducted a series of studies<sup>11</sup> using states' legalization of access to OC for eighteen- to twenty-one-year-olds as an exogenous policy change to separate the empirical consequences of increased oral contraceptive access from other developments during this time period.<sup>12</sup> Her studies have found that women's access to OC increased their labor force participation, wages, and family incomes, as well as their children's ability to complete college decades later.<sup>13</sup> She also linked increased determination of when to have children with positive impacts on quality-of-life indicators, including educational attainment, economic stability, lasting union formation, and mental health and happiness.<sup>14</sup>

More broadly, the ability to plan whether and when to be pregnant leads to its own positive spillover effects. This control has increased both the proportion and the number of

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10 Martha J. Bailey et al., *Recent Evidence on the Broad Benefits of Reproductive Health Policy*, 32 J. POL'Y ANALYSIS & MGMT. 888, 889 (Autumn 2013).

11 Despite the effective methodology employed in these studies, it is hard to duplicate or expand their use. Bailey's studies make use of a policy change that occurred in a distinct time period, which usefully varied slightly across states. Now that access to OC has expanded enormously, it would be hard, if not impossible, to isolate such a change in a similar contemporary study. This makes any such contemporary research perhaps less able to isolate the impact of a particular policy. The more relevant consideration today, instead of OC's availability, would be the consistency and adequacy of use. Before any such study could be done, though, more time would need to pass so that relevant data would be available, making it less relevant for contemporary policy decisions. For modern policy concerns, what is important to glean from these studies is that access to OC, when it was new and its impact most easily visible, markedly improved several quality-of-life indicators for United States women. This should inform present efforts to increase access for all segments of the female United States population. See SONFIELD ET AL., *supra* note 3, at 27; Martha J. Bailey, *More Power to the Pill: The Impact of Contraceptive Freedom on Women's Life Cycle Labor Supply*, 121 Q. J. ECON. 289, 317–18 (2006).

12 SONFIELD ET AL., *supra* note 3, at 27.

13 SONFIELD ET AL., *supra* note 3, at 27; Martha J. Bailey, *Fifty Years of Family Planning: New Evidence on the Long-Run Effects of Increasing Access to Contraception* (Nat'l Bureau of Econ. Research, Working Paper No. 19493, 2013) [hereinafter Bailey, *Fifty Years*] (determining how precisely access to OC impacts indicators like education level or lifetime labor supply, by isolating an exogenous change in availability, to compare the before and after statistics and how the changes correlate).

14 Bailey, *Fifty Years*, *supra* note 13, at 1.

women in professional degree programs.<sup>15</sup> Women with high educational achievement are then able to benefit financially by delaying childbirth, as they can complete more schooling and concentrate on advancing their careers.<sup>16</sup> The increased ability to plan when to have children also leads to stronger relationships,<sup>17</sup> less anxiety and depression, and higher happiness levels for parents.<sup>18</sup> The use of birth control pills can also allow women to form more stable partnerships; OC reduces the effect of unexpected pregnancies on women's decision to marry, meaning that the partnerships formed by women utilizing OC can be made later on in life and so can be more considered.<sup>19</sup>

### 1. Who Benefits Most from Oral Contraception?

As for who benefits most from oral contraception, studies that have been done to date have not adequately broken down the data. Nearly all of the studies in this area have focused on either the averages of large samples or specific subgroups for methodological reasons, which is not helpful in assessing OC's long-term impact for certain demographic groups.<sup>20</sup> While there has been considerable work completed examining the correlation between increased control over the timing of one's pregnancy and other quality-of-life factors, there has been little study of how this increased control affects women who are marginalized or multiply-marginalized.<sup>21</sup> These studies have missed women on certain relevant margins, and so it is possible that available studies have neglected the most salient impact of increased access to OC. The few studies that have considered these women indicate that

contraceptive access or unintended pregnancy may influence different women in different ways, according to their income, race and ethnicity, marital status and other characteristics. Young women who start out disadvantaged—for example, without many individual or familial economic resources—may benefit most from completing their education

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15 Bailey, *Fifty Years*, *supra* note 13, at 9.

16 See *supra* note 13, at 17.

17 SONFIELD ET AL., *supra* note 3, at 19.

18 SONFIELD ET AL., *supra* note 3, at 22.

19 SONFIELD ET AL., *supra* note 3, at 19.

20 SONFIELD ET AL., *supra* note 3, at 27.

21 SONFIELD ET AL., *supra* note 3, at 27.

and may be least able to achieve income and relationship stability when facing the demands of teen motherhood. Single mothers, who do not have the benefit of sharing expenses and the time and emotional demands of parenthood with a partner, may have less ability than do other mothers to invest in their own education and to pursue high-income careers with employers supportive of working mothers.<sup>22</sup>

This distinction is relevant in that it is precisely those who would likely stand to benefit most from an increased ability to plan pregnancies are left out of many studies, and are largely excluded from insurance coverage under the ACA, as well.<sup>23</sup>

Further, women on the margins may also simply benefit less than non-marginalized women from the ability to plan their pregnancies further in advance and with more certainty, under the current prescription-only system:

Unfortunately, judging from the limited number of studies that explore differences across groups of women, it does not appear that all United States women have benefited equally from access to contraception. Being able to plan whether and when to have children, for example, has not benefited low-income women and women of color in terms of their education as greatly as it has benefitted their higher-income and white counterparts. Similarly, because lower-income and single mothers with lower levels of education may have less freedom in their choices of when and where to work than do other women, their job security does not benefit as much from contraceptive access.<sup>24</sup>

This is not to say that low-income women, women of color, and single mothers do not benefit from access to OC—they simply do not benefit in the same ways as white women, women with higher incomes, or women with other relevant characteristics.<sup>25</sup> With a diversity of available benefits comes a diversity of reasons for seeking OC. However,

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22 SONFIELD ET AL., *supra* note 3, at 27. The disconnect between data-driven social science methods and women's studies analyses of intersectionalities in general has been noted by Leslie McCall. Leslie McCall, *The Complexity of Intersectionality*, 30 J. WOMEN IN CULTURE & SOC'Y 1771, 1794–96 (2005).

23 See *infra* text accompanying notes 70–75.

24 SONFIELD ET AL., *supra* note 3, at 29.

25 SONFIELD ET AL., *supra* note 3, at 29.

the current insurance-based health care system fails to provide the flexibility needed to accommodate women's varying needs.<sup>26</sup>

## 2. Reasons for Using (or Not Using) Oral Contraception

It is a simplification to assume that all American women are looking for or expecting the same benefits when they get a prescription for OC. To fully understand women's demand for OC, looking to women's own individual accounts is instructive. Their reasons differ across characteristics like age, education, race, and income. Unemployment is a particularly strong driver of demand for OC across many different segments of the female population.<sup>27</sup> Although female study participants do not always cite cost as an important factor in their use of OC, empirical evidence indicates that increased costs, both monetary and nonmonetary, decrease women's demand for OC. Examining these distinctions sheds light on the incentives women consider when they decide to use OC. To explore what explains the differences cited, economists have asked women to describe their personal reasoning and then analyzed connections within the data.

A study of women receiving services from specialized family planning clinics corroborates the assertion that women on the margins, as opposed to women who fit into an aggregated norm, cited more reasons for seeking OC.<sup>28</sup> In this study, women reported a range of reasons for using birth control, including: taking better care of themselves and their families, supporting themselves financially, finishing their education, and keeping or getting a job.<sup>29</sup> Young women, women without children, and women who were not married reported more reasons than other women.<sup>30</sup> Being young and being single were correlated with the most reasons for seeking OC, and these indicators were followed by education, race, and income.<sup>31</sup>

Unemployment constitutes another significant reason for seeking access to OC: unemployment was a very important self-reported factor for over a quarter of study

26 For a discussion of how structural factors impact these varying needs, see *infra* notes 66–78 and accompanying text.

27 Frost & Lindberg, *supra* note 8, at 467.

28 Frost & Lindberg, *supra* note 8, at 468.

29 Frost & Lindberg, *supra* note 8, at 468.

30 Frost & Lindberg, *supra* note 8, at 468.

31 Frost & Lindberg, *supra* note 8, at 468.

participants.<sup>32</sup> In the study, the particular magnitude of this statistic is attributed to coincidence of the completion of the study and the financial crisis of 2008, but under the ACA's access structure for OC such a consideration is telling no matter the health of the overall economy. Currently, as the ACA funds OC under employer-sponsored insurance plans, an unemployed woman seems to have both more demand for and interest in OC and yet less access and funding for it. Drawing this comparison one step further, because insurance is linked to employment under the ACA, women who are unemployed are more likely to be uninsured as well—and, uninsured women are more likely than insured women to use no contraceptive method at all and also less likely to use OC, due to issues of access, not preference.<sup>33</sup>

#### a. Cost as a Factor For Oral Contraceptive Usage

In contrast to other factors, women only sometimes cite cost as a deterrent from seeking OC access. In one study, a mere fourteen percent of women aged eighteen to twenty-nine stated that cost was a factor in choosing to use less effective forms of contraception.<sup>34</sup> Another study found that women visiting family planning clinics also rarely mention cost as a reason for not using contraception.<sup>35</sup> Young women attending community college stated that they did not worry about low-cost access to contraception—mostly thanks to the reproductive services resources Planned Parenthood makes available.<sup>36</sup> This particular statistic is slightly incongruous, though, as one in ten women in the same study cite the difficulty of accessing contraception as their reason for non-use.<sup>37</sup>

This does not necessarily mean that increased cost does not lessen demand for OC. There are several reasons why these studies did not pick up costs' effects. For example,

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32 Frost & Lindberg, *supra* note 8, at 467.

33 JENNIFER J. FROST ET AL., GUTTMACHER INST., *IN BRIEF: IMPROVING CONTRACEPTIVE USE IN THE UNITED STATES* 6 (2008).

34 NAT'L CAMPAIGN TO PREVENT TEEN & UNPLANNED PREGNANCY, *MAGICAL THINKING: YOUNG ADULTS' ATTITUDES AND BELIEFS ABOUT SEX, CONTRACEPTION, AND UNPLANNED PREGNANCY* 11 (2008), <http://thenationalcampaign.org/sites/default/files/resource-primary-download/magicalthinking.pdf> [<http://perma.cc/VC7D-QHTN>].

35 FROST ET AL., *supra* note 33, at 6.

36 Joanna Reed et al., *Consistent and Inconsistent Contraception Among Young Women: Insights from Qualitative Interviews*, 63 *FAM. REL.* 244, 256 (2014).

37 *Id.*

many women may find it difficult to admit in an interview<sup>38</sup> that cost is an issue. Or, perhaps the question and study design themselves diminish the influence of cost: contrary to the aforementioned studies, in a 2009 study women most frequently cited “worry about side effects, worry about weight gain, and cost” as “reasons for not obtaining desired contraception.”<sup>39</sup> Framing the question to be about what factors are barriers, as opposed to which are draws, better elicited women’s cost concerns. It is also plausible that women who cannot afford OC are simply left out of the sample size, as most studies survey women who are already accessing family planning services.<sup>40</sup>

Changes in the amount of subsidies for contraceptive access also reveal how pricing affects women’s demand for OC. Medicaid changes and the Deficit Reduction Act (“DRA”) indicate how changes in price correlate with changes in usage, and such legislation has specific detrimental effects cost-wise for women utilizing family planning clinic services. As previously discussed, OC offers more potential benefits to women who are marginalized, and women on the margins disproportionately utilize public resources like federally funded clinics to access OC.<sup>41</sup> As such, how changes in subsidy amounts affect usage of OC is particularly relevant when considering how best to implement a law changing the structure of OC access.<sup>42</sup> Medicaid subsidies, for example, effectively decrease the cost of OC. When subsidies are cut back, the cost of OC rises, and “the cost of effective contraception puts upward pressure on the rate of unintended pregnancy.”<sup>43</sup>

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38 For discussion on the various problems associated with qualitative interviewing, see, e.g., ROBERT S. WEISS, *LEARNING FROM STRANGERS: THE ART AND METHOD OF QUALITATIVE INTERVIEW STUDIES* 147–50 (1994); Mark Goldszmidt et al., *On the value of the ‘subjective’ in studies of human behavior and cognition*, *PERSP. ON MED. EDUC.* 1 (Jan. 2015), <http://link.springer.com/article/10.1007/s40037-015-0154-3> [<http://perma.cc/UQQ8-239U>]; Kathryn Roulston et al., *Interaction Problems in Research Interviews*, 14 *QUALITATIVE RES.* 277 (2014).

39 Juell B. Homco et al., *Reasons for Ineffective Pre-Pregnancy Contraception Use in Patients Seeking Abortion Services*, 80 *CONTRACEPTION* 569, 571 (2009).

40 See SONFIELD ET AL., *supra* note 3, at 21–22.

41 See FROST ET AL., *supra* note 33.

42 See FROST ET AL., *supra* note 33.

43 Adam Thomas, Note, *Unintended Pregnancy and Public Policy*, 26 *NOTRE DAME J.L. ETHICS & PUB. POL’Y* 501, 512 (2012).

Economists have specifically calculated the change in use that an increase in price of OC will cause using a sample of college women.<sup>44</sup> The DRA cut college health centers' subsidy for birth control pills, which raised the cost of OC at these centers by fifty percent. This cut substantially lowered college women's demand for birth control pills<sup>45</sup>—the result of the DRA reduced usage of birth control pills by three to four percent among college women.<sup>46</sup> As a secondary effect of lessened access to birth control pills, college women who stopped taking OC due to rising prices will either engage in riskier sexual activity or decrease their sexual activity.<sup>47</sup> Neither is optimal for achieving both public health goals and reproductive freedom.

Some commentators have gone further than just observing the effects of such policy changes and have applied an equal protection argument to the DRA's impact. There is an argument that the DRA of 2005 constitutes a violation of equal protection because it deprives women of benefits that they are entitled to under Title X and Medicaid by making contraception “exorbitantly expensive” and therefore unavailable.<sup>48</sup> The DRA specifically declined to include community and campus health centers as organizations that could receive an exemption for subsidizing their prescriptions, making OC more expensive for the women seeking care at either type of clinic.<sup>49</sup> Again, considering how women seeking the services at these clinics are likely to stand to benefit in more ways from increased access to OC, these changes impede some of the most important benefits birth control pills have to offer.

Cost is also a complicated issue because, apart from monetary cost, additional barriers to access—or nonmonetary costs—increase a woman's perceived cost of taking OC as well.<sup>50</sup> Currently, to get a prescription for OC, a woman needs to schedule an appointment

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44 Collins & Hershbein, *supra* note 9.

45 Collins & Hershbein, *supra* note 9.

46 Collins & Hershbein, *supra* note 9 (calculating that women's elasticity of demand, then, for birth control pills is between -.09 and -.04).

47 Collins & Hershbein, *supra* note 9.

48 Rachel V. Rose, *Cutting Funds for Oral Contraceptives: Violation of Equal Protection Rights and the Disparate Impact on Women's Health Care*, 5 MOD. AM. 23, 27 (2009).

49 *Id.*

50 Amanda Dennis & Daniel Grossman, *Barriers to Contraception and Interest in Over-the-Counter Access Among Low-Income Women: A Qualitative Study*, 44 PERSP. ON SEXUAL & REPROD. HEALTH 84, 88 (2012).

with a doctor, disclose a large amount of personal information (including sexual history and activity), usually have an exam, and then make arrangements to receive the pills themselves—likely through some kind of pharmacy—but only after checking with her insurance to make sure it covers that particular source of medication.<sup>51</sup> These might seem like small nuisances,<sup>52</sup> but they can provide substantial barriers to obtaining OC and to using it consistently.<sup>53</sup> The overall combination of both the actual price plus the additional nonmonetary costs constitutes the cost practically relevant to women when they are deciding among contraceptive options.

## II. Why Do the ACA's Provisions for Oral Contraception Fall Short?

The main focus of the ACA was insurance industry reform,<sup>54</sup> not increasing OC use. Nevertheless, the ACA did seek to shift OC's cost allocation, but this shift did not do much to help those whose access was previously most impaired. This result is due to the way that the employer-sponsored system interacts with other characteristics, like race, primary language, income level and type of work arrangement, geography, and age, to create barriers that impede access to OC more for some women than it does for others. Because of this confluence of factors, the access structure under the ACA is still unequal. The ACA additionally shifted public support and policy energy away from the issue of OC access, by creating controversy around the employer-sponsored structure.

Contraception was one of several services for which the ACA sought to reduce out-of-pocket patient costs, specifically by requiring insurance plans to cover OC with no cost to patients.<sup>55</sup> This shifted the monetary costs of OC from individuals to insurance companies

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51 *Id.* at 87.

52 Some women feel that they are just that and that they do not pose a larger issue. *Id.*

53 *Id.*

54 *Key Features of the Affordable Care Act by Year*, HHS, <http://www.hhs.gov/healthcare/facts/timeline/timeline-text.html> [<http://perma.cc/8HPD-W3FH>] (last visited Jan. 27, 2015).

55 *Id.* The ACA requires that new private health plans written on or after August 1, 2012, cover “contraceptive counseling and services and all U.S. Food and Drug Administration-approved methods without out-of-pocket costs to patients.” GUTTMACHER INST., STATE POLICIES IN BRIEF 1 (Mar. 1, 2015), [http://www.guttmacher.org/statecenter/spibs/spib\\_ICC.pdf](http://www.guttmacher.org/statecenter/spibs/spib_ICC.pdf) [<http://perma.cc/2XW9-HN9Y>]. Older plans do not have to meet that requirement, but they will be phased out of protection under the ACA over the next few years. *Id.* *Burwell v. Hobby Lobby, Inc.* may allow certain employers to opt out of this coverage. 134 S. Ct. 2751, 2751 (2014). Currently twenty-eight states require insurers providing contraceptive coverage to cover the full-range of FDA-approved contraceptive drugs and devices. Twenty states allow some exceptions (states vary with how

and the government, allowing women with either private or public insurance to more easily and fully access OC. For women falling outside these categories, the ACA originally mandated that states expand Medicaid access to people with incomes falling within one hundred thirty-two percent of the poverty level, to hopefully provide public insurance to these women.<sup>56</sup> This provision could have been helpful to balance the uneven benefit of reducing costs only for existing insurance holders. The Supreme Court's decision in *National Federation of Independent Businesses ("NFIB") v. Sebelius*, however, prevented the complementary expansion of the Medicaid program, by refusing to make such an expansion mandatory for states to implement, meaning that access remains uneven across income levels.<sup>57</sup>

As it stands, in terms of OC access, the ACA mainly benefits women with existing access to an employer-sponsored insurance plan,<sup>58</sup> and it does not address the nonmonetary costs of OC under a prescription system.<sup>59</sup> Initial implementation of the ACA has resulted in an increase in the number of privately insured women paying nothing for OC from 15% to 40%.<sup>60</sup> Neither the percentage of publicly insured women paying nothing for OC nor the percentage of women who are uninsured paying nothing

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permissive these exceptions are) to compliance with the contraceptive mandate and eight states do not permit any exceptions. STATE POLICIES IN BRIEF, at 2. These exceptions vary from limited, only allowing churches and church associations to claim exemptions, to expansive, allowing religious organizations, including some hospitals—one state exempts secular organizations as well. *Id.*

56 SONFIELD ET AL., *supra* note 3, at 30.

57 Nat'l Fed'n of Indep. Bus. v. Sebelius, 132 S. Ct. 2566, 2566 (2012).

58 The ACA leaves in place the United States employer-sponsored insurance system. This system began to develop in the 1930s but has received much criticism. This system not only makes large corporations major players in the health care system, but it also leaves Americans dependent on them for their health care needs. See KANT PATEL & MARK E. RUSHEFSKY, HEALTH CARE POLITICS AND POLICY IN AMERICA 27 (2014). Employer-sponsored because, although individuals now must have a plan, if it is not sponsored by an employer, the individual is still spending more money than they would have without insurance. Even if they are not specifically paying for birth control, they are not saving costs because their out-of-pocket expenses have increased.

59 Scout Richters, Note, *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, 404–05 (2013).

60 Lawrence B. Finer et al., *Changes in out-of-pocket payments for contraception by privately insured women during implementation of the federal contraceptive coverage requirement*, 89 CONTRACEPTION 97, 97 (2014).

for OC has changed.<sup>61</sup> Unemployment remains a major reason why individuals are not insured.<sup>62</sup> Similarly, while young women are allowed to stay on their parents' health insurance plans until the age of twenty-six, this does not guarantee that they have access to a full range of reproductive services. A young woman may have difficulty accessing OC on a parental plan, if she and her parents have differing views on contraception.<sup>63</sup>

The ACA also leaves the nonmonetary costs of accessing OC unaddressed.<sup>64</sup> For any woman, and especially for a woman who is a single mother, a woman working several part time jobs, or a woman who is trying to complete a degree, prescription access's nonmonetary costs are significant. Leaving such costs in place threatens potential societal benefits for increased access to OC.

Even if the main purpose of the ACA was to reform health insurance,<sup>65</sup> the unequal way it affects OC costs for different women is detrimental to reproductive freedom. Furthermore, "[e]xpanding the rights of the insured while at the same time limiting contraceptive options with such devices as '[p]arental consent laws, for-profit health care, welfare reform policies, and immigration policies impact[s] women's health choices and detrimentally affect[s] the quality of care available.'"<sup>66</sup> While this particular concern was articulated in the context of contraceptive equity laws passed by states like California and Georgia, the ACA essentially implements the same policy<sup>67</sup> in terms of OC access, and "[i]n securing expanded coverage for insured Americans, the privilege of having insurance and the intersection with gender, socioeconomic, and racial or ethnic characteristics amplify the

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61 *Id.* The prevention of Medicaid expansion prevented women on public insurance plans from fully benefitting from these provisions. *See Sebelius*, 132 S. Ct. at 2566.

62 KAISER FOUND., KEY FACTS ABOUT THE UNINSURED POPULATION 2 (2013), <https://kaiserfamilyfoundation.files.wordpress.com/2013/09/8488-key-facts-about-the-uninsured-population.pdf> [<http://perma.cc/5XDD-ZS5L>].

63 *See* Hartz, Note, *supra* note 3 (noting also that young women who are still on their parents' health insurance will not have access to abortion coverage).

64 Hartz, Note, *supra* note 3.

65 *Key Features of the Affordable Care Act by Year*, *supra* note 54.

66 McCandless, Note, *supra* note 3, at 1116–17 (quoting Loretta J. Ross et al., *Just Choices: Women of Color, Reproductive Health, and Human Rights*, in *POLICING THE NATIONAL BODY: RACE, GENDER, AND CRIMINALIZATION* 147 (Jael Silliman & Anannya Bhattacharjee eds., 2002)).

67 The notable difference simply being that the ACA will not allow insurance companies to pass on the cost of birth control through the cost of the plan, which was a loophole allowed under contraceptive equity laws. *Id.*

deficiencies of the underprivileged, including the uninsured.”<sup>68</sup> This problem is specifically applicable to OC access.

In other words, the ACA’s contraceptive provision and its continued reliance on employer-sponsored health care<sup>69</sup> create distinct challenges for OC access that vary based on individual, overlapping characteristics.<sup>70</sup> While there is considerable policy concern over women’s reproductive issues, as well as concern over immigration, unemployment,

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68 *Id.* at 1133–34.

69 Like most aspects of the American health care system, this is a complicated proposition. Some argue that the ACA, because of its tax structure, will push employers away from offering plans to their employees, moving many Americans to individual plans purchased on exchanges; at the same time others argue that because the ACA did not fully equalize tax breaks for employer-sponsored and government exchange insurance plans, companies will not fully move away from the employer-sponsored system. *See, e.g.*, ACADEMY HEALTH, THE AFFORDABLE CARE ACT AND EMPLOYER-SPONSORED HEALTH INSURANCE FOR WORKING AMERICANS 6–8 (2011), [http://www.academyhealth.org/files/nhpc/2011/AH\\_2011AffordableCareReportFINAL3.pdf](http://www.academyhealth.org/files/nhpc/2011/AH_2011AffordableCareReportFINAL3.pdf) [<http://perma.cc/HZ3R-NZ38>]; *but see, e.g.*, Stuart M. Butler, *Bye, Bye Employer Sponsored Health Insurance?*, BROOKINGS INST. OP. (Aug. 15, 2014), <http://www.brookings.edu/research/opinions/2014/08/15-bye-employer-sponsored-healthcare-butler> [<http://perma.cc/3GFD-RJSV>]:

By combining a cap on the tax-free status of employer-sponsored insurance with tax credits and subsidies for exchange plans, the ACA takes some steps down the road of reducing the tax bias associated with employer-controlled coverage. But the design of the ACA falls short of what is needed. In an unwise effort to prop up the employment-based system and to contain the program’s budget cost, the ACA’s sponsors flinched from equalizing the tax breaks and subsidies for exchange plans and employer-sponsored health insurance. Yet that tax and subsidy disparity actually threatens to undermine employer-sponsored coverage in firms with many lower-paid workers. That’s because the government subsidies available for many such families enrolling in exchange plans are much larger than the tax benefits of employer-sponsored insurance, encouraging employers and workers to drop employer-sponsored insurance in favor of extra cash earnings.

Regardless of how the system evolves in the next few decades, for the moment, employer-sponsored health insurance remains dominant.

70 This relates to intersectionality theory. *See* Kimberlé Crenshaw, *Mapping the Margins: Intersectionality, Identity Politics, and Violence Against Women of Color*, 43 STAN. L. REV. 1241, 1245 (1991) (defining structural intersectionality). The particular complexity of how the ACA creates difficulties for individual women of intersectional identities is difficult to pin down, given how these difficulties can vary across incomes and location, in addition to identity components like gender and race, although McCall suggests that it is possible to measure them. *See* McCall, *supra* note 22 at 1787–91. As far as the scope of this paper is concerned, it is sufficient to state that these complexities require a more flexible system than prescription-only access, less tied into structural inequalities. For a discussion of how OTC OC access is a more flexible system, *see infra* Part III.

or education, rarely are these facets fully considered together.<sup>71</sup> The ACA granted increased benefits to insured women, but not all groups of women are insured at equal rates. 32% of the 47.3 million uninsured Americans are Latino, while 19% are Black.<sup>72</sup> 30.4% of Latinos and 32% of Alaska Natives and American Indians in the United States are uninsured, compared with 12.7% of white people and 17.8% of Black people.<sup>73</sup> Unequal insurance rates, under the ACA's provisions, correspond with unequal access for OC.

Language and legal status largely factor in as well. Barriers to communication, stemming from differing language, but also differing cultural perceptions, make certain women's experience with OC access wholly different. It is more difficult for women whose primary language is not English to communicate effectively with some health care providers to obtain a prescription for OC, and, in the United States, this particularly affects Latina women.<sup>74</sup> Undocumented women, additionally, are not affected in the same way as other women.<sup>75</sup> Without access to Medicaid or an employer's health care plan, which

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71 For a full explanation of the shortcomings of research on these interplays and an explanation of how the employer-based insurance system creates disparities for women with these characteristics, see *supra* Parts I.B–C.

72 KEY FACTS ABOUT THE UNINSURED POPULATION, *supra* note 62. That statistic is just out of the 47.3 million people who are uninsured.

73 *Health of Hispanic or Latino Population*, CTR. FOR DISEASE CONTROL & PREVENTION, <http://www.cdc.gov/nchs/fastats/hispanic-health.htm> [<http://perma.cc/RJT5-VCMA>] (last accessed Feb. 3, 2015); *Health of White Non-Hispanic Population*, CTR. FOR DISEASE CONTROL & PREVENTION, <http://www.cdc.gov/nchs/fastats/white-health.htm> [<http://perma.cc/N7WB-NC9W>] (last accessed Feb. 3, 2015); *Health of Black or African American Non-Hispanic Population*, CTR. FOR DISEASE CONTROL & PREVENTION, <http://www.cdc.gov/nchs/fastats/black-health.htm> [<http://perma.cc/T5ZD-YB5N>] (last accessed Feb. 3, 2015).

74 Shelly Campo et al., *It Isn't All About Language Communication Barriers for Latinas Using Contraceptives*, J. TRANSCULTURAL NURSING 1 (2014). The second most common primary language in the United States is Spanish, which means that this problem affects Latina women, as a group, more prevalently than others. CAMILLE RYAN, U.S. CENSUS BUREAU, LANGUAGE USE IN THE UNITED STATES: 2011 AMERICAN COMMUNITY SURVEY REPORTS (2013), <https://www.census.gov/prod/2013pubs/acs-22.pdf> [<https://perma.cc/AA69-83C8>].

75 Difficulties in communication could include needing an interpreter, for appointments with doctors who don't speak English, or miscommunications if either the doctor or patient is speaking in a secondary language. Further, for doctors who are not native Spanish speakers or for women who are not native English speakers, communicating about reproductive decision-making can present tricky language barriers. See *Contraceptive Equity*, NAT'L LATINA INST. FOR REPRODUCTIVE HEALTH, <http://latinainstitute.org/en/what-we-do/contraceptive-equity> [<http://perma.cc/ED5G-N2P7>] (last accessed Feb. 3, 2015); Kimberly Inez MacGuire, *Increased Health Risks for Latina Women Don't Stop at the Border*, HUFFINGTON POST (May 16, 2014, 11:47 EST), [http://www.huffingtonpost.com/kimberly-inez-mcguire/increased-health-risks-fo\\_b\\_5338150.html](http://www.huffingtonpost.com/kimberly-inez-mcguire/increased-health-risks-fo_b_5338150.html) [<http://perma.cc/797C-EFKC>].

would come with legal employment, the barriers to access for OC are much more than simply the time cost of a doctor's visit. Geography is another factor that further magnifies the disparate impact of the contraceptive mandate. Often people are not in charge of their own mobility—factors outside their control, like poverty or unemployment, can be very limiting<sup>76</sup>—and so some individuals end up in areas where there is less access to reproductive services or doctors who can prescribe OC. This is truer in rural areas compared to cities.<sup>77</sup>

The way the labor market is currently set up exacerbates these selective barriers to OC access as well. Income contributes to the problem by determining those who are able to have insurance in the first place. Thirty-eight percent of the uninsured have a family income of less than the federal poverty level, and thirty-one percent are within two hundred percent of the federal poverty level.<sup>78</sup> This statistic is unsurprising, given that the ACA was originally meant to extend Medicaid to cover at least some of these individuals but could not under *NFIB v. Sebelius*.<sup>79</sup> Data suggests that the employer-sponsored insurance system itself effectually discriminates against women, as jobs that offer health care benefits are not allocated equally between males and females,<sup>80</sup> meaning that women have less access to health insurance on the whole.<sup>81</sup> Women also tend to have less continuous careers than men do, which often disrupts their insurance coverage.<sup>82</sup> Finally, as women in heterosexual relationships are more often the ones who choose not to work outside the home while their

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76 PATEL & RUSHEFSKY, *supra* note 58, at 224.

77 PATEL & RUSHEFSKY, *supra* note 58, at 224.

78 KEY FACTS ABOUT THE UNINSURED POPULATION, *supra* note 62, at 206–09; *see also* PATEL & RUSHEFSKY, *supra* note 58, at 209. Data also reveals that lower-paying service jobs are much less likely to offer insurance than comparably paid manufacturing jobs. As the United States economy becomes more focused on service professions, the amount of jobs with employer-sponsored plans shrinks. Similarly part-time jobs generally do not offer insurance and rarely offer insurance for spouses or dependents. Additionally, smaller firms also struggle to fund the cost of health insurance for employees. This all contributes to individuals with lower incomes being less likely to have an employer-sponsored health plan and less likely to then have access to OC without any out-of-pocket costs.

79 *Nat'l Fed'n of Indep. Bus. v. Sebelius*, 132 S. Ct. 2566, 2566 (2012).

80 39.4% percent of women who work have insurance, compared to 51.5% of working men. PATEL & RUSHEFSKY, *supra* note 58, at 219.

81 Nancy S. Jecker, *Can an Employer-Based Health Insurance System Be Just?*, 18 J. HEALTH CARE POL. POL'Y & L. 657, 657 (1993). For an explanation of the theory, *see* PATEL & RUSHEFSKY, *supra* note 58, at 206.

82 PATEL & RUSHEFSKY, *supra* note 58, at 219.

partner does, divorce can disrupt insurance coverage as well.<sup>83</sup> The ACA's contraceptive mandate perpetuates these issues, by tying contraceptive access to the employer-sponsored health insurance system.<sup>84</sup> Leaving the employer-sponsored insurance system in place also allows insurers to retain substantial market power over drug pricing—this could potentially affect the competitiveness of a market for OC, if an OTC system existed along with prescription access.<sup>85</sup>

Prescription-only access for OC based on an employer-sponsored insurance system could also hurt women living with intimate partner violence, reproductive coercion,<sup>86</sup> or contraceptive sabotage.<sup>87</sup> In situations where a woman depends on her partner for insurance coverage, the prescription-only system means that her partner has something of a say in her contraceptive decisions. At the very minimum, the partner will know, from insurance disclosures, about doctor's visits and OC prescriptions. A violent partner can more easily coerce reproductive decisions if they have this information. As such, tying access to OC to prescriptions could negatively impact women living in these situations.

Despite these real issues with how the ACA's contraceptive provision interacts with other societal forces, the public controversy surrounding the law was not focused on these phenomena.<sup>88</sup> *NFIB v. Sebelius* greatly divided the country over the issue, and because of

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83 PATEL & RUSHEFSKY, *supra* note 58, at 219.

84 *But see* PATEL & RUSHEFSKY, *supra* note 58.

85 See *infra* Part IV.A for a detailed discussion of this possibility and how to prevent it.

86 For background on reproductive coercion, see AM. COLLEGE OF OBSTETRICIANS & GYNECOLOGISTS, REPRODUCTIVE AND SEXUAL COERCION 1 (2013), <http://www.acog.org/-/media/Committee-Opinions/Committee-on-Health-Care-for-Underserved-Women/co554.pdf?dmc=1&ts=20150303T1110232282> [<http://perma.cc/94DH-TYDF>].

87 For background on contraceptive sabotage, see Leah A. Plunkett, *Contraceptive Sabotage*, 28 COLUM. J. GENDER & L. 97, 102–07 (2014).

88 At this point, I would like to note the issue of long acting reversible contraceptives (“LARC”). Many reproductive rights activists, as well as medical professionals and healthcare providers, have endorsed these contraceptive mechanisms, as more effective than birth control. See, e.g., AM. COLLEGE OF OBSTETRICIAN & GYNECOLOGISTS COMM., ACOG COMMITTEE OPINION NO. 450: INCREASING USE OF CONTRACEPTIVE IMPLANTS AND INTRAUTERINE DEVICES TO REDUCE UNINTENDED PREGNANCY (2009), <http://www.acog.org/Resources-And-Publications/Committee-Opinions/Committee-on-Gynecologic-Practice/Increasing-Use-of-Contraceptive-Implants-and-Intrauterine-Devices-To-Reduce-Unintended-Pregnancy> [<http://perma.cc/E9CM-W8G6>]. This raises the question whether a push for OTC OC would similarly remove needed focus from LARCs. In response, OC, while less effective than LARCs, can provide a somewhat different set of benefits than LARCs can, which may appeal to certain women over others. First, OC can provide contraceptive benefits, but it can

the way the issue was framed, supporters of reproductive freedom largely backed increased insurance coverage.<sup>89</sup> This increased reliance of women on both insurance and their employer for birth control pills. At the same time, those who support limiting women's access to contraception and abortion in general came out strongly in favor of leaving responsibility on individuals.<sup>90</sup> A health care system based on autonomy and freedom in reproductive decision-making would ideally allow women full access to OC, without having to consider or rely on the religious beliefs of their employers. Neither side of the debate surrounding *NFIB v. Sebelius* comports fully with that idea, and the polarization the ACA caused has created an environment where discussing viable solutions to these issues is difficult.<sup>91</sup> Moreover, increasing contraceptive access within insurance plans is not relevant for millions of uninsured women in the US and has resulted in highly polarized public opinion on the matter. Decreasing the rate of unintended pregnancies requires a broader policy solution.<sup>92</sup>

In light of the drawbacks of the current contraceptive access system, two overarching solutions have been proposed to address them—a fully nationalized healthcare system or a much more modest proposal of OTC OC. Moving to a more nationalized health care system would make it easier to address inequity at a more basic level, but currently it would likely not get the needed political support,<sup>93</sup> based on the national reaction to the ACA itself. So then the question arises as to whether OTC access is a workable solution.

### III. Why Would Over-the-Counter Access Be An Improvement?

OTC access for OC is a feasible policy change that would ameliorate a substantial portion of the problems with prescription-only access described in the last section for several reasons: (1) OTC access for OC directly addresses the structural issues of the

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also help regulate periods or treat acne, two effects some LARCs do not provide. Second, LARCs require a medical procedure for insertion, and they can cause several side effects that some women may want to choose to avoid. As such, OC is important in its own right and deserves the expenditure of some political will to move it to an OTC system.

89 Nat'l Fed'n of Indep. Bus. v. Sebelius, 132 S. Ct. 2566 (2012).

90 See *infra* Part IV.B.

91 How this controversy has led Republicans to propose a premature OTC plan that would actually hurt access is discussed in Part V.C of this Note.

92 McCandless, Note, *supra* note 3, at 1138.

93 McCandless, Note, *supra* note 3, at 1139.

ACA's OC access system; (2) OTC access for OC protects women's autonomy over reproductive decisions, as it is a medically safe option that women would use accurately without supervision and that women *want* to use without supervision; and (3) the examples of OTC emergency contraception in the United States and OTC access to OC in other countries support that the proposition is a workable one.

#### A. Over-the-Counter Access Addresses Structural Issues Created by the ACA.

Legalizing the ability to purchase OC OTC will make the ability to access it more equal among United States women. Having an OTC system means that any woman with access to a pharmacy—not only those with access to doctors or reproductive services clinics—would be able to purchase OC.<sup>94</sup> This would greatly increase the use of OC, as “[m]any women . . . stated they were likely to use contraceptives like birth control pills if they did not need a prescription.”<sup>95</sup> Being unemployed or undocumented would no longer prevent access to OC, provided OTC prices for OC are competitive.<sup>96</sup> As such, the women who could benefit most from OC, and who state the most reasons for seeking to obtain it, would actually have equal access.

OTC access would also greatly reduce the existing nonmonetary costs of OC under the ACA. Nonmonetary costs, like scheduling an appointment, taking time from work or other responsibilities, answering personal questions, and finding a pharmacy that works with their insurance plan (for insured women) or finding a reproductive clinic that will serve them (for uninsured women) would all be reduced through OTC access.<sup>97</sup> Also, women would not need to have their prescription for OC renewed once a year, removing yet another hurdle.<sup>98</sup> Lessening these barriers would also increase women's consistency

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94 McCandless, Note, *supra* note 3, at 1139–41.

95 McCandless, Note, *supra* note 3, at 1140 (citing PHARMACY ACCESS PARTNERSHIP, NATIONAL SURVEY ON ATTITUDES AND INTEREST FOR PHARMACY ACCESS FOR HORMONAL CONTRACEPTION AMONG WOMEN AT RISK FOR UNINTENDED PREGNANCY 8, 10 (2004) (63% of women in a household survey said that they would)).

96 See *infra* Part IV.A for a discussion of why high costs of OTC OC are not likely to be an issue.

97 Richters, Note, *supra* note 59, at 407.

98 As is currently required by United States law. See *Birth Control Pill*, PLANNED PARENTHOOD, <http://www.plannedparenthood.org/health-info/birth-control/birth-control-pill> [<http://perma.cc/3RYZ-PW5U>] (last accessed Jan. 2, 2015); but see *Video Visit*, PLANNED PARENTHOOD, <http://www.plannedparenthood.org/get-care/online/video-visit> [<http://perma.cc/YZ7Y-Z9WC>] (last accessed Jan. 2, 2015) (Planned Parenthood clinics in Washington State and Minnesota are making renewal visits accessible by video conference, thereby significantly reducing nonmonetary costs, while retaining the prescription system).

of OC use.<sup>99</sup> OTC access would further benefit women in situations of intimate partner violence, reproductive coercion, or contraceptive sabotage.<sup>100</sup> By alleviating dependence on insurance, OTC access would allow women with a violent partner to make decisions about OC without the partner knowing. Removing this information from insurance disclosures and also removing the need to take time off work to see a doctor would make a violent partner less able to sabotage. With an OTC system, women would be able to obtain replacement OC, if they are sabotaged, although that is leaving aside an added cost. The need to negotiate condom usage with a violent partner would also decrease with increased access to OC OTC.<sup>101</sup>

The issue of how the ACA's contraceptive mandate intersects with income, race, primary language, age, or geography to block certain women's access is not as easily cured. As mentioned earlier, some women with potentially marginalizing characteristics seem to have benefitted less from OC in the past. They not only have a harder time accessing OC under the current prescription-only system, but even when they are able to access it, they are less able to collect the long-term benefits of OC.<sup>102</sup> OTC OC access will not necessarily allow women who face these barriers to overcome them, as there are more structural factors at play. What it will do, though, is move access to OC outside of the employer-sponsored health care system, which creates certain inequities in its own way.<sup>103</sup> Additionally, as women on the margins report more reasons for using birth control pills, increased OTC OC access will have different effects for them, compared with benefits that are more often reported.<sup>104</sup> The bottom line is that OTC OC access would not be harmful, unless its price

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99 Amanda Dennis & Daniel Grossman. *Barriers to Contraception and Interest in Over-the Counter Access Among Low-Income Women: A Qualitative Study*, 44 *CONTRACEPTION* 84 (2012).

100 See *supra* notes 86–87 and accompanying text for a description of the problems created by prescription-only access for these women.

101 The one caveat to these benefits is that, if women did not need to visit a health care provider to obtain OC, health care providers might be less able to screen for abuse. The ACOG's answer to these concerns is that a yearly health care provider visit is recommended anyway to screen for these types of abuses, as well as to do a preventive check for other health problems. See *infra* note 119 and accompanying text.

102 See *supra* notes 21–24 and accompanying text.

103 See *supra* notes 71–77 and accompanying text.

104 More often because studies that have been done already have not considered sufficiently women on the margins and how their benefits can differ. See *supra* notes 22–25 and accompanying text.

were too high for most women to realistically purchase.<sup>105</sup> If the price is reasonable,<sup>106</sup> though, at least some of the structural barriers to OC will be removed for all women. This is an overall improvement compared with the current structure under the ACA.

## **B. Over-the-Counter Access Protects Women's Autonomy Over Reproductive Decisions.**

OTC availability for OC would increase women's perceived and actual bodily autonomy. Women will reasonably construe a system that highly regulates and restricts use of OC, despite the fact that OC is acknowledged to be safe without a health care provider's opinion,<sup>107</sup> as a system that does not respect their autonomy over their own bodies and reproductive decisions. The contraceptive mandate supports ideas of autonomy and reproductive freedom for women by reducing the cost of OC, which in turn allows some women more control over their own contraceptive decisions.<sup>108</sup> But, overall, it still restricts OC and leaves in place nonmonetary barriers to access. By reducing these barriers, reproductive autonomy would be advanced.

### **1. Women Will Properly Self-Diagnose and Utilize Birth Control Pills Over-the-Counter.**

In order for OC to be safely sold OTC, the FDA requires that OC not be toxic in the event of an overdose, not be addictive, and allow women to properly self-prescribe whether birth control pills would be appropriate. These first three criteria are easily satisfied for OC.<sup>109</sup> The FDA, though, also requires that women be able to take birth control pills without a health care provider's instructions and be able to identify whether birth control pills pose any particular, individual risk.<sup>110</sup> These other two requirements raise answerable questions about how women could self-diagnose and follow through on usage of OC. Studies about how accurately and efficiently American women would be able to do both of these indicate

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105 See *infra* Part IV.A.

106 See *infra* notes 170–174 and accompanying text.

107 COMMITTEE OPINION NO. 544: OTC ACCESS, *supra* note 4.

108 Hartz, Note, *supra* note 3.

109 Hartz, Note, *supra* note 3.

110 Daniel Grossman, Michael Cackovic & Michael J. Paidas, *Viewpoints: Should Oral Contraceptives be Sold Over-the-Counter*, CONTEMP. OB/GYN, Sept. 2008, at 63–74.

that in all likelihood women would self-prescribe and use OC on their own without issue in the large majority of cases.<sup>111</sup> As such, OTC access could be implemented to greatly reduce nonmonetary costs of access without harming important public safety goals.

**a. Self-Prescription Would Be Safe.**

The first public health issue relevant to OTC access is whether women would be able to safely assess their own eligibility to utilize OC. Birth control pills are widely considered safe for most women, except for those who have certain risk factors.<sup>112</sup> For OTC access to be safe, women with these risk factors, called contraindications, would need to accurately self-identify them and refrain from purchasing and using OC once they are identified. Research shows that self-identification of contraindications would not be a problem if women are provided proper packaging and accompanying information for OTC OC purchases.

A 2006 study compared a self-evaluation survey given to women to an identical questionnaire given to their health care provider regarding medical eligibility for OC. Participants' assessments agreed with their providers' at or above 90% of the time for 17 out of 20 eligibility questions.<sup>113</sup> The lowest percentage of agreement was for "Do you usually get your period every month?" and that was 83.6%.<sup>114</sup> Despite these very high levels of agreement, a potential limitation to the study is that it failed to survey women who do not speak English, which leaves out a segment of the female United States population on the margins who might be most likely to benefit from OTC access.<sup>115</sup> A remedy for this potential issue would be public informational campaigns, including information in Spanish and other widely spoken languages, and including comprehensive information on birth control pills' packaging, to ensure women picking them up at pharmacies are aware of relevant considerations. This measure would be in addition to ensuring that birth control would be packaged with a similar questionnaire as utilized in the study, to allow women to easily complete their self-evaluation.

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111 See, e.g., Solmaz Shotorbani et al., *Agreement Between Women's and Providers' Assessment of Hormonal Contraceptive Risk Factors*, 73 *CONTRACEPTION* 501 (2006).

112 Hanna Xu et al., *Medical contraindications in women seeking combined hormonal contraception*, 210 *AM. J. OBSTETRICS & GYNECOLOGY* 210.e1 (2014) (finding that 97.62% of women had no contra-indications and could safely take OC).

113 Shotorbani et al., *supra* note 111, at 501.

114 Shotorbani et al., *supra* note 111, at 503.

115 See *supra* note 74 and accompanying text.

Additionally, in a 2010 study, the 48% of participants who thought that oral contraceptives were not safe for them were just as likely to be medically eligible for birth control pills as the participants who thought that they were eligible.<sup>116</sup> This indicates that women tend to be overly cautious about their self-prescription, rather than the reverse. Further, legalizing OTC access to oral contraceptives could contribute to an increased perception that birth control pills are generally safe for most women to use.<sup>117</sup>

Perhaps most tellingly, in 2012 the American College of Obstetricians and Gynecologists (“ACOG”) announced their support for OTC access for oral contraceptives, and they are joined by the American Medical Association (“AMA”).<sup>118</sup> The ACOG identified certain drawbacks and benefits to OTC access but concluded that the positives outweighed the negatives. The ACOG considered the evidence of how women’s self-assessments compare with their health care providers’ assessments of their eligibility for OC to conclude that OTC access for birth control pills would be safe in this regard. The ACOG also contemplated the importance of yearly oral contraceptive prescription visits for preventive cervical cancer and sexually transmitted infections (“STIs”) screening, only to conclude that oral contraceptive visits do not technically require such screenings and the potential preventive benefits do not outweigh the benefits of easier access.<sup>119</sup> To further increase the accuracy of self-analysis, the ACOG recommends utilizing a simple checklist system to allow women to self-screen their eligibility for birth control usage.<sup>120</sup> As such, the safety concerns of self-prescribing are not a problem for liberalizing OTC access as a way to reduce women’s nonmonetary costs of OC.

#### **b. Women Will Utilize Birth Control Pills Properly Without Supervision.**

A related but slightly different question is that of whether women would utilize birth control pills properly without the yearly supervision of their health care providers. This

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116 Daniel Grossman et al., *Perceptions of the Safety of Oral Contraceptives Among a Predominantly Latina Population in Texas*, 81 *CONTRACEPTION* 254, 254 (2010) [hereinafter Grossman et al., *Perceptions of OC Safety*].

117 *Id.*

118 COMMITTEE OPINION NO. 544: OTC ACCESS, *supra* note 4; Adam Sonfield & Sneha Barot, *Birth Control Pills Should Be Available Over the Counter, But That’s No Substitute for Contraceptive Coverage*, GUTTMACHER INST. (Sept. 11, 2015), <http://www.guttmacher.org/media/inthenews/2014/09/11> [<http://perma.cc/R3BA-32J3>].

119 COMMITTEE OPINION NO. 544: OTC ACCESS, *supra* note 4, at 3 (recommending yearly preventive screening visits regardless of birth control pill usage).

120 COMMITTEE OPINION NO. 544: OTC ACCESS, *supra* note 4, at 3.

is a particularly salient question because the effectiveness of this contraceptive method depends so heavily on how consistently women use it. OC is more effective when used consistently,<sup>121</sup> and ease of access promotes consistency of use.<sup>122</sup> Women express greater willingness to utilize OC if they could access it OTC, which indicates that they may utilize it more consistently as well.<sup>123</sup> The counterargument is that OTC access would assuredly involve less oversight. However, there is no guarantee that the oversight under the current system actually leads to more consistent usage.

In fact, a yearly health care provider visit does not necessarily ensure consistent usage of OC and therefore should not be an obstacle to liberalizing access OTC. A 2014 study determined that efficacy, actions, and attitudes of male partners, being in a long-term relationship, experience with side effects, and misinformation or erroneous reasoning about pregnancy risk were the most important indicators of how consistently women use birth control.<sup>124</sup> This suggests again that visiting a health care provider is not very significant in determining whether a woman will consistently use her birth control pills, and so should not be considered a risk to liberalizing OTC access to birth control.

Prescriptions and visits to a health care provider not only do not increase consistency of usage. In fact, the ACOG responds to concerns about decreasing consistency of usage<sup>125</sup> if OTC access is implemented by citing a study finding that women living in El Paso, who were able to purchase OC OTC by travelling to Mexico, were more consistent in their usage than other women in the United States, who obtained OC in packs containing multiple

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121 Reed et al., *supra* note 36, at 245.

122 Reed et al., *supra* note 36, at 246:

To keep contraception consistent, a woman needs to go to the doctor, renew her prescription before her supply of pills runs out, and remember to take pills daily. If she is relying on condoms or withdrawal, she may need to be assertive with a partner to keep contraception going. These somewhat burdensome behaviors are necessary for consistency.

123 See McCandless, Note, *supra* note 3, at 1140; *cf.* Reed et al., *supra* note 36, at 256 (noting that efficacy is helped by “[f]or those whose problem is low efficacy in remembering to schedule appointments on time, provision of prescriptions for more months of oral contraceptives so as to minimize needed follow-up clinic visits would help.”).

124 Reed et al., *supra* note 36, at 244 (including in the study all types of birth control, but holding consistent for oral contraceptives).

125 COMMITTEE OPINION NO. 544: OTC ACCESS, *supra* note 4 (citing K.O. White et al., *Continuation of prescribed compared with over-the-counter oral contraceptives*, 118 *OBSTETRICS & GYNECOLOGY* 618 (2011) (women given multiple pill packs tend to continue usage more than women who only receive one pack)).

months' supply from a family planning clinic.<sup>126</sup> This finding suggests that OTC access, with its lower nonmonetary costs, could in actuality encourage consistent use<sup>127</sup>—which casts significant doubt on opposing arguments about needing prescriptions to encourage women to take OC regularly.

One potential obstacle is American women's own attitudes, which could negatively impact women's demand for OTC OC. A 2006 study determined that 63% of women felt that OTC access for OC would be safe only if a pharmacist's screening were required before purchase.<sup>128</sup> Additionally, in another study, women raised safety concerns for minors and women with medical conditions using OTC contraceptives.<sup>129</sup> Despite this perception, as earlier indicated, liberalizing OTC access would do much to increase women's perceptions that birth control pills are a highly safe option.<sup>130</sup> Women, on the whole, do not accurately know what to do when they miss an OC pill.<sup>131</sup> To help mitigate this, packaging should contain not only clear explanations of what the proper procedure for missed pills is, but also a graphic illustration.<sup>132</sup> These measures should be seriously considered in the implementation of an OTC system.

## 2. Women Want Over-the-Counter Access.

As with any reproductive policy question, whether women actually want OTC access to oral contraceptives should be a primary consideration. The resounding answer found in the data is yes, they do. Women's collective desire for OTC OC should lend considerable weight to the push for making the option available. Too often, American reproductive policy decisions have ignored women's autonomy.<sup>133</sup>

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126 Joseph E. Potter et al., *Continuation of prescribed compared with over-the-counter oral contraceptives*, 117 *OBSTETRICS & GYNECOLOGY* 551 (2011).

127 *Id.* at 556.

128 Landau, *supra* note 5, at 463.

129 Dennis & Grossman, *supra* note 50, at 84.

130 Grossman et al., *Perceptions of OC Safety*, *supra* note 116, at 254.

131 Lauren B. Zapata et al., *Patient understanding of oral contraceptive pill instructions related to missed pills: a systematic review*, 87 *CONTRACEPTION* 674, 684 (2013).

132 *Id.* It is important, though, to balance provision of easily understood safety instructions with ensuring that such instructions do not seem patronizing or overbearing.

133 *See, e.g., Pa. Planned Parenthood of Se. Pennsylvania v. Casey*, 505 U.S. 833, (1992); Alexis Ura,

Empirical studies reveal just how popular OTC access would be. 68% of women in the United States favor OTC access to OC.<sup>134</sup> 41% of those in favor were women who would start to use OC if it were available in pharmacies, and women who are uninsured and women with low incomes are proportionately more interested in OTC access.<sup>135</sup> This result correlates precisely with which women report the most to gain from OTC access to birth control pills.<sup>136</sup> In another study, which indicated that 62% of United States women favor OTC access to OC, being younger, being divorced or separated, living with an unmarried partner, being uninsured, living in the South,<sup>137</sup> currently using OC, or not currently using any contraception were likely indicators that a women would support an OTC option.<sup>138</sup> Further, 60.2% of non-oral contraceptive users in a study stated that they would be more likely to use oral contraceptives if there were available over the counter—importantly, this study was conducted among a mostly Latina population.<sup>139</sup>

In a study of women utilizing a family planning clinic for abortion services, even though only 42% indicated that they would use birth control pills after their abortion, 61% said they would use them if they were available over the counter.<sup>140</sup> Women who were older than nineteen, were uninsured, had ever used oral contraceptives, had had difficulty obtaining a prescription refill for hormonal contraceptives, or planned to use birth control

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*Appeals Judges Grill Lawyers Over Abortion Law*, TEX. TRIBUNE (Jan. 7, 2015), <http://www.texastribune.org/2015/01/07/federal-appeals-judges-question-texas-abortion-law> [<http://perma.cc/AVP3-4YAM>].

134 Landau, *supra* note 5, at 463.

135 Landau, *supra* note 5, at 463.

136 See *supra* Part I.C.

137 This is an interesting correlation, and it makes sense given how cultural attitudes towards reproductive rights vary within the United States. Politicians from the South are more likely to oppose reproductive autonomy, and Southern states on the whole have more restrictive legislation regarding abortion than other regions. Given the likelihood of these politicians exercising their moral veto over reproductive options, understandably women living in these states would want to ensure that they would be able to purchase OC OTC. See MARVIN D. FEIT & BARBARA A. RIENZO, *THE POLITICS OF YOUTH, SEX, AND HEALTH CARE IN AMERICAN SCHOOLS* 111 (2002) (stating that, at least for clinics treating students, “the South and Sunbelt regions, acknowledged to be the most culturally traditional of the country, are home to 90% of the clinics offering the fewest sexuality services.”). For a discussion of how traditional morality impacts the social debate surrounding OC, see *infra* Part IV.C.

138 Daniel Grossman et al., *Interest in Over-the Counter Access to Oral Contraceptives Among Women in the United States*, 88 *CONTRACEPTION* 544, 544 (2013) [hereinafter Grossman et al., *Interest in OTC Access*].

139 Grossman et al., *Perceptions of OC Safety*, *supra* note 116, at 254 (again referencing a minority group standing to benefit largely from such access).

140 Grindlay et al., *Attitudes Toward OTC Access*, *supra* note 5, at 83.

pills post-abortion were more likely to state that they would use OC if it were available OTC. These characteristics comport those with which women also indicated were more incentives for seeking birth control.<sup>141</sup> At the same time, non-white women were less likely than white women to state that they would use an OTC option.<sup>142</sup> This finding could make sense, given that non-white women do not seem to benefit in the same ways as white women do from access to OC; it is less clear how they do benefit, given the lack of studies in this area.<sup>143</sup> It could also indicate a greater need for increased public information about what OTC access for OC would do. Or, it could indicate that non-white women are more concerned that OTC OC would be more expensive than prescription OC.<sup>144</sup>

Going back to the choice of women living in El Paso, Texas, to either get a prescription for birth control pills or purchase them over the counter in Mexico, helps illustrate women's interest in OTC access for OC as well.<sup>145</sup> One study found that of the women who chose to go to Mexico to obtain OC, 40% cited cost, while 27% cited avoiding going to a doctor to get a prescription as their main motivation.<sup>146</sup> While women without any possibility of OTC access to OC are satisfied with a clinic option, women with a realistic ability to purchase OC OTC take advantage of it, citing both monetary and nonmonetary costs as their motivation.<sup>147</sup> This further establishes that both types of costs influence women's decisions about birth control pill usage. As for individual characteristics of those who chose to go to Mexico for OTC access:

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141 See *supra* notes 28–31 and accompanying text.

142 See *supra* notes 28–31 and accompanying text. This runs counter to other data stating that women on the margins express a greater interest in OTC access—this could be a weakness in sample size, could indicate a need to increase public education about the safety of birth control pills, or could be a result of how some women do not currently have equal ease of access for OC. See *supra* notes 70–74 and accompanying text. If the prescription-only ACA coverage system disproportionately impairs certain women, women of color and Latinas in particular, from accessing OC, it is less likely that they will initially see an OTC system as markedly different due to perceived economic issues (high price in particular) of switching to such a system. See *infra* Part IV.A.

143 See *supra* note 25 and accompanying text.

144 See *infra* Part IV.C for a discussion as to why that should not be the case.

145 Over the counter access is legal in Mexico. Kate Grindlay et al., *Prescription Requirements and Over-the-Counter Access to Oral Contraceptives: A Global Review*, 88 *CONTRACEPTION* 93, 93 (2013) [hereinafter Grindlay et al., *Prescription Requirements and OTC Access*].

146 Joseph E. Potter et al., *Clinic Versus Over-the-Counter Access to Oral Contraception: Choices Women Make Along the US-Mexico Border*, 100 *AM. J. PUB. HEALTH* 1130, 1130 (2010).

147 See *id.*; Reed et al., *supra* note 36, at 256.

Clinic users were younger than were pharmacy users, were somewhat more likely to be single, to have fewer children, and to have somewhat higher levels of education. Clinic users were also more likely to speak English more fluently than they did Spanish and to have been born in and completed their last year of schooling in the United States, but were less likely to be frequent border crossers. Finally, clinic users were slightly more likely than were pharmacy users to have received assistance from US government poverty programs such as Women, Infants, and Children's Program; Temporary Assistance to Needy Families; or food stamps. They were more likely than were pharmacy users to have US health insurance coverage, although coverage was extremely low for both groups, and typically the plans did not pay for [oral contraceptives.]<sup>148</sup>

The finding that pharmacy users were more likely not to have insurance is unsurprising, but important, when considering how access under the ACA can be improved. The language and birth country distinction supports the assertion that the current prescription-only system imposes additional barriers on Spanish-speaking, Latina women who are not citizens.<sup>149</sup> This study indicates that OTC access for OC could help remove some of these selective barriers. Further, the fact that women who have lower levels of education were more likely to use the pharmacy option reflects the finding that women who have less education would benefit more from being able to plan their pregnancies and correspondingly would benefit more from increased accessibility of birth control pills—both of which increase reproductive autonomy.<sup>150</sup> Their interest in OTC access is clear from this situation where they realistically have this option because of their geographic location, as opposed to most other women in the United States.

#### a. Successful Examples of OTC Access

Just as the example of border crossing demonstrates that OTC access to OC can serve women well in the United States, the legalization of OTC access for emergency contraception and the legalization of OTC access to OC in other countries also suggest that an OTC system could be a success.

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148 Potter et al., *supra* note 146, at 1035.

149 See *supra* notes 74–75 and accompanying text.

150 See SONFIELD ET AL., *supra* note 3.

### i. Example of Emergency Contraception

Legalizing OTC OC is often compared to the legalization of emergency contraception. Understanding the shift from prescription-only to OTC for emergency contraception elucidates, in some ways, how a similar shift of OC could occur. However, the two medications have important distinctions that are important to consider when envisioning the transition from prescription-only to OTC OC access. Although administrative procedures were convoluted for emergency contraception's OTC legalization and costs rose, women's usage of emergency contraception has increased as their access has increased—and this is the relevant consideration for an OC comparison.

The administrative process for legalizing OTC access to emergency contraception was long, drawn-out, and unusual.<sup>151</sup> While the Center for Reproductive Rights first petitioned the FDA to allow emergency contraception to be sold over the counter in 2001, the FDA only legalized OTC sales in 2006 and only removed any age and point-of-sale limitations in 2013.<sup>152</sup> After the first petition by the Center for Reproductive Rights, a panel of FDA experts approved emergency contraception, but the head of the office announced that normal procedure would not be followed. He stated that the office needed to first reject the proposal, then approve emergency contraception with an age limit in order to be politically viable.<sup>153</sup> A Government Accountability Office study conducted in 2005 officially determined that, compared with the FDA's process of switching sixty-seven other drugs to OTC status, the process it employed regarding OC was atypical.<sup>154</sup>

While emergency contraception is safe for teenagers,<sup>155</sup> the FDA refused to make it available to them until 2013 as mentioned. Political pressures seem to have influenced this move, as HHS Secretary Sebelius personally blocked the FDA's approval of OTC emergency contraception access for those under eighteen, and President Obama stood

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151 U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-06-109, DECISION PROCESS TO DENY INITIAL APPLICATION FOR OVER-THE-COUNTER MARKETING OF THE EMERGENCY CONTRACEPTIVE DRUG PLAN B WAS UNUSUAL (2005).

152 *The Fight for Emergency Contraception: Every Second Counts*, CTR. FOR REPRODUCTIVE RTS., <http://reproductiverights.org/emergency-contraception-timeline> [<http://perma.cc/MMV8-NF2P>] (last accessed Jan. 25, 2015).

153 *Id.*

154 GAO-06-109, *supra* note 151.

155 Alastair J.J. Wood et al., *The Politics of Emergency Contraception*, 366 NEW ENG. J. MED. 101, 101–02 (2012).

behind her decision.<sup>156</sup> On the one hand, these difficulties warn that switching OC to OTC status could also come with strong political resistance. On the other hand, the FDA and HHS staff might have learned that their attempted blocking of the emergency contraception proposal was costly, resulting in litigation and investigation,<sup>157</sup> and OTC OC could therefore be approved more easily.

However muddled the legalization process was, OTC access to emergency contraception increased availability, although the impact of that increase is uncertain. As a case study representing the trends that happened in the United States more broadly, in Iowa the number of pharmacies carrying emergency contraception increased from 58% under a prescription system, to 70% once the FDA implemented OTC access.<sup>158</sup> However, the effect of this increase has not been unequivocally isolated. Some studies have found that this increase in access decreased abortions in the relevant time period following the switch, while others have found that it had no effect.<sup>159</sup> A 2014 study found that the main impact of the increase in access was changing the location where most women obtained emergency contraception, from hospital emergency rooms to pharmacies. This same study concluded that this change actually resulted in fewer reports of sexual assault. Because women no longer needed to visit the emergency room, they did not report their sexual assault in order to get emergency contraception.<sup>160</sup> Additionally, emergency contraception seems to have slightly increased the instance of STIs among women aged fifteen to twenty-nine.<sup>161</sup>

A final effect of switching emergency contraception to OTC access is that while its cost on the whole to society decreased markedly, its price for individuals

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156 *The Fight for Emergency Contraception: Every Second Counts*, *supra* note 152.

157 *See* GAO-06-109, *supra* note 141.

158 Melissa Lehan Mackin & Kathleen Clark, *Emergency Contraception in Iowa Pharmacies Before and After Over-the Counter Approval*, 28.4 PUB. HEALTH NURSING 317, 317 (July/August 2011).

159 *See* Anjali D. Oza, *Plan B as Insurance: The Effect of Over-the-Counter Emergency Contraception on Pregnancy Termination and STIs* (Oct. 2009) (unpublished manuscript on file with the University of Chicago Harris School of Public Policy Studies) (finding that increased access for emergency contraception was responsible for around 37.2% of the decrease in abortion between the years of 2005 and 2007); *but see* Tal Gross et al., *What Happens the Morning After? The Costs and Benefits of Expanding Access to Emergency Contraception*, J. POL'Y ANALYSIS & MGMT. 70 (Winter 2014) (finding that the switch had no statistically significant influence on abortion rates).

160 Gross et al., *supra* note 159, at 86–88.

161 Oza, *supra* note 159.

skyrocketed.<sup>162</sup> The cost for society decreased because when women had to obtain emergency contraception in emergency rooms, this required the full cost of a hospital visit, which can be very high.<sup>163</sup> OTC emergency contraception effectively eliminated that expense. However, costs to individuals for emergency contraception increased because the market was not fully liberalized. Emergency contraception was still available from health care providers for no cost, which skewed OTC demand.<sup>164</sup>

Despite some probable similarities, the negative side effects of increasing access to emergency contraception are unlikely to transfer to OTC access for OC. Emergency contraception usage differs significantly from OC because women are most likely to use emergency contraception when they are unsure if they had safe sex. This same situation is not associated with birth control usage, and so the effects will likely be similar but not identical.<sup>165</sup> Emergency contraception is a reactive measure, while OC is a proactive one. In practical terms, it is more common to use emergency contraception after unexpected sexual encounters—that is, often, when a woman is not in a relationship.<sup>166</sup> Additionally, OC does not have the same relation to sexual assaults that emergency contraception does. As such, the benefits of being able to plan pregnancies, or being able to plan on not being pregnant, apply to increasing access to OC, whereas they would not apply to emergency contraception. Politically, OC could be less problematic than emergency contraception, as OC is less culturally divisive than emergency contraception.<sup>167</sup> Economically, OC is already

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162 Dennis & Grossman, *supra* note 50, at 89.

163 The distinction here should be made between visits to emergency rooms by survivors of sexual assault, and women who simply wanted access to emergency contraception after having had unprotected sex. Before emergency contraception was available OTC, both required a visit to a hospital or doctor. For women who simply wanted to obtain emergency contraception, the cost of a hospital visit was clearly unneeded and was effectively eliminated once emergency contraception became available OTC. On the other hand, even with OTC access, sexual assault survivors obtain emergency contraception from hospitals, and unfortunately high costs can result, despite the Violence Against Women Act's protections for survivors. Kris van Cleave, *For some sex assault victims, ordeal carries price tag*, CBS NEWS (Nov. 12, 2014, 12:04 PM), <http://www.cbsnews.com/news/for-some-sex-assault-victims-rape-kits-come-at-a-price> [<http://perma.cc/L5G9-T8FJ>].

164 Cf. Ya-Chen Tina Shih et al., *The effect on social welfare of a switch of second-generation antihistamines from prescription to over-the-counter status: A microeconomic analysis*, 24 CLINICAL THERAPEUTICS 701 (2002).

165 Tal Gross et al., *supra* note 159, at 75–76.

166 Whereas women in long-term, monogamous relationships are more likely to use OC. See *supra* note 34.

167 Abortion opponents believe that emergency contraception is, like an abortion, ending a life. While these groups still do not approve of oral contraception, the reasoning is different. Oral contraception is seen more as a facilitator for promiscuity, rather than akin to an abortion. For a discussion of the cultural issues surrounding OC, see *infra* Part IV.C.

marketed in the United States by fifty drug manufacturers, while emergency contraception is marketed by only four,<sup>168</sup> meaning that the market for OC would be substantially more competitive than it was for emergency contraception. These important differences imply that OC could transition to OTC status quite differently than emergency contraception.<sup>169</sup>

## ii. Comparative Legal Perspective: Examples from Other Countries

A number of countries have successfully implemented OTC access for OC, providing further evidence that a similar system could work in the United States as well. In fact, the majority of the world lives in a country where birth control pills are available without a prescription.<sup>170</sup> Despite this widespread access, nearly all Western European countries, Canada, Australia, the United States, Japan, Saudi Arabia, and a few others still require a prescription in order to use birth control pills.<sup>171</sup>

Around the world, several different access models for birth control pills exist. There are the two simple, but opposite, models of legal OTC access (24% of the world's countries) and prescription access (31%).<sup>172</sup> Then, there are countries where OTC access is not technically legal, but the population and their government generally recognize that pharmacies carry birth control pills (38%), and women regularly purchase them OTC.<sup>173</sup> There are also countries where OTC access is legally allowed, but only with the added requirement of a pharmacist's screening before purchase (8%).<sup>174</sup> Finally, a few countries require a prescription to access birth control pills initially, but then allow OTC refills after

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168 *Directory of Hormonal Contraceptives*, INT'L PLANNED PARENTHOOD FED., <http://contraceptive.ippf.org/search?search.searchtext=&search.component=&search.countrycode=US> [<http://perma.cc/PB9J-WGQ2>] (last accessed Feb. 20, 2015).

169 For a discussion of the differences and similarities of potential OTC pricing for OC compared to emergency contraception, see *infra* Part IV.A.

170 This includes both countries where birth control pills are legally sold over the counter and countries where birth control pills are informally available in pharmacies, although there is no specific law authorizing their sale there. Grindlay et al., *Prescription Requirements and OTC Access*, *supra* note 145, at 93.

171 Grindlay et al., *Prescription Requirements and OTC Access*, *supra* note 145, at 93.

172 Grindlay et al., *Prescription Requirements and OTC Access*, *supra* note 145, at 93.

173 Grindlay et al., *Prescription Requirements and OTC Access*, *supra* note 145, at 93.

174 Grindlay et al., *Prescription Requirements and OTC Access*, *supra* note 145, at 93.

that.<sup>175</sup> Compared with lower-income countries, high GDP countries, like those in Europe, the United States, Australia, and Canada, are much more restrictive about how women can legally access birth control pills.<sup>176</sup> South Asian countries generally have legalized OTC access, South American countries mostly informally allow OTC purchases, and countries in Africa have the greatest regional diversity in the type of access allowed.<sup>177</sup> As many other countries have successfully legalized OTC OC, it seems that no comparative legal issues indicate a potential issue with OTC access in the United States.

Higher-income countries have started to show signs of interest in switching to OTC OC. London very successfully completed a pilot program of allowing OTC access for OC to women and girls above the age of sixteen in April 2012. The results of the program indicated that OTC access to OC reduced consumption of emergency contraception.<sup>178</sup> The National Health Service concluded that

[t]rained community pharmacists are able to provide an oral contraceptive service under a [Patient Group Direction]. The service has been largely accessed by local women aged 20-24 years. Most consultations have been with black British, Caribbean and African women, and 46% of initial pill supplies have been to first time pill users. . . . Service users have valued the service highly, in particular the convenience, anonymity, drop-in system, long opening hours and lack of waiting time. Possible improvements could be made to accessing the service and signposting from counter staff. [Emergency contraception] has declined in the pharmacy providing the most oral contraception. Local GP practices and sexual and reproductive health services have referred clients to the service, and therefore opened up the possibility of a future service model aiming to shift activity from [prescription] services.<sup>179</sup>

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175 These countries include Botswana, the British Virgin Islands, Burkina Faso, New Zealand, and Zimbabwe. Grindlay et al., *Prescription Requirements and OTC Access*, *supra* note 145, at 93.

176 *Global Oral Contraception Availability*, OCS OTC WORKING GROUP, <http://ocsotc.org/wp-content/uploads/worldmap/worldmap.html> [<http://perma.cc/4LLL-R5S8>] (last accessed Jan. 23, 2015).

177 Grindlay et al., *Prescription Requirements and OTC Access*, *supra* note 145, at 93.

178 *Widen over-the-counter pill access, says NHS report*, BBC NEWS (Apr. 25, 2012), <http://www.bbc.com/news/health-17847069> [<http://perma.cc/AR8K-6A3X>].

179 BRITISH NAT'L HEALTH SERV., SOUTH EAST LONDON, EVALUATION OF ORAL CONTRACEPTION IN COMMUNITY PHARMACY PILOT IN SOUTHWARD AND LAMBETH 4 (2012), [http://ocsotc.org/wp-content/uploads/2012/04/NHS-2012\\_Evaluation-of-pharmacy-provision-of-OCs-in-London-1-2012.pdf](http://ocsotc.org/wp-content/uploads/2012/04/NHS-2012_Evaluation-of-pharmacy-provision-of-OCs-in-London-1-2012.pdf) [<http://perma.cc/W76K-2HBA>].

It is notable that emergency contraception use declined with the implementation of OTC access for OC. This could prove more effective than a system where emergency contraception alone is available without a prescription—effective because emergency contraception usually indicates a reactive decision, whereas OC provides the benefit of being able to plan in advance. Additionally, the women benefitting from this program immediately cited, as a primary benefit, the reduction in nonmonetary costs that OTC access provides, illustrating once again how great a barrier these costs actually pose. The success of this pilot program, in a country similarly positioned economically and culturally to the United States, suggests that the United States (and other higher income countries) should implement OTC access as it is both practically feasible and effective.

#### **IV. If Over-the-Counter Access Makes So Much Sense, Why Not Implement It Immediately?**

The findings above clearly demonstrate that women want OTC access to OC, and moreover that OTC access would be safe, would address issues with the ACA's insurance coverage-only system, would save both monetary and nonmonetary costs, and would make birth control pills available for those women who would benefit most from its use. Yet an immediate switch from the prescription system could have a number of downsides. These include: (1) OC could increase women's out-of-pocket costs for OC, while saving insurers money; (2) OC could become a partisan fight; and (3) cultural attitudes about reproductive autonomy might inhibit effective implementation. There are ways to temper these issues, though, and successfully implement OTC OC. Namely, HHS should require Medicaid and insurance companies to reimburse women for OTC OC purchases, so that women do not have to choose between convenience and out-of-pocket costs and so that insurers are invested in a competitive OTC market. Additionally, the recent change in Republicans' messaging regarding OC could signal a shift in the political and cultural debate over contraception. This would be helpful for OTC implementation, particularly through citizens' petitions to the FDA.

##### **A. Economic Issues**

Switching any drug, including OC, to being available OTC makes sense from an economic standpoint when the social benefit of the switch outweighs any social cost.<sup>180</sup> In economics, this is referred to as the net social benefit. This cost-benefit analysis differs from an individual valuing whether or not the price of birth control pills is worth it to them. Net

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180 Peter Temin, *Costs and Benefits in Switching Drugs From Rx to OTC*, 2 J. HEALTH ECON. 187, 187 (1983).

social benefit takes into account both monetary and nonmonetary costs, assumes that all individuals would face the same types of both costs (an assumption that does not bear out in reality), and is based on potential benefit to “society” as a whole.<sup>181</sup> Economists refer to this societal benefit as “minimizing the deadweight loss” of a certain policy.<sup>182</sup> Calculating the net societal benefit means comparing new benefits minus new costs with old benefits minus old costs. If this difference is positive, the switch to over the counter access will be beneficial because, overall, costs will be saved.<sup>183</sup> Economic theory predicts that the price of drugs switched to OTC access will be cheaper than they were under prescription-only OTC access because more companies will enter the market to compete for new business and that competition will lower prices. The lower prices, in turn, will then increase consumer demand. Individuals who had initially been priced out of the prescription market will then be able to enter and buy the drug.<sup>184</sup>

There are a few characteristics that increase the chance that a switch to OTC access will be a success, under this theory. Drugs that are not patented<sup>185</sup> are better candidates for OTC access because drugs that are still under patent protection will tend to be over-priced as only a limited number of companies are allowed to manufacture them.<sup>186</sup> More companies producing the drug means more competitive pricing, which in turn reduces the deadweight loss to society. Additionally, drugs that are offered only through OTC access, not both OTC and prescription access, are also better candidates. Only being offered OTC will stabilize both price and demand for the drug<sup>187</sup> and will ensure that the cost savings flowing from

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181 See, e.g., Mandy Ryan & Brian Yule, *Switching Drugs from prescription-only to over-the-counter availability: Economic Benefits in the U.K.*, 16 HEALTH POL'Y 233, 234–36 (1990); Temin, *supra* note 180.

182 Deadweight loss simply means any increased net cost resulting from a policy change, not transferred as a benefit to another party. See, e.g., Temin, *supra* note 180.

183 See Temin, *supra* note 180.

184 Shih et al., *supra* note 164.

185 See Amanda Holpuch, *Generic Emergency Contraception: Age Restriction to Remain in Place*, GUARDIAN: U.S. NEWS (July 24, 2013, 17:03 EST), <http://www.theguardian.com/world/2013/jul/24/american-generic-emergency-contraception-age-restriction> [<http://perma.cc/B47A-RYXQ>].

186 Shih et al., *supra* note 164, at 703.

187 Demand for drugs available both ways is said to be elastic—elasticity of demand describes how responsive individuals' demand is to small changes in price. This means that, because someone could opt out of the over-the-counter option by going to a doctor and getting a prescription for a drug, that would then be covered by insurance, a small change in the price of a drug available both over-the-counter and by prescription would lead to a relatively large change in demand. This makes the drug very susceptible to price shocks. Conversely, a drug that is only available over-the-counter will be relatively inelastic because individuals who

increased OTC demand goes to individuals purchasing the drug, as opposed to insurance companies.<sup>188</sup> Finally, drugs that do not have a large risk of harm caused by inappropriate usage after self-diagnosis are better candidates for OTC access, because this decreases the risk of a large cost being placed on a single individual.<sup>189</sup>

Oral contraceptives would be a good candidate for OTC access based on the above criteria and would likely decrease in price after a switch to OTC availability. The AMA and the ACOG have found that birth control pills do not pose a great risk from improper usage for many women, and so this also decreases the potential of a huge cost of misuse, born by only some individuals.<sup>190</sup> Birth control pills are not patent-protected, and there are generic oral contraceptives readily available.<sup>191</sup> This means that monopolistic pricing<sup>192</sup> would not be as much of an issue for OC. Fifty manufacturers currently produce oral contraceptives of varying kinds, and so competition for the OTC market would likely be robust.<sup>193</sup> A competitive market means low prices and high availability for OC. For example, allergy medicine, although initially only available with a prescription, successfully transitioned

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need the drug will have no choice but to purchase it from pharmacies. This means that small changes in the price of the drug would have much less of an effect on demand. *See, e.g.,* Shih et al., *supra* note 164.

188 Insurance companies stand to benefit most from a reduction in the cost to society that occurs when a drug is moved to over-the-counter availability because they are the ones who no longer have to pay for health care provider visits where the drug is prescribed, and, if the drug is not included in a plan provision covering over-the-counter purchases, the individual would assume the cost of the drug itself too, whereas before the insurance company would have been responsible. *See* Susan E. Andrade et al., *The Effect of an Rx-to-OTC Switch on Medication Prescribing Patterns and Utilization of Physician Services: The Case of H2-Receptor Antagonists*, 37 MED. CARE 434 (1999); Patrick W. Sullivan et al., *Transitioning the Second-Generation Antihistamines to Over-the-Counter Status: A Cost-Effectiveness Analysis*, 41 MED. CARE 1382 (Dec. 2003).

189 This large cost would be the cost of dealing with injury or harm after an improper self-diagnosis. Social cost analysis includes both monetary and nonmonetary costs, so medical care and pain and suffering would be included. It would be a large and concentrated cost if there was a relatively low chance that a relatively large harm would befall someone who improperly used an OTC drug. *See* Shih et al., *supra* note 164.

190 *See* COMMITTEE OPINION No. 544: OTC ACCESS, *supra* note 4; Sonfield & Barot, *supra* note 118.

191 *Bayer Healthcare Pharm., Inc. v. Watson Pharm., Inc.*, 713 F.3d 1369, 1369 (Fed. Cir. 2013) (holding patent protection for oral contraceptives invalid for obviousness).

192 Monopolistic behavior refers to the phenomenon where, because only one or a few producers are in the market for a certain good, they have disproportionate control over the price of their goods. A market that is controlled by monopolistic pricing is said to be “noncompetitive.”

193 *See supra* note 168.

to OTC access and is commonly available, fairly cheaply, in local pharmacies.<sup>194</sup> It would seem that the market for OTC OC would produce similar results. For a graphic depiction of how a switch to OTC access would save societal costs, see Appendix A.

OC, like allergy medicine, in all likelihood would sell for reasonable prices on pharmacy shelves.<sup>195</sup> According to a 2013 study of a representative national sample of women at risk for unintended pregnancy, women are willing to pay approximately \$20 per monthly pack of birth control pills purchased over the counter, meaning that they would only pay \$240 per year.<sup>196</sup> This estimate includes nonmonetary cost savings, as the women interviewed are including in their calculations the increased ease of obtaining birth control pills when they estimate that their maximum price is \$20. Some generic birth control pills are already available at self-pay prices of around \$15 or \$20 a month,<sup>197</sup> and liberalizing OC will only drive down those prices further. As such, from a purely economic perspective, women are likely to take advantage of the OTC option.

Despite this evidence, some critics assert that OTC birth control pills would only be available at exorbitant costs,<sup>198</sup> citing the high prices of emergency contraception when

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194 Sullivan et al., *supra* note 188; see also *Claritin Indoor & Outdoor Allergies*, RITE AID PHARMACY, <https://shop.riteaid.com/claritin-indoor-outdoor-allergies-original-prescription-strength-10-mg-tablets-20-tablets-0335007> [<https://perma.cc/2PDY-QS7W>] (last accessed Feb. 21, 2015) (twenty tablets available for \$18.99); *Claritin Tablets 24 Hour Allergy*, CVS PHARMACY, <http://www.cvs.com/shop/health-medicine/allergy-asthma/allergy-sinus-medicine/claritin-tablets-24-hour-allergy-skuid-210285> [<http://perma.cc/WSY9-FCY6>] (last accessed Feb. 21, 2015) (twenty tablets available for \$19.79).

195 The only caveat could be that OTC prices could increase to accommodate OC manufacturers' concerns about potential class actions. This seems unlikely to be a significant concern though because of how widely used OC already is. The risk would therefore not increase substantially with an OTC switch.

196 Grossman et al., *Interest in OTC Access*, *supra* note 138, at 544. This is also making the assumption that women would be happy with a generic OC, specifically for the purpose of preventing pregnancy. OC is also currently prescribed for other purposes like regulating periods or controlling acne. These uses would still require a health care provider visit and might result in a more specific demand for one type of birth control pill. It also could result in an increased willingness to pay for a specific brand or dosage.

197 *Price of the Pill*, WNYC, <http://project.wnyc.org/birth-control-prices/embed.html?layer=undefined> [<http://perma.cc/S7YH-PQG8>] (last accessed Feb. 21, 2015) (stating that the price of Aviane at a Rite Aid in Manhattan would cost \$19.99 a month for a self-pay patient).

198 See, e.g., Maria Liasson, *Changing Tack: GOP Candidates Support Over-the-Counter Birth Control*, NPR SHOTS: HEALTH NEWS BLOG (Sept. 12, 2014, 3:30 EST) <http://www.npr.org/blogs/health/2014/09/12/347749930/changing-tack-gop-candidates-support-better-access-to-birth-control> [<http://perma.cc/VSX9-P5Z5>] (citing Democratic pollster Cellinda Lake to say that OTC OC could cost “\$600 per year”).

it was first made available OTC.<sup>199</sup> There are several flaws in this comparison. First, when emergency contraception was legalized for OTC access, it was still protected by a patent. Plan B was the sole brand legally permitted to market emergency contraception in pharmacies. The FDA only legalized sale of generic emergency contraceptives in 2014—eight years after legalizing OTC sale of Teva Pharmaceutical's Plan B One Step.<sup>200</sup> The initial monopoly power of Teva was part of the reason for the increase in emergency contraception's pricing. The competitive effects of legalizing generic sales have been slow to take effect (generics are about \$10 cheaper than Plan B)<sup>201</sup> because of the way it was initially legalized and because the FDA, as part of its earlier agreement with Teva, insists on labeling generic emergency contraception as only for women above the age of seventeen.<sup>202</sup> Additionally, ten times as many manufacturers sell OC currently than sell emergency contraception.<sup>203</sup> As such, there would not be the same monopolistic pricing problem, preventing prices from becoming competitive, for OC. Second, in addition to economic differences, emergency contraception and OC are utilized for different purposes, meaning that women's purchasing patterns would be more consistent and demand would also be larger for OC.<sup>204</sup>

There is a concern that if OTC OC access were legalized while a prescription option was still available, and still covered by insurers, this could skew the market for OC.<sup>205</sup> If

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199 See, e.g., Amelia Thompson-Deveaux, *Offering Birth Control Over the Counter Wouldn't Make It Any Cheaper*, FIVE THIRTY-EIGHT POLITICS (Nov. 18, 2014, 7:10 EST), <http://fivethirtyeight.com/features/offering-birth-control-over-the-counter-wouldnt-make-it-any-cheaper> [<http://perma.cc/UB57-U7R3>]; Sonfield & Barot, *supra* note 118.

200 See Amanda Holpuch, *Generic emergency contraception: age restriction to remain in place*, GUARDIAN (July 24, 2013, 17:03 EST), <http://www.theguardian.com/world/2013/jul/24/america-generic-emergency-contraception-age-restriction> [<http://perma.cc/4BLJ-FM7N>].

201 *Compare Plan B One-Step Emergency Contraceptive*, CVS PHARMACY, <http://www.cvs.com/shop/sexual-health/condoms-contraceptives/female-contraceptives/plan-b-one-step-emergency-contraceptive-skuid-876669> [<http://perma.cc/T5GW-ADRC>] (last accessed Feb. 21, 2015) (\$49.99), with *CVS Take Action Emergency Contraceptive Tablet*, CVS PHARMACY, <http://www.cvs.com/shop/product-detail/CVS-Take-Action-Emergency-Contraceptive-Tablet?skuId=966195> [<http://perma.cc/L6KC-4EDN>] (last accessed Feb. 21, 2015) (\$39.99).

202 Amanda Holpuch, *supra* note 200.

203 See *supra* note 168 and accompanying text.

204 See *supra* notes 142–143 and accompanying text.

205 This is based on the logic that drugs offered under a dual prescription and OTC system are likely to not be completely competitive priced and to give insurance companies the benefit of reduced prices as opposed to

the current relatively low cost of OC is driven by insurers' bargaining power with drug companies, then insurers will require women to continue getting prescriptions to preserve these insurers' advantage.<sup>206</sup> This effectively would save insurers money, as some women would choose to pay the sticker price in their pharmacy instead of getting a prescription, generating savings on both the cost of women's health care provider's visits and OC itself.<sup>207</sup> At the same time, women who could not afford OTC OC would continue relying on insurance.<sup>208</sup> With this option still in place, there would be less demand than should exist for the OTC option, and, as a result, suppliers would likely raise prices.<sup>209</sup> This price increase for OTC OC would hurt uninsured women most, who generally have no option aside from OTC access.<sup>210</sup>

However, this model of insurers' bargaining power is not necessarily correct. OC could simply be a relatively inexpensive drug. If this is true, insurers should not resist the OTC system very strongly. HHS itself maintains that, as OC prevents the significantly higher health care costs associated with unintended pregnancies, OC is in fact a cost saving measure, rather than an expense. Justice Alito focuses on this issue in his *Burwell v. Hobby Lobby* opinion,<sup>211</sup> and research supports it as well. The Guttmacher Institute found that \$1

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consumers. *See supra* notes 161–162 and accompanying text.

206 Eric P. Brass, *Changing the Status of Drugs from Prescription to Over-the-Counter Availability*, 345 NEW ENGL. J. MED. 810, 815 (2001).

207 *See id.*; PATEL & RUSHEFSKY, *supra* note 58, at 262–63; *cf.* Jessica Cohen et al., *Price Subsidies, Diagnostic Tests, and Targeting of Malaria Treatment: Evidence from a Randomized Controlled Trial* (Nat'l Bureau of Econ. Research, Working Paper No. 17943, 2012), <http://www.nber.org/papers/w17943> [<http://perma.cc/C6W7-XJH4>] (detailing the success of government subsidies for high need drugs in a low-income country).

208 *Cf.* Bruce Stewart & James Grana, *Are Prescribed and Over-the-Counter Medicines Substitutes?*, 33 MED. CARE 487 (1995) (finding that when insurers will cover drugs with prescriptions, but not those OTC, individuals will continue to go to the doctor for prescriptions).

209 *Cf. supra* note 164.

210 Richters, Note, *supra* note 59, at 407.

211 134 S. Ct. 2751, 2781 (2014):

It seems likely, however, that the cost of providing the forms of contraceptives at issue in these cases (if not all FDA-approved contraceptives) would be minor when compared with the overall cost of ACA. According to one of the Congressional Budget Office's most recent forecasts, ACA's insurance-coverage provisions will cost the Federal Government more than \$1.3 trillion through the next decade. . . . If, as HHS tells us, providing all women with cost-free access to all FDA-approved methods of contraception is a Government interest of

of public funding used for contraception saves \$3.74 in pregnancy and maternal health care expenses.<sup>212</sup> Contraceptive funding also saves abortion costs.<sup>213</sup> Under this model, insurance companies should rationally prefer to provide coverage for contraceptives, instead of later dealing with higher medical costs.

Regardless of whether or not insurers will resist the switch, given that the ACA provides some women OC without any out-of-pocket costs, these women will necessarily face higher prices with OTC access. As a solution to this issue, HHS could change their policy so that both Medicare and private insurance plans would be required to reimburse women for their purchase of OC OTC.<sup>214</sup> If insurance companies and Medicare were required to cover the cost of OTC OC, first, women would not be individually responsible for paying out-of-pocket, and, second, insurance companies and the federal government<sup>215</sup> would have a vested interest in making sure the price of OTC remains competitive. Implementation of this system would be technically easy. HHS currently specifies that insurance companies must provide coverage for “all FDA approved contraceptive measures,” “as prescribed.”<sup>216</sup> If HHS included OC “purchased over-the-counter,” this would effectively eliminate women’s out-of-pocket cost for that access option too.

In fact, Medicaid already incorporates coverage for OTC medicines, which could extend to OC.<sup>217</sup> Medicaid allows states to approve coverage of OTC emergency contraception

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the highest order, it is hard to understand HHS’s argument that it cannot be required under RFRA to pay *anything* in order to achieve this important goal.

212 Adam Sonfield, *The Case for Insurance Coverage of Contraceptive Services and Supplies Without Cost Sharing*, GUTTMACHER POL’Y REV. (Winter 2011), <http://www.guttmacher.org/pubs/gpr/14/1/gpr140107.html> [<http://perma.cc/455K-AYAQ>].

213 Jeffrey F. Peipert et al., *Preventing Unintended Pregnancies by Providing No-Cost Contraception*, 120 OBSTETRICS & GYNECOLOGY 1291 (2012).

214 See, e.g., Sonfield & Barot, *supra* note 118.

215 The federal government has a lot of clout in this arena because the government is the single largest purchaser of health care in the United States, accounting for 29% of total expenditure. PATEL & RUSHEFSKY, *supra* note 58, at 25.

216 *Affordable Care Act Prevention Coverage Expands Women’s Health and Well-Being*, HRSA, <http://www.hrsa.gov/womensguidelines> [<http://perma.cc/VTW5-JGHS>] (last accessed Jan. 30, 2015); see also Kevin Drum, *Should Liberals Support OTC Access to Oral Contraception?*, MOTHER JONES (Sept. 9, 2011), <http://www.motherjones.com/kevin-drum/2014/09/should-liberals-support-otc-access-oral-contraceptives> [<http://perma.cc/CWC7-QWU4>].

217 Sonfield & Barot, *supra* note 118; NAT’L HEALTH LAW PROGRAM, *OVER THE COUNTER OR OUT OF REACH?* (2007),

specifically if it is treated like a prescription. This, in most states, requires some kind of verification from a health care provider, which has similar nonmonetary costs to an actual prescription. However, several states, including New York, have waived this requirement. Ensuring that no such requirement would come along with OTC OC would be crucial. The catch is that the failure of the ACA's complementary expansion of Medicare provision means, even if Medicare did reimburse women for purchasing OC OTC, there is still a segment of women in need of that assistance who are not receiving it.

A temporary government price control could be useful to allow all women who want to enter the market to do so. However, the United States, unlike many less developed countries, does not implement drug price controls.<sup>218</sup> The limitations Medicaid and Medicare place on reimbursing health care providers for drugs are the closest the United States comes to regulating drug prices. These limitations specify that government programs will only reimburse patients for the cost of a generic drug, if a suitable one is available. However, this is comparatively ineffective. The government, besides the Department of Defense and the Veterans Affairs Administration, is not allowed to negotiate lower prices with drug manufacturers, unlike insurance companies or hospital networks.<sup>219</sup> This is why reimbursement is important for an effective OTC system. Otherwise, insurance companies have no stake in lowering the price of OC overall, and the government would not be able to do anything about it.

A contingency consideration is what happens if Republicans make good on their campaign promise to attack the ACA. While President Obama is in office, Republicans will not be able to repeal the Act. However, it is possible that the Republicans will be able to significantly alter it.<sup>220</sup> Also, looking to the next presidential election, the ACA's staying

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<http://www.healthlaw.org/component/jsfsubmit/showAttachment?tmpl=raw&id=00Pd00000077hMMEAY>  
[<http://perma.cc/XR6S-MCLD>].

218 See F.M. Scherer, *The Pharmaceutical Industry—Prices and Progress*, 351 *NEW ENG. J. MED.* 927, 929–31 (2004).

219 This affords insurers large benefits in terms of price reductions, compared to the government. See *id.* at 929–31; PATEL & RUSHEFSKY, *supra* note 58, at 262–63; cf. Cohen et al., *supra* note 207 (detailing the success of government subsidies for high need drugs in a low-income country).

220 Most likely provisions to be candidates for reforms include the employer mandate, the individual mandate, and the device tax that the ACA implements. *Can the GOP Repeal the Affordable Care Act?*, *AL JAZEERA AM.* (Nov. 13, 2014), <http://america.aljazeera.com/watch/shows/inside-story/articles/2014/11/13/can-the-affordablecareactberepealedandreplacedbythegop.html> [<http://perma.cc/KZ5B-NYCU>]. Another potential way of challenging the ACA is through litigation, but, after the Supreme Court struck down a second challenge to the law, this may be a less viable avenue. See *King v. Burwell*, 135 S. Ct. 2480 (2015).

power into 2017 could be uncertain as well. If the contraceptive mandate is repealed, and full OTC access implemented simultaneously, this could result in a fully competitive market, but would also mean an increase in women's costs for OC out-of-pocket. This means less access for all women, but particularly for those who are marginalized. Such a hypothetical underscores the need to expand insurance coverage for OC purchased OTC, as a transition, as opposed to simply expanding access.

## B. Political Issues

The fall of 2014, at first glance, seemed like an exciting time for advocates of OTC OC. Republican United States congressional candidates began to voice their support for OTC sales of birth control pills. It may have seemed like the beginning of widespread agreement over increased reproductive freedom and access. A more careful look, however, reveals that campaign promises of OTC access are fairly empty, as it is the FDA, not Congress, who would make this decision. Further, immediate implementation of an OTC system might not actually increase access to the extent that politicians have begun to claim.

Listening to Republican politicians suggests they have internalized all of the information cited about the benefits of widespread access to OC for women's general wellbeing. Republicans like Rep. Barbara Comstock (R-Va.), Rep. Cory Gardner (R-Col.), Senate candidate for Virginia Ed Gillespie, Senate candidate for Minnesota Mike McFadden, and Republican Senate candidate for North Carolina Thom Tillis have recently come out in favor of legalizing OTC access for birth control pills.<sup>221</sup> These candidates cite how the option would be safe, how this would lessen government's interference with women's reproductive decisions, and how OTC access would be more convenient.<sup>222</sup>

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221 Anna Altman, *Why Are Republicans in Favor of Over-the-Counter Birth Control?*, N.Y. TIMES OP. TALK (Sept. 29, 2014, 6:10 EST), [http://op-talk.blogs.nytimes.com/2014/09/29/why-are-republicans-in-favor-of-over-the-counter-birth-control/?src=recg&\\_r=0](http://op-talk.blogs.nytimes.com/2014/09/29/why-are-republicans-in-favor-of-over-the-counter-birth-control/?src=recg&_r=0) [<http://perma.cc/ABC7-BBSA>]; Thomas M. Burton & Natalie Andrews, *New Discord Brews on Over-the-Counter Contraceptives*, WALL ST. J. ONLINE (Sept. 10, 2014, 13:15 EST), <http://www.wsj.com/articles/new-discord-brews-on-over-the-counter-contraceptives-1410377872?cb=logged0.8794443022925407> [<http://perma.cc/QG87-AAJG>]; *Barbara Comstock for Delegate*, <http://www.comstockfordelegate.com/home.aspx> [<http://perma.cc/BL72-DL4V>] (last accessed Jan. 25, 2015); Sandhya Somashekhar, *GOP Senate Hopefuls Favor Over-the-Counter Birth Control*, WASH. POST, Sept. 2, 2014, at A3, available at [http://www.washingtonpost.com/national/health-science/gop-senate-hopefuls-favor-over-the-counter-birth-control/2014/09/02/1916bef2-32c0-11e4-a723-fa3895a25d02\\_story.html](http://www.washingtonpost.com/national/health-science/gop-senate-hopefuls-favor-over-the-counter-birth-control/2014/09/02/1916bef2-32c0-11e4-a723-fa3895a25d02_story.html) [<http://perma.cc/55NA-A7LW>]; Liasson, *supra* note 198.

222 Altman, *supra* note 221.

Unfortunately, despite proposing ideas that advocates of reproductive freedom could support, these conservative candidates' agendas are suspect. This list of candidates is not known for its genuine attention to women's reproductive freedom. Most notably, Tillis and Comstock were avid supporters of North Carolina's and Virginia's proposals requiring pre-abortion transvaginal ultrasounds.<sup>223</sup> It is increasingly apparent that women voters do not support candidates who restrict access to reproductive services,<sup>224</sup> and so these candidates might be changing their message accordingly. Planned Parenthood has criticized these proposals as shortsighted, citing the potential for OTC birth control pills' price to skyrocket if implemented without insurance coverage for such an option, alongside a repeal of the contraceptive mandate.<sup>225</sup> Similarly, experts who have supported OTC access to OC for decades have come out against these Republicans' stated plan. They say that it is not feasible and is simply an individual liberty mask for making access more difficult.<sup>226</sup> Democrats are resisting the option for their own reasons. The ACA and its contraceptive mandate were politically costly, and they do not want to see that effort dismantled.<sup>227</sup>

Also frustrating is the realization that these candidates are making mere campaign promises, as Congress would not be in charge of a switch to OTC access, as this decision under the FDA's purview.<sup>228</sup> Elected representatives and senators would have little to no control over such a policy change. Additionally, the switch is unlikely to happen anytime soon; no drug company has made an application to sell their oral contraceptive pill OTC yet, according to FDA records.<sup>229</sup> Until that happens, an OTC option will not be seriously

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223 Altman, *supra* note 221.

224 *Protecting Access to Reproductive Health Care and Abortion as an Electoral Priority*, GREENBERG QUINLAN ROSNER RESEARCH (2014), <http://plannedparenthoodaction.org/files/7714/1580/3490/11-11-14-NARAL-PPAF-Post-Election-Poll-Memo.pdf> [<http://perma.cc/E995-59G2>].

225 *The Truth About Over-the-Counter Access to Birth Control*, PLANNED PARENTHOOD, <http://www.plannedparenthoodaction.org/elections-politics/newsroom/press-releases/truth-about-over-counter-access-birth-control> [<http://perma.cc/73UU-HJRF>] (last accessed Jan. 25, 2015). Not to mention that many Republican candidates support defunding Planned Parenthood altogether. *See, e.g., Romney Reiterates Defunding Planned Parenthood*, POLITICO (Oct. 10, 2012, 15:50 EST), <http://www.politico.com/blogs/burns-haberman/2012/10/romney-reiterates-defunding-planned-parenthood-138063.html> [<http://perma.cc/6UFX-E8FP>].

226 Thompson-Deveaux, *supra* note 199.

227 *Cf. Health Care*, DEMOCRATS.ORG, [http://www.democrats.org/issues/health\\_care](http://www.democrats.org/issues/health_care) [<http://perma.cc/M5R8-3HA4>] (last accessed Apr. 2, 2015).

228 Burton & Andrews, *supra* note 221.

229 Burton & Andrews, *supra* note 221.

considered. As exemplified with emergency contraception's switch to OTC status, FDA approval might pose problems with administrative politics. The FDA also might balk at allowing OTC OC access for women under eighteen for political reasons, although the option is safe and would be helpful, if the emergency contraception example is any indication.<sup>230</sup>

To combat these issues, the public would need to be engaged and supportive of OTC OC, and the FDA would need to learn from the critiques of its treatment of emergency contraception.<sup>231</sup> Despite its relative futility, a few senators tried to introduce a bill that would encourage the FDA to look into OTC OC. The bill did not pass.<sup>232</sup> It is also important to note that sometimes citizen petitions from organizations other than drug companies can lead to legalized OTC access. This is rare, but possible. This is what happened for allergy medicine; Blue Cross Blue Shield of California submitted a petition, instead of a drug company, and the FDA responded.<sup>233</sup> That the insurer obviously had the incentive to apply for the change indicates that, while an OTC system switch would have saved society money, drug companies were likely benefitting by keeping a prescription access system. If drug companies are similarly resistant to an OTC switch, as are insurers,<sup>234</sup> perhaps another group, like health care providers, could write the petition instead, as technically any citizen may submit a petition for a rulemaking.<sup>235</sup>

These factors leave the debate regarding OTC access to oral contraceptives with only suboptimal policy options on the table. The status quo is inadequate because the ACA's structure disproportionately favors women with more resources and insurance, and it leaves out large numbers of women. The Republican idea, similarly, would result in

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230 See *supra* notes 130–131 and accompanying text.

231 See Lisa Heinzerling, Note, *The FDA's Plan B Fiasco: Lessons for Administrative Law*, 102 *Geo. L.J.* 927, 981 (2014).

232 Preserving Religious Freedom and a Woman's Access to Contraception Act, S. 2605, 113th Cong. § 3 (2014).

233 Sullivan et al., *supra* note 188, at 1383.

234 This is what one would expect if their current low costs of birth control are due to their bargaining power with drug manufacturers. See *supra* notes 181–189 and accompanying text.

235 *Comment on Proposed Regulations and Submit Petitions*, FDA.Gov, [http://www.fda.gov/RegulatoryInformation/Dockets/Comments/default.htm?utm\\_source=rss&utm\\_medium=rss&utm\\_campaign=comment-on-proposed-regulations-and-submit-petitions](http://www.fda.gov/RegulatoryInformation/Dockets/Comments/default.htm?utm_source=rss&utm_medium=rss&utm_campaign=comment-on-proposed-regulations-and-submit-petitions) [<http://perma.cc/649G-W5P7>] (last visited Mar. 4, 2015).

lessened access to OC, particularly if they are able to work towards a repeal of the ACA's contraceptive mandate. Under this plan, OC would be available only with a prescription and with a high out-of-pocket cost for all individuals. This is where a hybrid solution, with a reimbursement requirement, could work to satisfy the concerns of both sides. The possibility of working to perfect such a middle solution is becoming increasingly plausible, given the shift in public discourse about OC in the past few months.

### C. Cultural Issues

An easy response to the question of why access to OC is such a political quagmire is that the United States has regulated women's access to OC since its introduction and that, culturally, the United States is not ready to allow women to have full access to contraception without regulation. In attempting to achieve reproductive autonomy, it is concerning that access to OC is continually framed as a female issue. While alternatives like male birth control have been proposed and are in development, society as a whole continues to see contraception, whether OC or another form, as a women's issue because women are the ones who get pregnant. Men, for obvious reasons, are not at risk for the same potential consequence.<sup>236</sup> In the 1970s, after *Griswold v. Connecticut*,<sup>237</sup> it seemed like the United States would fully liberalize access to contraception—removing government regulation from the matter entirely.<sup>238</sup> This was not what happened. Instead, the frame of the debate shifted entirely. Conservatives reframed the issue as a moral problem, and the argument surrounding contraception moved away from focusing on reproductive freedom.<sup>239</sup>

Still, the truth of the OC story is more complicated than this cultural argument portrays it. Access to contraceptives, as well as abortion, have had incredibly varied support over the past century. They have intermittently been intensely controversial, as well as not.<sup>240</sup> Plus, the controversies that have existed remained even when more of the public skewed

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236 Luiza AK Hoga et al., *Adult Men's Beliefs, Values, Attitudes and Experiences Regarding Contraceptives: a Systematic Review of Qualitative Studies*, 23 J. CLINICAL NURSING 927, 930 (2014).

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

238 Rebecca Leber, *It's Astounding that We're Still Debating the Pill after 50 Years*, NEW REPUBLIC (Oct. 12, 2014), <http://www.newrepublic.com/article/119776/jonathan-eig-birth-control-and-reproductive-rights> [<http://perma.cc/6ZCK-LL7E>].

239 *Id.*

240 The 1910s, 1930s, and 1960s all saw great advancements for contraception, with little pushback. GENE BURNS, *THE MORAL VETO* 11 (2005).

towards consensus. Issue framing arguably explains this quirky history.<sup>241</sup> Limiting frames refer to how politicians and political groups shape their message on certain topics, so that they are not directly negating what their opponents are saying. Instead, they conceive of the problem differently and insist that the other side is missing the point.<sup>242</sup> Debates that frame issues like this often also bring intense moral views along with them. Counter-intuitively, issues that create significant controversy, particularly moral controversy, achieve fewer goals than issues that garner less attention.<sup>243</sup> This is true even if the most vocal opposition is only a small minority. By using a kind of “moral veto” this opposition can effectively block policy change, and this has effectively happened for the issue of access to OC.<sup>244</sup>

These observations are both good and bad news for OTC OC. Encouragingly, given the wide array of potential benefits OC offers and the ways in which it can benefit individual women differently, OTC OC could muster an array of interests to champion its cause. A diverse coalition would hopefully yield more successful results, once a diverse coalition is involved. Nonetheless, the marked increase in Americans’ acceptance of sexual liberty and reproductive autonomy<sup>245</sup> might not help while the issue is still so polarized. Even if the majority of the United States supports OTC OC,<sup>246</sup> a small minority might exercise their moral veto.

The potential of using such a moral veto makes it particularly interesting that Republicans have started supporting OTC OC at all. A diverse coalition would hopefully yield more successful results. In essence, the candidates that have voiced their support for

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241 *Id.* at 6.

242 Obvious examples of this are the pro-choice and pro-life frames for arguing about the availability of abortion. *Id.* at 7–10.

243 *Id.* at 11 (stating that movements that have a plurality of differing, but combined, interests in support of its goal—even if for varying reasons—generally achieve their objectives more successfully).

244 *Id.* at 23 (“Groups that exercise moral vetoes do so because they tap into general cultural predispositions that may be somewhat inchoate but that nevertheless exist. For example, the potential to link contraception to unpopular images of sexual promiscuity was . . . central to the veto that the Roman Catholic hierarchy exercised on numerous legislatures.”).

245 See, e.g., Arland Thornton & Linda Young-DeMarco, *Four Decades of Trends in Attitudes Toward Family Issues in the United States: The 1960s through the 1990s*, 63 J. MARRIAGE & FAM. 1009, 1009 (2001) (finding that, among Americans in the 1990s as opposed to the 1960s, more people supported cohabitation before marriage, unmarried childbearing, premarital sex, and first marriage at a later age).

246 Including people who are religious. Laura F. Romo et al., *Sociocultural and religious influences on the normative contraceptive practices of Latino women in the United States*, 69 CONTRACEPTION 219, 219 (2004).

OTC access have relinquished their moral veto of contraception. Consequently, the frame abruptly shifted from contraception as a moral issue regarding promiscuity to regulated access to OC as a personal liberty issue—as in, OC changed from a bad to be avoided to a good to be liberalized. Liberals have responded that OTC access leaves out women on the margins and have opposed its implementation.<sup>247</sup>

It is true that the Republican proposal ignores several pressing concerns, but without the moral dimension, the disagreement then stems, not from whether OC itself is good or bad, but from how much support the government gives, or requires insurance companies to give, to women who would not be able to purchase OC on their own. Such a dispute does not carry the same intense polarization. Many policy issues in America split over this same divide—taxation and unemployment benefits being a few of them. This new frame also gives a wider margin of mutually agreeable solutions, which makes OTC OC more likely to be a success.<sup>248</sup> Whether or not a policy change is for the best, the reality is that, in the United States, although scientific data and empirical conclusions are often brandished in health care debates, values and ideologies have as much to do with shaping policy outcomes, as do the numbers.<sup>249</sup>

## CONCLUSION

OTC access for OC should be implemented in the United States. An OTC system would address existing issues within the ACA regarding reproductive access and provide OC's benefits to women who could gain the most from them. Women want an OTC option, and it would be safe. OTC OC is a success in other countries. OTC access would save societal costs on health care, and it would reduce women's individual nonmonetary costs of using OC. Perhaps most importantly, OTC OC would increase women's control over their contraceptive decisions—just knowing that OC would be available in a pharmacy, without numerous procedural difficulties to first maneuver through, would empower women to obtain the OC they clearly want.

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247 Drum, *supra* note 216.

248 BURNS, *supra* note 240, at 11.

249 PATEL & RUSHEFSKY, *supra* note 58, at 3:

Debates over health policy are played out through the rhetorical use of language and the strategic portrayal of social situations. Policy making revolves around the naming and framing of a problem, the specification of problem boundaries, and the definition and negotiation of the ideas and values that guide the ways citizens create a shared meaning that motivates them to act.

The most compelling counterargument is that OTC OC would cost more than women on the margins are able to pay for it, and that racial effects, income effects, and other structural disadvantages would prevent these women from benefitting as much from OTC OC, even if they could access it. But, in response to this valid cost concern, a simple administrative policy change would potentially help: by requiring Medicaid and private insurers to reimburse women for OTC purchases, the powerful players in the health care system would then be invested in driving down the cost for OTC OC. This would ensure that the demand for OTC OC rose to meet increased supply and those prices became reasonable and competitive. With the recent shift in the political framing of the contraceptive issue, it is possible that this is a practically feasible proposition.

As for how this would help women who are not prevented under the ACA from realizing the full benefits of OC, OTC access would not be able to correct these disparities entirely. There is, though, the likely possibility that increased access to OC outside of doctors' offices would be more beneficial to these women than a prescription-only system, and the spillover benefits of being more able to plan pregnancies would expand to women on the margins. This possibility makes OTC OC worthwhile.

Too often in the United States, decisions about women's reproductive health have not been based on public health data, economic theory, or women's own opinions. OTC OC is a policy change backed by all three of these considerations. Public support for OTC OC is important to put the pressures necessary for implementation on drug manufacturers, insurers, and the FDA. As such, understanding fully why OTC access would be beneficial, what policy would make it workable, and what its potential tradeoffs could be is critical. Even if not a panacea for all the issues that women currently face with regard to autonomy in reproductive decisions, this is a chance to open up access in a meaningful and beneficial way—to put reproductive autonomy on local pharmacy shelves.

APPENDIX A

