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BRINGING HORMONAL BIRTH CONTROL OVER THE COUNTER

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INTRODUCTION

Since its introduction to the market in 1957, hormonal contraception has been a topic of debate. However, whereas the focus used to be on the morality of its use, today, 91 percent of Americans consider it morally acceptable.[1] Moreover, the World Health Organization (WHO) recognizes contraception availability and use as an indicator of individual and societal health. In fact, the WHO emphasizes that: "Promotion of family planning—and ensuring access to preferred contraceptive methods for women and couples—is essential to securing the well-being and autonomy of women, while supporting the health and development of communities."[2] As a result of such general acceptance, the focus of today's debate has largely shifted toward best practices surrounding the use of birth control as a public health intervention, including increasing availability to women or integrating prescribing into routine medical screenings.

Currently, and for the majority of women in the United States, access to non-barrier,[3] self-administered birth control methods can be obtained only through a three-step process that requires a physician consultation, a prescription and then a pharmacy visit.[4] And thus, while birth control is legal and widely prescribed, it is not necessarily easily obtained, as it requires time, transportation and money.

Despite such barriers, throughout its long history, hormonal birth control has proven to be a safe and effective form of family planning. And, in recent years, birth control advocates have made great strides to expand insurance coverage and decrease out-of-pocket costs. However, it is also vital to address the unnecessary, top-down regulatory hurdles women face when acquiring birth control. Doing so will not only greatly improve access but will also improve measures of health for women who use it, including fewer unintended pregnancies, decreased risk of cancers, management of gynecological disorders and improved regularity of menstrual cycles.

Since the 1960s, popular hormonal contraceptives have only been available by prescription in the United States. In more recent years, however, medical professionals have questioned the necessity of keeping these methods prescription-only.

1. "In Depth Topics A to Z: Moral Issues," *Gallup*, May 1, 2019. https://news.gallup.com/poll/1681/moral-issues.aspx.

2. "Family planning/Contraception," World Health Organization, Feb. 8, 2018. https://www.who.int/news-room/fact-sheets/detail/family-planning-contraception.

3. Non-barrier birth control methods are contraceptives that do not need to be used every time a person engages in sex. These include male and female sterilization and hormonal forms of birth control. See, e.g., Office on Women's Health, "Birth control methods fact sheet," Dept. of Health and Human Services, Jan. 16, 2017. https://www.womenshealth.gov/files/fact-sheet-birth-control-methods.pdf.

4. Advance practice nurse practitioners, certified nurse midwives, physician's assistants and some other medical professionals can prescribe birth control.

Accordingly, many groups, such as the American College of Obstetricians and Gynecologists (ACOG), the American Academy of Family Physicians (AAFP), the American Medical Association (AMA), the American Nurses Association (ANA) and the North American Society for Pediatric and Adolescent Gynecology, have called for over-the-counter access to birth control pills.[5]

Such calls for regulatory reform have received bipartisan support, as removing burdensome regulations will directly improve public health by expanding opportunities for women to control their reproductive health and plan their childbearing.[6] Given that the distribution of hormonal birth control in the United States is a function of both the state and federal governments, now is the time to take advantage of this opportunity to both improve public health and to respect and promote the principles of limited government.

BIRTH CONTROL 101

There are many forms of contraceptives including barrier methods; female or male sterilization; and hormonal forms of contraception, which use several delivery methods and hormone combinations and are the most widely used form.[7] Hormonal contraception can broadly be considered in two categories, short-acting reversible contraception and long-acting reversible contraception.

The major differences between short-acting hormonal birth control methods and their long-acting counterparts are the route of delivery, type of hormone and frequency of administration. This first category includes birth control pills, patches and vaginal rings, which deliver hormones to prevent pregnancy—either as a combination of estrogen and progestogens or as progestin only. These forms of birth control are reversible, meaning that once administration of hormone is discontinued, fertility returns quickly and completely. They are also short acting, which means that administration is required at intervals ranging from daily or weekly to maintain effectiveness.

On the other hand, long-acting reversible contraceptives (LARCs) include intrauterine devices (IUDs) (also sometimes called intrauterine systems) and subdermal, hormonal implants that prevent pregnancy for three to ten years at a time. Once administered, these methods require no action on the part of the patient, which contributes to their extremely high rate of effectiveness.[8]

The contraceptive injection (Depo-Provera®) is also a long-acting form of hormonal birth control that must be administered via intramuscular injection by a medical professional every three months.[9] Although Depo-Provera® is administered infrequently, it is not generally accepted as a reversible contraception method because it can take more than one menstrual cycle for fertility to return after discontinuation and therefore is not reversible in the same way as IUDs and hormonal implants.

Use and Unintended Pregnancy in the United States

Nearly 100 percent of sexually active women between the ages of 15-44 have ever used any method of birth control, and 82 percent have ever used the contraceptive pill.[10] From 2015-2017, 65 percent of reproductive-age women in the United States were currently using some type of contraception, with hormonal being the most popular (which includes oral contraception, implants, most intrauterine devices, injections and patches).[11] However, important differences in birth control use and unintended pregnancy exist based on race, ethnicity, marital status, education, geography and income.[12]

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5. See, e.g., "Committee Opinion, Over-The-Counter Access to Oral Contraceptives," The American College of Obstetricians and Gynecologists, 2012. https://www.acog.org/Clinical-Guidance-and-Publications/Committee-Opinions/Committee-on-Health-Care-for-Underserved-Women/Access-to-Contraception?IsMobileSet=false; "Over-the-Counter Oral Contraceptives," The American Academy of Family Physicians, 2019. https://www.aafp.org/about/policies/all/otc-oral-contraceptives.html; Eileen Francis, "AMA Encourages Oral Contraceptive OTC Options in Policy Update," Pink Sheet Pharma Intelligence, June 21, 2018. https://pink.pharmaintelligence.informa.com/PS123343/AMA-Encourages-Oral-Contraceptive-OTC-Options-In-Policy-Update; "What do providers think about OTC access to the pill?", Ibis Reproductive Health, 2019. http://ocsotc.org/faqs.

6. Ted Cruz, @tedcruz, "I agree. Perhaps, in addition to the legislation we are already working on together to ban Members of Congress from becoming lobbyists, we can team up here as well. A simple, clean bill making birth control available over the counter. Interested?", June 12, 2019, 12:09PM. Tweet. https://twitter.com/tedcruz/status/1138840867777712128?ref_src=twsrc%5Etfw%7Ctwcamp%5Etweetembed%7Ctwterm%5E1138840867777712128&ref_url=https%3A%2F%2Fwww.fiercehealthcare.com%2Fhospitals-health-systems%2Fdemocrats-introduce-bill-to-make-birth-control-available-over-counter; Alexandria Ocasio-Cortez, @AOC, "Psst! Birth control should be over-the-counter, pass it on," June 9, 2019, 4:53PM. Tweet. https://twitter.com/AOC/status/1137100279894224896; S.930, Allowing Greater Access to Safe and Effective Contraception Act, 116th Congress; Abigail Abrams, "Can Over-the-Counter Birth Control Become a Bipartisan Issue?", Time, June 21, 2019. https://time.com/5609049/over-counter-birth-control-bipartisan; Anna North, "The strange politics of over-the-counter birth control, explained," *Vox*, June 13, 2019. https://www.vox.com/identities/2019/6/13/18677710/ted-cruz-birth-control-aoc-otc-counter.

7. Kimberly Daniels and Joyce Abma, "Current Contraceptive Status Among Women Aged 15–49: United States, 2015–2017," *NCHS Data Brief* No. 327, 2018. https://www.cdc.gov/nchs/products/databriefs/db327.htm.

8. "Long-Acting Reversible Contraception: Intrauterine Device and Implant," The American College of Obstetricians and Gynecologists, January 2018. https://www.acog.org/Patients/FAQs/Long-Acting-Reversible-Contraception-Intrauterine-Device-and-Implant?IsMobileSet=false.

9. "Physician Information: Depo-Provera® Contraceptive Injection," Pharmacia and Upjohn Company, June 2002. https://www.accessdata.fda.gov/drugsatfda_docs/label/2003/20246scs019_Depo-provera_lbl.pdf.

10. Kimberly Daniels et al., "Contraceptive Methods Women Have Ever Used: United States, 1982–2010," *National Health Statistics Reports* No. 62, 2013, pp. 3-4. https://www.cdc.gov/nchs/data/nhsr/nhsr062.pdf.

11. Daniels and Abma, p. 1. https://www.cdc.gov/nchs/products/databriefs/db327.htm.

12. Less effective methods include male and female condoms, spermicide, withdrawal and fertility-awareness based methods. See, e.g., "Effectiveness of Family Planning Methods," Centers for Disease Control, last accessed Nov. 24, 2019. https://www.cdc.gov/reproductivehealth/contraception/unintendedpregnancy/pdf/Contraceptive_methods_508.pdf.

With respect to birth control use, for example, 15 percent of non-Hispanic white women use oral contraceptive pills, which is significantly higher than the rates among non-Hispanic black women and Hispanic women.[13] Three-quarters of married women use contraception, compared to 42 percent of women who have never been married.[14] Unmarried women who are cohabitating with a male partner are less likely to use birth control than single or married women.[15] The proportion of women who currently use oral contraceptive pills increases with educational attainment.[16] Women living in urban areas are more likely to use less effective methods of birth control, such as condoms or withdrawal, than women living in rural areas. And, women below 100 percent of the poverty rate are less likely to use oral contraceptive pills than women at 300 percent or higher, whereas the opposite is true for odds of using female sterilization to prevent pregnancy.[17]

Rates of unintended pregnancy follow similar patterns to those of effective birth control use among different demographic populations. For example, women living at 100 percent of the poverty rate— $12,490 for one person or $25,750 annual income for a family of four in 2019—experience five times as many unintended pregnancies as women living at 200 percent of the poverty rate.[18] Black women and Hispanic women have higher rates of unintended pregnancy than white women.[19] Roughly one-quarter of women at 100 percent of the poverty level have experienced more than one unintended pregnancy, which is almost twice the rate among women living at 200 percent of the poverty level.[20] Compared to white women, black and Hispanic women are about three and two times more likely to experience multiple unintended pregnancies, respectively.[21] Meanwhile, married women report the lowest proportion of unintended pregnancies, while roughly half of those among unmarried women who are cohabitating with a male partner are unintended, and this proportion rises to two-thirds for unmarried women not living with a partner.[22]

There are many risks that accompany unintended pregnancy.[23] With respect to the mother, it is associated with adverse health and social outcomes including depression, delayed prenatal care, intimate partner violence and social stigma.[24] For teen pregnancies, the risks are even greater and include lower educational attainment and lower lifetime earnings.[25] Children who result from unplanned pregnancy experience higher incidence of low birth weight and birth defects, as well as lower cognitive attainment and more behavioral problems if the unplanned pregnancy occurs during the mother's teenage years.[26]

In addition, unintended pregnancies impact the United States financially. For example, as recently as 2010, publicly funded insurance programs covered the medical costs associated with almost 70 percent of unintended births in the United States, which cost $21 billion in federal and state tax dollars.[27] And, this does not account for the indirect economic cost of unintended pregnancy to employers and individuals.[28]

Support for Increased Access to Contraception

Despite the facts—that nearly all women have used a method of birth control at least once and that an overwhelming majority of Americans favor its use—continued high rates of unintended pregnancy suggest a disconnect between acceptance and consistent use. Unfortunately, research that aims to identify any barriers to accessing the most effective methods of birth control has generally been limited to oral

13. Daniels and Abma. https://www.cdc.gov/nchs/products/databriefs/db327.htm.

14. Jo Jones et al., "Current Contraceptive Use in the United States, 2006–2010, and Changes in Patterns of Use Since 1995," *National Health Statistics Report* No. 60, Oct. 18, 2012. https://www.cdc.gov/nchs/data/nhsr/nhsr060.pdf.

15. William Mosher et al., "Nonuse of contraception among women at risk of unintended pregnancy in the United States," *Contraception* 92:2 (2015), pp. 170-76. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6413311.

16. Daniels and Abma. https://www.cdc.gov/nchs/products/databriefs/db327.htm.

17. Megan L. Kavanaugh and Jenna Jerman, "Contraceptive method use in the United States: trends and characteristics between 2008, 2012 and 2014," Contraception 97:1 (2018), pp. 14-21. https://www.contraceptionjournal.org/article/S0010-7824(17)30478-X/fulltext#s0030.

18. Lawrence Finer and Mia Zolna, "Unintended pregnancy in the United States: Incidence and disparities, 2006," Contraception 84:5 (2011), pp. 478-85. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3338192/pdf/nihms317258.pdf.

19. Theresa Kim et al., "Racial/Ethnic Differences in Unintended Pregnancy: Evidence From a National Sample of U.S. Women," *American Journal of Preventative Medicine* 50:4 (2016), pp.427-35. https://doi.org/10.1016/j.amepre.2015.09.027.

20. Ibid.

21. Ibid.

22. William Mosher et al., "Intended and Unintended Births in the United States: 1982–2010," *National Health Statistics Reports* No. 55 (Dec. 20, 2012), p. 7. https://www.cdc.gov/nchs/data/nhsr/nhsr055.pdf.

23. See, e.g., Emily M. Johnston et al., "Beyond Birth Control: Family Planning and Women's Lives," Urban Institute, March 2017. https://www.urban.org/sites/default/files/publication/88801/prevalence_and_perceptions_of_unplanned_births.pdf.

24. Office of Disease Prevention and Promotion, "Family Planning," Office of Disease Prevention and Promotion, U.S. Dept. of Health and Human Services, last accessed Nov. 24, 2019. https://www.healthypeople.gov/2020/topics-objectives/topic/family-planning; See, e.g., Whitney Smith et al., "Social Norms and Stigma Regarding Unintended Pregnancy and Pregnancy Decisions: A Qualitative Study of Young Women in Alabama," *Perspectives on Sexual and Reproductive Health* 48:2 (June 2016), pp. 73-81. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5022769.

25. Office of Disease Prevention and Promotion. https://www.healthypeople.gov/2020/topics-objectives/topic/family-planning.

26. Ibid.

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

28. See, e.g., National Women's Law Center, "Covering Prescription Contraceptives in Employee Health Plans: How this Coverage Saves Money," February 2012, p. 1. https://www.nwlc.org/sites/default/files/pdfs/contraceptive_coverage_saves_money_fact_sheet.pdf.

contraceptives. However, it is plausible that these conclusions may extend to other forms of short- or long-acting hormonal birth control. And, on this account, a nationally representative survey conducted in 2004 indicated that 28 percent of women have experienced difficulties obtaining or filling their birth control prescriptions, which may indicate a barrier to consistent birth control use.[29] Another factor that may cause differences in contraceptive use across racial groups is access to medical care, and more specifically, quality counseling from a medical provider regarding birth control options.[30] Overall, it has been reported that Hispanic and black women report greater barriers to obtaining birth control, however more research is required to determine what those specific barriers are.[31]

Much of the existing research on over-the-counter (OTC) oral birth control shows promising evidence that women are interested in obtaining it without a prescription. Several studies have found that women favor over-the-counter access to birth control for its convenience and because they do not need to see a healthcare provider.[32] A survey conducted in 2011 found that 37 percent of women would be likely to use OTC oral contraceptives.[33] Of those, 58 percent were current oral contraceptive users, 28 percent currently used no method of birth control and 33 percent were using birth control methods with lower efficacy than oral contraceptives.[34] The survey also found that women living in the southern states, women ages 18-24, and uninsured and privately insured women (as opposed to publicly insured) had higher odds of using OTC oral contraceptives than women in other categories.[35] Notably, several of these demographic categories experience higher-than-average rates of unintended pregnancy. This survey also found that half of women agreed that OTC birth control access would make it easier to stay on the pill without interruptions in use, which is vital to prevent unintended pregnancy.[36]

Women also indicate that OTC access to oral contraceptives would allow them to purchase more than a one-month supply, which is noted as a barrier to continuous use of birth control pills.[37] In fact, several studies show that oral contraceptive adherence is improved when women receive a three- to six-month supply of their medication.[38] Many insurance providers will not authorize pharmacies to dispense more than a one-month supply and will not authorize refills until near the predicted end of the pack.[39] And, these limitations associated with prescription-only access are only compounded when accessing a pharmacy is difficult because of geography, transportation, disability, travel or any number of other logistical challenges. Moreover, evaluations of the real-world effects of OTC birth control access have found that 91 percent of women who live along the U.S.-Mexico border and purchase their birth control pills over the counter in Mexico do so because they do not need to see a doctor for a prescription, and 87 percent cited the convenience of a family member or friend being able to obtain pills for them.[40]

Most of the above findings are echoed in a study that surveyed women seeking access to abortion services at clinics across the United States. Forty-two percent of women surveyed said they planned to use the pill after their abortion, however, this percentage increased by 20 points when asked if they would use birth control pills if they were available OTC.[41] Among women planning to use no form of contraception or only condoms after their abortion, about one-third of women in each group said they would use an OTC oral contraceptive.[42] Other indicators of interest in using an OTC birth control pill included being older than 19, being uninsured, having used the pill in the past and reporting past difficulties with obtaining oral contraceptive prescription refills.[43]

Together, these findings suggest that policies that decrease barriers to access, whether perceived or actual, will help women obtain birth control more easily. They also suggest

29. Amanda Dennis and Daniel Grossman, "Barriers to Contraception and Interest In Over-the-Counter Access Among Low-Income Women: A Qualitative Study," *Perspectives on Sexual and Reproductive Health* 44:2 (2012), pp. 84-91. https://www.jstor.org/stable/42004105.

30. Megan Sweeney and R. Kelly Raley, "Race, Ethnicity, and the Changing Context of Childbearing in the United States," *Annual Review of Sociology* 40 (2014), pp. 539-58. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4618673.

31. Ibid.

32. See, e.g., Kate Grindlay et al., "Attitudes Toward Over the Counter Access To Oral Contraceptives Among a Sample Of Abortion Clients in the United States," *Perspectives on Sexual and Reproductive Health* 46:2 (2014), pp. 83-89. https://doi.org/10.1363/46e0714; and Dennis and Grossman. https://doi.org/10.1363/4408412.

33. Daniel Grossman et al., "Interest in over-the-counter access to oral contraceptives among women in the United States," *Contraception* 88:4 (2013), pp. 544-52. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3769514.

34. Ibid.

35. Ibid.

36. Ibid.

37. See, e.g., Dennis and Grossman. https://doi.org/10.1363/4408412.

38. See, e.g., "Committee Opinion, Over-The-Counter Access to Oral Contraceptives." https://www.acog.org/Clinical-Guidance-and-Publications/Committee-Opinions/Committee-on-Gynecologic-Practice/Access-to-Hormonal-Contraception; Joseph Potter et al., "Continuation of Prescribed Compared with Over-the-Counter Oral Contraceptives," *American Journal of Obstetrics and Gynecology* 117:3 (2011), pp. 551-57. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3606883; Dennis and Grossman. https://doi.org/10.1363/4408412.

39. Ibid.

40. Joseph Potter et al., "Clinic Versus Over-the-Counter Access to Oral Contraception: Choices Women Make Along the US–Mexico Border," *American Journal of Public Health* 100:6 (2010), pp. 1130-36. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2866585.

41. "Attitudes Toward Over the Counter Access To Oral Contraceptives." https://doi.org/10.1363/46e0714.

42. Ibid.

43. Ibid.

that a decrease in unintended pregnancies is plausible if birth control pills were available OTC.

IMPROVING BIRTH CONTROL ACCESS

Many public health advocates and medical practitioners consider the current system of birth control prescribing to be designed to fail and thus suggest that it should be changed. And indeed, requirements for a physician visit or limiting supply to one dosing regimen (for example, a 30-day cycle of birth control pills if reimbursed through an insurance provider) puts many women at risk of missing one or several doses.[44] Therefore, relaxing regulations that prevent over-the-counter access to contraceptive pills may be a means to equalize access to birth control and decrease the unintended pregnancy rate.

Furthermore, removing barriers to access hormonal birth control has a financial impact as well. Using existing estimates, doing so for oral contraceptives would result in a 7 to 25 percent decrease in the number of unintended pregnancies among low-income women.[45] With estimates of average cost per publicly funded birth ranging from $12,770 to $20,716 in 2010, OTC sales of oral contraceptives could greatly reduce these health expenditures.[46]

While there are several considerations that must be weighed before making any form of hormonal birth control available over the counter, if done carefully, allowing women unrestricted access to hormonal contraception will benefit public health and decrease rates of unintended pregnancy. Accordingly, the following sections outline various measures that can be taken in order to make these goals a reality.

Allow over-the-counter access

The Food and Drug Administration (FDA) regulates all prescription and over-the-counter (OTC) nonprescription drugs in the United States. Currently, the FDA uses its monograph drug system to classify OTC drugs or a company can apply for OTC status through a New Drug Application process.[47] The FDA offers five broad requirements for OTC approval: that abuse is unlikely, that the condition for use is self-diagnosable, that the drug's benefits are greater than its risks, that labeling is clear and effective for proper administration, and that a medical intermediary is unnecessary for administration.[48] Additionally, the FDA can pursue "studies to learn if potential OTC consumers understand the Drug Facts label, can properly choose the medicine for their needs, and use it according to the directions," if necessary.[49]

For short-acting contraception methods, the timeliest federal regulatory reform for birth control would be to allow birth control pills to be available OTC through an FDA review process. After all, birth control pills already meet the FDA requirements for safe OTC use, women's healthcare professionals largely support OTC status and the well-documented history of birth control pill use in the United States shows a clear trend in the direction of safe and effective use without mandated doctor prescriptions. The fact that hormonal contraceptives are already available without a prescription in about 70 percent of countries also provides evidence that the United States should begin transitioning hormonal contraceptives toward OTC sale.[50]

Of course, it is important to recognize that there are some situations wherein a physician visit is in the best interest of the user, for example, in the case of adolescents or first-time birth control users who may not be able to self-screen for contraindications if purchasing hormonal contraceptives OTC.[51] One study estimates that 16 percent of American women have conditions where hormonal contraceptives may be contraindicated, and that statistic approaches 40 percent in some regions.[52] However, studies have shown that most women, including adolescents, are able to reliably self-screen for contraindications for both progestin-only pills and estrogen/progestin combination birth control pills.[53]

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44. American Public Health Association, "Policy Statement: Universal Access to Contraception," *American Public Health Association*, November 3, 2015. https://www.apha.org/policies-and-advocacy/public-health-policy-statements/policy-database/2015/12/17/09/14/universal-access-to-contraception.

45. Diana Foster et al., "Potential public sector cost-savings from over-the-counter access to oral contraceptives," *Contraception* 91:5 (2015), pp. 373-379. https://doi.org/10.1016/j.contraception.2015.01.010

46. Sonfield and Kost. https://www.guttmacher.org/report/public-costs-unintended-pregnancies-and-role-public-insurance-programs-paying-pregnancy.

47. "Development and Regulation of OTC (Nonprescription) Drugs," U.S. Food and Drug Administration, last accessed Nov. 24, 2019. https://www.fda.gov/drugs/current-good-manufacturing-practices-cgmp-drugs-reports-guidances-and-additional-information/otc-nonprescription-drugs.

48. "Division of Nonprescription Drugs (DNDP)," U.S. Food and Drug Administration, last accessed Nov. 24, 2019. https://www.fda.gov/about-fda/center-drug-evaluation-and-research/division-nonprescription-drugs-dndp.

49. "How FDA strives to ensure the safety of OTC products," U.S. Food and Drug Administration, last accessed Nov. 24, 2019. https://www.fda.gov/drugs/special-features/how-fda-strives-ensure-safety-otc-products.

50. Kate Grindlay et al., "Prescription requirements and over-the-counter access to oral contraceptives: a global review," *Contraception* 88:1 (July 2013), pp. 91-96. https://www.contraceptionjournal.org/article/S0010-7824(12)01029-3/abstract.

51. Dennis and Grossman. https://doi.org/10.1363/4408412.

52. Su-Ying Liang et al., "User characteristics and out-of-pocket expenditures for progestin-only versus combined oral contraceptives," *Contraception* 86:6 (2012), pp. 666-72. https://www.ncbi.nlm.nih.gov/pubmed/22770791.

53. See, e.g., Kennedy et al., "Should oral contraceptive pills be available without a prescription? A systematic review of over-the-counter and pharmacy access availability," *BMJ Global Health* 4:3 (June 25, 2019. https://www.ncbi.nlm.nih.gov/pubmed/31321085; Rebekah Williams et al., "Adolescent self-screening for contraindications to combined oral contraceptive pills," *Contraception* 92:4 (2015), p. 380. https://www.contraceptionjournal.org/article/S0010-7824(15)00360-1/fulltext; Daniel Grossman et al. "Accuracy of Self-Screening for Contraindications to Combined Oral Contraceptive Use," *Obstetrics and Gynecology* 112:3 (2009), pp. 572-78. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2615461; Solmaz Shotorbani et al., "Agreement between women's and providers' assessment of hormonal contraceptive risk factors," *Contraception* 73:5 (2006), pp. 501-06. https://www.ncbi.nlm.nih.gov/pubmed/16627034.

Drug label comprehension is also an important factor in OTC drugs, and increased attention to consumer-friendly labels, as opposed to black box warnings that are intended for physician and pharmacist education, can further decrease the risk of unintended consequences such as contraindications, missed doses and side effects.[54] Health labels are considered to be an important source of medical information for consumers and it has been shown that products with comprehensive health or warning labels increase health knowledge and responsible action on the part of the consumer.[55]

Indeed, the transition of emergency contraceptive pills from prescription-only to OTC gives some indication that, given appropriate labeling and package information in combination with other education efforts, women would be able to evaluate their own suitability.[56] The American College of Clinical Pharmacy has also suggested that any safety concerns could be addressed by requiring that over-the-counter access be available in locations where a pharmacist is on duty.[57] This solution would not require women to speak with the pharmacist before purchase, but it would ensure access to a medical professional should questions arise.

Moreover, the use of progestin-only pills (POP) can alleviate the concerns about most contraindications, as they have fewer and rarer contraindications than combined estrogen/progestin oral contraceptives.[58] For this reason, a progestin-only pill is probably best suited to become the first OTC offering, given its improved safety profile and suitability to a larger population of women. The existing availability of progestin-only OTC emergency contraception (e.g., Plan B One Step®) also offers a foundation for approval of a progestin-only contraceptive pill.

Pending success of progestin-only oral contraception, other short-acting hormonal contraceptives should become eligible for sale OTC.[59] For example, since the hormonal composition and contraindications for combination pills are similar to those for the birth control patch and ring, which are also self-administered, it is reasonable to suggest that the birth control patch and ring may follow similar regulatory practices. At any rate, if a wider selection of hormonal contraceptives were eventually made available OTC, it is likely that an even larger proportion of women would choose to use them.

Expand the pharmacy access model

Since over-the-counter birth control access of any kind would require FDA approval, in the interim, another regulatory reform worth highlighting is the pharmacy access model, which allows pharmacists to prescribe birth control directly. Currently, 11 states plus the District of Columbia allow pharmacists to prescribe several forms of hormonal birth control.[60] In every state, this includes the pill, but many also allow the patch, ring and injections. This model has caught on largely because the ability of pharmacists to assess a patient's need for contraception, and their expertise in medicine, make them well suited to prescribe birth control. And, as a result, early outcomes of this kind of access are promising. In 2015, Oregon became the first state to offer pharmacists prescribing authority for birth control and since then, it has seen an increase in prescriptions and a decrease in unintended pregnancies.[61] In fact, Oregon pharmacists wrote 10 percent of all new birth control prescriptions given to Medicaid patients in the two years after implementation, and prevented an estimated 50 unintended pregnancies.[62]

While OTC access is better for short-acting forms of birth control, the pharmacy access model is better suited for the injection form (e.g. Depo-Provera®) because it is likely that a woman is unable to become pregnant for several months after stopping injections. Accordingly, interaction with the pharmacist creates a point of intervention to ensure that the woman understands this. Moreover, since 1994, pharmacists have been able to inject vaccinations and thus it is feasible to

54. Small Business Assistance Center for Drug Research and Evaluation. "Bringing an Over-the-Counter (OTC) Drug to Market Overview: Label Comprehension," U.S. Food and Drug Administration https://www.accessdata.fda.gov/scripts/cder/training/OTC/topic3/topic3/da_01_03_0170.htm; Tricia Meyer et al., "The Relevance of Black Box Warnings," Newsletter: *The official Journal of the Anesthesia Patient Safety Foundation* 21:1 (2006 https://www.apsf.org/article/the-relevance-of-black-box-warnings.

55. Jesse Catlin and Eric Brass, "The Effectiveness of Nonprescription Drug Labels in the United States: Insights from Recent Research and Opportunities for the Future," *Pharmacy (Basel, Switzerland)* 6:4 (December 2018), p. 119. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6306891.

56. Elizabeth Raymond et al., "Comprehension of a Prototype over-the-Counter Label for an Emergency Contraceptive Pill Product," *Obstetrics & Gynecology* 100:2 (2002), pp. 342–49. https://www.ncbi.nlm.nih.gov/pubmed/12151161.

57. McIntosh et al., "Changing Oral Contraceptives from Prescription to Over the Counter Status: An Opinion Statement of the Women's Health Practice and Research Network of the American College of Clinical Pharmacy," *Pharmacotherapy* 31:4 (April 2011), pp. 424-37. https://accpjournals.onlinelibrary.wiley.com/doi/10.1592/phco.31.4.424.

58. Ibid.

59. Kate Grindlay and Daniel Grossman, "Interest in Over-the-Counter Access to a Progestin-Only Pill among Women in the United States," *Women's Health Issues* 28:2 (March-April 2018), pp. 144-51. https://www.ncbi.nlm.nih.gov/pubmed/29395780.

60. Timothy Aungst, "New Hampshire Moves to Allow Pharmacists to Provide Oral Birth Control Without a Prescription," *Pharmacy Times*, Nov. 30, 2017. https://www.pharmacytimes.com/contributor/timothy-aungst-pharmd/2017/11/new-hampshire-moves-to-allow-pharmacists-to-provide-oral-birth-control-without-a-prescription.

61. Molly Harbarger, "Oregon pharmacists wrote 10% of all birth control prescriptions since landmark law passed," *The Oregonian*, May 15, 2019. https://www.oregonlive.com/health/2019/05/oregon-pharmacists-wrote-10-of-all-birth-control-prescriptions-since-landmark-law-passed.html.

62. Ibid.

expand their scope-of-practice to include the administration of injectable birth control.[63]

Expand scope of practice in clinical settings

Although not suitable for access outside of a clinical setting without significant innovation and simplification of administration, it is still feasible to reduce barriers to access LARCs (IUD and hormonal implants) by expanding the scope of practice beyond physicians and advanced practice clinicians to include registered nurses (RNs).[64] Additionally, in most cases all contraceptive methods can be provided safely in one appointment rather than two—which some offices recommend for IUDs; this can also decrease burdens to access, such as additional copays, travel costs and the need to take additional time off work.[65]

As more data develops around LARC administration by nurses in other countries, states could undertake nursing regulatory reform similar to the pharmacy access model, and begin to allow RNs to insert and/or remove LARCs. This, in addition to providing Title X clinics with funding to offer LARCs at lower cost and education about more effective methods of birth control, will have a measurable impact on the health of women, children and their communities.

For example, research on allowing registered nurses to administer LARCs is growing. For example, an Australian study found that attitudes of RNs and medical officers toward IUD administration by RNs are positive.[66] Additionally, nurse auxiliaries in countries like Korea, Honduras, Guatemala and Turkey are allowed to administer IUDs and have shown both capability and competence in doing so.[67] Promising work out of Brazil and Columbia also shows indirect evidence that nurse administration of IUDs was associated with lower healthcare costs and that there may be no difference between nurses and doctors in IUD failure rates.[68]

Allowing more medical professionals to train for and administer LARCs would benefit patients and the medical workforce alike. As described, injectable methods should extend to pharmacist prescription authority, and IUD administration could be taken on by registered nurses. Both short-acting methods and LARCs have room for regulatory improvements along these lines, and doing so would enable more women to access their preferred birth control methods.

CONCLUSION

Despite broad approval of birth control and widespread use, rates of unintended pregnancy persist. This is likely due to various barriers to access that make it more difficult for women to obtain and continue birth control use. For this reason, updated regulatory models could ensure that various forms of birth control are accessible based on current medical standards. Enabling women to control their reproductive outcomes by providing safe, effective and accessible contraceptives follows the principles of limited government, is highly cost effective and most importantly, ensures women's unencumbered participation and contribution to society on their own terms.

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63. Michael Hogue et al., "Pharmacist involvement with immunizations: a decade of professional advancement," *Journal of the American Pharmacists Association* 46:2 (2006), pp. 168-79. https://www.ncbi.nlm.nih.gov/pubmed/16602227.

64. See, e.g., Kirsteen Fleming et al., "Inclusion of intrauterine device insertion to registered nurses' scope of clinical practice," *Collegian* 26:1 (February 2019), pp. 28-32. https://www.sciencedirect.com/science/article/pii/S1322769617301798#bib0045; Deborah Lee, "Training to insert intrauterine devices," Trends in *Urology Gynaecology & Sexual Health* (November/December 2009), pp. 24-28. https://onlinelibrary.wiley.com/doi/pdf/10.1002/tre.122; "Should nurses insert and remove intrauterine devices (IUDs)?", World Health Organization, last accessed Nov. 24, 2019. https://optimizemnh.org/files/NUR%2012.3.%20Framework.pdf.

65. See, e.g., The American College of Obstetricians and Gynecologists, "Long-Acting Reversible Contraception: Implants and Intrauterine Devices," *ACOG Practice Bulletins* No. 186, November 2017. https://www.acog.org/-/media/Practice-Bulletins/Committee-on-Practice-Bulletins----Gynecology/Public/pb186.pdf?dmc=1&ts=20171025T1219247445; "Same-Visit Contraception: A Toolkit for Family Planning Providers," Family Planning National Training Center, April 2019, pp. 3-4. https://www.fpntc.org/sites/default/files/resources/fpntc_smvst_toolkit_2018-12-07.pdf.

66. Fleming et al., pp. 28-32. https://www.sciencedirect.com/science/article/pii/S1322769617301798#bib0045.

67. See, e.g., Ricardo Vernon, "Nurse auxiliaries as providers of intrauterine devices for contraception in Guatemala and Honduras," *Reproductive Health Matters* 17:33 (May 2009), pp. 51-60. https://www.ncbi.nlm.nih.gov/pubmed/19523582; Ayse Akin, "Training Auxiliary Nurse-Midwives to Provide IUD Services in Turkey and the Philippines," *Studies in Family Planning* 11:5 (May 1980), pp. 178-87. https://www.jstor.org/stable/1965760?seq=1#page_scan_tab_contents.

68. "Should nurses insert and remove intrauterine devices (IUDs)?" https://optimizemnh.org/files/NUR%2012.3.%20Framework.pdf.