Asia Pacific Journal of Health Law & Ethics
Vol.10 No. 3, July 2017, pp.107-144

Increasing Access to Oral Contraceptives, State by State: There's an App for That*

Brittany S. Brown**

Abstract

This comment argues that access to oral contraceptives should be increased in the United States by embracing birth control applications (apps), which are governed by state telehealth laws.

The best-case scenario for the issue of access would be for oral contraceptives to be made available truly over-the-counter, without a prescription, and covered by public insurance. However, this initiative is highly unlikely, as the Federal Government and the Food & Drug Administration (FDA) have failed to prioritize it. This comment contemplates the political and financial motivations of the FDA and pharmaceutical companies not to push for an over-the-counter switch, as well as the political climate surrounding and shaping this issue. This comment also evaluates state pharmacy prescriber laws that were designed to increase access despite these roadblocks, and concludes that these laws are insufficient as standalone strategies.

Finally, this comment introduces and evaluates state telehealth laws governing birth control apps, and argues that states should draft such laws in a way that legitimizes telehealth. These apps fly under the political radar,[1] do not require legislative approval, and effectively elevate access to oral contraceptives to virtually over-the-counter status. This comment specifically recommends states use California's telehealth regulatory framework as a workable model, which deems telehealth a legitimate means of healthcare, and requires its public insurance [Medi-Cal] to reimburse some forms of telehealth.

Keywords: Telehealth, Oral Contraceptives, Technology, Women'S Health, Birth Control Pill

* Stacey Colino, *Birth Control Without a Doctor's Visit? There's an app for that*, U.S. NEWS (June 30, 2016), http://health.usnews.com/wellness/articles/2016-06-30/birth-control-without-a-doctors-visit-theres-an-app-for-that.

** Juris Doctorate Candidate, Emory University School of Law

[1] Pam Belluck, *Birth Control via App Finds Footing Under Political Radar*, THE NEW YORK TIMES (June 19, 2016), http://www.nytimes.com/2016/06/20/health/birth-control-options-websites.html.

Introduction[2]

Oral contraceptives are prescription-only pharmaceutical drugs in the United States, requiring women to have a prescription from a licensed health professional to obtain them.[3] It is harder to access oral contraceptives in the United States than in most other parts of the world,[4] yet women in the United States rely on oral contraceptives more heavily than on any other pregnancy prevention method.[5] According to 2015 statistics, roughly 50% of all pregnancies in the United States are unplanned,[6] and increasing access to oral contraceptives would very likely reduce this number.[7]

In addition to preventing unwanted pregnancies, "[s]tudies have shown that investing in family planning helps reduce poverty, improve health, promote gender equality, enable adolescents to finish their schooling, and increases labor-force participation."[8] Additionally, the United Nations recognized access to family planning as an intrinsic human right,[9] yet in the United States many women struggle for access.[10]

The United States is one of only 45 countries that require a prescription for birth control pills, as compared to the 102 countries, including China and India,[11] that allow the pill to be sold over-the-counter (OTC) or after a simple screening.[12] Some South

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[2] This comment won first prize in the Public Citizen's 2017 Hogan/Smoger Access to Justice Essay Competition.

[3] Megan Donovan, *Over the Counter: The Next Big Step for Birth Control*, CENTER FOR REPRODUCTIVE RIGHTS 3-4 (2016).

[4] Sarah Mac Dougall, *Over-the-Counter Access to Oral Contraception: Reproductive Autonomy on Pharmacy Shelves or a Political Trojan Horse?,* 30 COLUM. J. GENDER & L. 204, 236 (2015) ("[T]he majority of the world lives in a country where birth control pills are available without a prescription").

[5] Sneha Barot, *Moving Oral Contraceptives to Over-the-Counter Status: Policy Versus Politics*, 18 GUTTMACHER POLICY REVIEW 85, 85 (2015).

[6] *Id.; see also* Fact Sheet, *Unintended Pregnancy in the United States*, GUTTMACHER INSTITUTE (Sept. 2016) https://www.guttmacher.org/fact-sheet/unintended-pregnancy-united-states.

[7] Barot, *supra* note 5.

[8] United Nations Population Fund, *State of World Population 2012*, *Summary* (2012), http://www.unfpa.org/sites/default/files/resource-pdf/EN-SWOP2012-Summary.pdf.

[9] *Id.*

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

[11] One World Nations Online, *Population Figures by Country*, NATIONSONLINE.ORG (Jan 27, 2017), http://www.nationsonline.org/oneworld/population-by-country.htm (China and India are the two largest countries in the world, by population, and the United States is the third largest).

[12] Anna Almendrala, *What You Need to Know About "Over-The-Counter" Birth Control Pills*, HUFFINGTON POST (Jan. 6, 2016), http://www.huffingtonpost.com/entry/over-the-counter-birth-control_us_568c5fdae4b0a2b6fb6dc14a; Steve Wisbauer, *Most countries allow women over-the-counter access to birth control pill¬without*

American countries technically require a prescription for access to oral contraceptives, yet allow them to be sold in their pharmacies, making them informally available OTC.[13] Thus, OTC birth control is not a new concept.[14]

Women who currently do not take oral contraceptives cite cost and lack of access as central barriers.[15] A recent study by the University of Texas indicated that women who obtained oral contraceptives OTC in Mexico were 60% more likely to continue taking them than women who obtained them in El Paso, Texas by prescription.[16] The women in this study were primarily low-income and uninsured,[17] and thus these results[18] indicate that ease of access is a key factor for such women who are deciding whether to continue taking oral contraceptives.[19] Per a recent study by the University of California, San Francisco, 21% of low-income women at risk for unintended pregnancy would start taking oral contraceptives if they were available over-the-counter for low or no cost.[20] Additionally, several studies have indicated that women in the United States want OTC access to oral contraceptives[21] and the autonomy to make decisions about their reproductive health.[22] A 2014 study indicates that this desire is global.[23]

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a prescription, NY DAILY NEWS (Jan. 2, 2013), http://www.nydailynews.com/life-style/health/world-women-pill-prescription-article-1.1231467; However, the statistics show that in China and in India, women rarely take oral contraceptives despite their availability. This is largely due to lack of education and awareness, and a societal preference of permanent irreversible birth control options. For example, in China, forced abortions by family planning officials are common. *See* Chengcheng Jiang, *What Happens When Only 1.2% of Chinese Women Take the Pill: 13 Million Abortions*, TIME.COM (2013), http://world.time.com/2013/09/30/what-happens-when-only-1-2-of-chinese-women-take-the-pill-13-million-abortions/.

[13] Mac Dougall, *supra* note 4.

[14] *See Id.*

[15] The American College of Obstetricians and Gynecologists, *Access to Contraception Comm. Opinion No. 615*, ACOG.ORG (2015), http://www.acog.org/Resources-And-Publications/Committee-Opinions/Committee-on-Health-Care-for-Underserved-Women/Access-to-Contraception [hereinafter *Comm. Opinion*].

[16] The University of Texas at Austin, *Women Who Obtain Birth Control Over the Counter in Mexico More Likely to Continue Use, New Research Shows*, UTNEWS (2011), https://news.utexas.edu/2011/02/23/contraceptives_mexico.

[17] *Id.*

[18] *Id.*

[19] *Id.*

[20] D.G. Foster, *Potential public sector cost-savings from over-the-counter access to oral contraceptives* (May, 2015), https://www.ncbi.nlm.nih.gov/pubmed/25732570.

[21] Over-the-counter access would allow women to walk into a grocery store or pharmacy and purchase birth control directly, rather than having to obtain a prescription. *See* Grossman, *supra* note 10.

[22] *See Id.*

[23] E.G. Raymond et al., *What some women want? On-demand oral contraception*, CONTRACEPTION (2014), http://www.contraceptionjournal.org/article/S0010-7824(14)00192-9/abstract.

Historically, oral contraceptives have been a politically charged topic in the United States.[24] Since the very beginning of American society, the proper role of a woman was understood as primarily that of wife and mother.[25] Thus, women's worth came from their ability to have children.[26] Sarah Primrose, a legal scholar on reproductive rights, highlighted President Roosevelt's statement from 1907 that "a white Protestant woman who avoided pregnancy was 'a criminal against the race,'" which sums up how women were viewed at this time in American history.[27] Some viewed the Bible as prohibiting the use of contraceptives because of their "promotion of lust."[28] Part of this reasoning contributed to the Comstock Act, passed on March 3, 1873, which deemed contraceptives illicit.[29] Under the Act, it was a federal offense to sell contraceptives across states or by mail.[30] As a result of the illegality of contraception,[31] the contraceptive rights movement was born.[32]

Although oral contraceptives are widely used and available with a prescription today, politics continue to drive the discussion of access, with religious undertones looming beneath the surface.[33] One example is the argument that minors should not have access to oral contraceptives because such access would signal to minors that promiscuous behavior is acceptable.[34] However, the assumption that the more access to birth control teens have, the more promiscuous they will be, is incorrect.[35] In a 2014 study by the Washington University School of Medicine, researchers found that providing free birth control to women aged 14-45 did not encourage them to engage in more risky sexual behavior.[36] Other studies indicate there is no correlation between a rise in

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24 *See generally,* Sarah Primrose, *The Attack on Planned Parenthood: A Historical Analysis*, 19 UCLA Women's L.J. 165 (2012).

25 *Id.* at 170.

26 *See Id.*

27 *Id.*

28 *Id.*

29 *See* The Pill, PBS.ORG (2001), http://www.pbs.org/wgbh/amex/pill/peopleevents/e_comstock.html.

30 *Id.*

31 *Id.*

32 *See* Primrose, *supra* note 24 at 168.

33 *See Comm. Opinion*, *supra* note 15.

34 *See* Roseann Termini, *Sex, Politics, and Lessons Learned from Plan B: A Review of the FDA's Actions and Future Direction*, 36 OKLA. CITY U.L. REV. 351, 361 (2011).

35 *Id.*

36 Marie Ellis, *Birth control does not result in more promiscuous behavior,* MEDICALNEWSTODAY.COM (March 10, 2014), http://www.medicalnewstoday.com/articles/273793.php; Kim Painter, *Study: Free birth control*

promiscuity and the accessibility of birth control pills OTC.[37] Further, women under the age of eighteen have had the right to obtain abortions as well as nonprescription contraceptives without parental consent for forty years.[38] Thus, those who argue that access without a minimum age requirement "raises eyebrows"[39] have no legal leg to stand on.

The impending reform of the Patient Protection and Affordable Care Act (ACA)[40] is an example of politics driving the discussion of access. The ACA at least grants women access to free oral contraceptives, although it still requires a prescription.[41] However, the Trump administration could easily cut out contraception from the list of preventative services that health insurance providers must fully cover under the ACA.[42] Interestingly, President Trump publicly supported getting rid of the prescription requirement for oral contraceptives in September 2016,[43] but this support is likely to be based on the ability to keep the pill from being covered by the ACA, rather

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does not increase risky sex, USA TODAY (March 6, 2014), http://www.usatoday.com/story/news/nation/2014/03/06/free-birth-control-sex/6128697/.

[37] Termini, *supra* note 34.

[38] *See Planned Parenthood of Missouri v. Danforth* 428 U.S. 52, 52 (1976) (holding that a state law requiring minors to obtain parental consent prior to getting an abortion violated their right to privacy and was thus unconstitutional); *Carey v. Population Services International*, 431 U.S. 678 (1977) (extending minors' right to privacy to include the ability to obtain nonprescription contraceptives without parental consent). Thus, if anything, OTC contraceptives would more easily allow minors to exercise a right they have possessed for many years, in a slightly new context.

[39] Leah Jessen, *App Delivers Birth Control without Doctor's Visit, Ages 12 and Up*, FAITHZETTE (April 2017), https://www.lifezette.com/faithzette/app-delivers-birth-control-without-doctors-visit-ages-12-and-up/; They also completely ignore that doctors are still writing these prescriptions, and oral contraceptives can be used for other purposes than the prevention of pregnancy, *see* Guttmacher Institute, *Many American Women Use Birth Control Pills for Noncontraceptive Reasons* (Nov. 15, 2011), https://www.guttmacher.org/news-release/2011/many-american-women-use-birth-control-pills-noncontraceptive-reasons.

[40] Patient Protection and Affordable Care Act, 42 U.S.C. § 18001 (2010); Jayne O'Donnell, *Obamacare repeal threatens public health funding to states*, USA TODAY, (Jan 16, 2017), http://www.usatoday.com/story/news/politics/2017/01/16/obamacare-repeal-threatens-public-health-funding-states/96535262/; Jillian Mincer, *U.S. States mull contraception coverage as Obamacare repeal looms*, REUTERS (Jan 12, 2017), http://www.reuters.com/article/us-usa-obamacare-contraception-idUSKBN14W1CD.

[41] *See* 42 U.S.C. § 300gg-13 (2012).

[42] Mincer, *supra* note 40 (However, a "[g]rowing numbers of U.S. states are seeking to ensure that women have continued access to free birth control in case the insurance benefit is dropped as part of President-elect Donald Trump's vow to repeal and replace the Affordable Care Act").

[43] Susan Scutti, *Trump supports birth control without prescription*, CNN.COM (Sept. 16, 2016), http://www.cnn.com/2016/09/15/health/trump-contraceptives-without-prescription/; Jacqueline Howard, *What could happen to birth control under President Trump?*, CNN.COM (Jan. 13, 2017), http://www.cnn.com/2016/11/10/health/birth-control-trump/.

than genuine concern for women's health.[44]

Politics aside, the few opposed to an OTC switch cite a lack of safety as a primary reason not to make the switch.[45] However, oral contraceptives are one of the safest drugs on the market.[46] Thus, the argument that the pill cannot safely[47] be sold OTC is either pre-textual or misinformed. Oral contraceptives are safer than many medications that have long been available in pharmacy aisles, such as pain medications like Motrin.[48] Taking oral contraceptives may slightly increase a risk of blood clots for some women,[49] but women can screen themselves at least as well as physicians for such risks.[50] Additionally, there is widespread agreement among health experts[51] that OTC access to oral contraceptives is overdue and would significantly improve access overall, if costs remained low.[52] The American Congress of Obstetricians and Gynecologists (ACOG) has supported a true OTC switch since 2012,[53] and most healthcare providers

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44 Ally Boguhn, *Making Contraceptives Available Over the Counter is No Replacement for the Birth Control Benefit*, REWIRE (Dec. 19, 2016), https://rewire.news/article/2016/12/19/making-contraceptives-available-counter-no-replacement-birth-control-benefit/.

45 *See* Sarah Watts, *An Over-the-Counter Pill Isn't Safe*, THE DAILY BEAST (June 15, 2015), http://www.thedailybeast.com/articles/2015/06/15/an-over-the-counter-pill-isn-t-safe.html.

46 *See* Barot, *supra* note 5 ("The evidence is quite strong that oral contraceptive pills meet the FDA criteria"); Wahlin B, Grindlay K and Grossman D, *Should oral contraceptives be available over the counter?* 4 FOOD AND DRUG POLICY FORUM, 1 (2014); Although combined oral contraceptives carry more risk than estrogen-only pills, all versions are "extremely safe" for most women (Barot, *supra* note 5 at 86).

47 Watts, *supra* note 45.

48 People with a history of ulcers are advised by package labeling not to take certain pain medications like Motrin, which can cause stomach bleeding. *See* Elizabeth Rosenthal, *Is It Time for Off-the-Shelf Birth-Control Pills?*, NY TIMES (April 30, 2013), http://www.nytimes.com/2013/04/21/sunday-review/is-it-time-for-off-the-shelf-birth-control-pills.html; The irrational fear that birth control pills are too dangerous to be sold OTC comes from "a knowledge deficit" about the pill (*Id.*).

49 Women who smoke and are over 35, or those with high blood pressure, are at a higher risk. *See* Rosenthal, *supra* note 48.

50 *See* Jennifer McIntosh, *Changing Oral Contraceptives from Prescription to Over-the-Counter Status: An Opinion Statement of the Women's Health Practice and Research Network of the American College of Clinical Pharmacy*, 31 PHARMACOTHERAPY 424, 426-427 (2011) (It is important to highlight that women who did experience side effects from taking oral contraceptives were still prescribed the pill. Thus, the complications were not known until after women were taking the pill. If the pill were available OTC, women could still see a physician if something goes wrong, as they do now).

51 *See Comm. Opinion*, *supra* note 15.

52 Barot, *supra* note 5 ("[L]eading medical groups—including the American Medical Association, American College of Obstetricians and Gynecologists and American Academy of Family Physicians—have endorsed making the pill OTC").

53 American College of Obstetricians and Gynecologists, *Over-the-Counter Access to Oral Contraceptives* Comm. Opinion, (Dec. 2012).

agree that a prescription is unnecessary.[54]

Despite the demonstrated need for increased access to oral contraceptives, the general support among health experts to increase access, and women's desire for such access, politics and money are keeping the pill at its prescription status. Pharmaceutical companies have no financial incentive to petition the FDA for an OTC switch, and want to avoid the political repercussions of such a switch.[55] Currently, insurance companies pay for oral contraceptives when they are prescribed, and thus pharmaceutical companies can charge more for oral contraceptives than they could if the pills were available OTC.[56] The Food and Drug Administration (FDA), although in discussion in 2016 with smaller companies about making an OTC switch,[57] is moving extremely slowly.[58]

In the meantime, state-level initiatives designed to increase access are in place and expanding. State pharmacist-prescriber laws,[59] which allow pharmacists to write prescriptions to women in the pharmacy, are increasing access minimally.[60] However, these laws look better on paper than in practice, as they essentially replace the physician as the gatekeeper.[61]

Telehealth birth control applications[62] are a game-changer for oral contraceptive access,[63] and could easily become more widely available. This comment argues that until the FDA decides to allow OTC access to oral contraceptives, states can continue to increase access by supporting telehealth apps to make birth control pills virtually (though not technically) available OTC.

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54 *Provider Opinions Regarding Expanding Access to Hormonal Contraception in Pharmacies*, WOMENS HEALTH ISSUES (2016).

55 *See* Barot, *supra* note 5.

56 *Id.*

57 *See* Telephone Interview with Dr. Nap Hosang, Professor of Public Health, University of California Berkeley, CEO, Pelagius Inc. (Oct. 14, 2016).

58 *See* Mac Dougall, *supra* note 4 at 247.

59 *See* OR. ADMIN. R. 855-019-0410 (2015); 2013 Cal. Stat. Ch. 469; 2016 Wash. Sess. Laws Ch. 132.

60 *See* American Congress of Obstetricians and Gynecologists, *ACOG Statement on Pharmacist Prescribing Laws*, ACOG.ORG (Jan. 4 2016), http://www.acog.org/About-ACOG/News-Room/Statements/2016/ACOG-Statement-on-Pharmacist-Prescribing-Laws ("only replacing one barrier with another").

61 *See* Telephone Interview with Hans Gangeskar, CEO, Nurx (Oct. 12, 2016).

62 These applications facilitate a doctor prescribing birth control to patients online through text, video or phone call. *See* Center for Connected Health Policy, *Online Prescribing*, *CCHPCA.ORG* (2016), http://cchpca.org/online-prescribing-0.

63 *See generally* Colino, *supra* note 1.

This comment proceeds in four parts. Part I begins by discussing the FDA process for allowing drugs to be sold OTC. Part I then explains why oral contraceptives pass all FDA requirements for an OTC switch, and contemplates why oral contraceptives are nonetheless still prescription (Rx)-only. Part I ends with a discussion of the importance of access in our current political climate. Part II introduces and evaluates state pharmacy prescriber laws that were aimed at increasing access, yet fail to do so sufficiently. Part III introduces birth control apps and the telehealth laws that govern them. Part III ends with a discussion of insurance coverage and regulatory issues that arise in the telehealth context. Part IV argues that birth control apps provide the best alternative to an OTC switch, and recommends that states legitimize telehealth, which would result in more inclusion of the apps.

Ⅰ. Background: The FDA Framework, Big Pharma, & Oral Contraceptive Status

This part discusses the regulatory framework laid out by the FDA for determining which drugs may be sold OTC, and which drugs must remain Rx-only. It then discusses how oral contraceptives meet all FDA requirements for making an OTC switch, yet are still stuck with an Rx-only status. This part concludes with a discussion of why the issue of access is so important.

A. Federal Regulations and the FDA

The FDA is responsible for ensuring the safety and effectiveness of both Rx and OTC pharmaceuticals on the market, under the Federal Food, Drug and Cosmetic Act (FDCA).[64] When a new drug is introduced to the market, it must meet a threshold level of safety and effectiveness to be approved.[65] Pharmaceutical companies seeking to have a drug approved are responsible for running the required testing of the drug,

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[64] 21 U.S.C. §301, §351-360(n) (2012). *See also What Does FDA Do?* http://www.fda.gov/AboutFDA/Transparency/Basics/ucm194877.htm (last visited Nov. 4 2016).

[65] 21 U.S.C. §§301, 351-360(n) (2012).

and then submitting a New Drug Application (NDA) to the FDA for review.[66] In that review, the FDA assesses the data discovered by the company, which may subsequently be considered a safety or efficacy study.[67] The FDA has exclusive authority under the FDCA to then approve or deny the application for the drug to be released to the market.[68]

A drug is restricted to Rx-only status when the FDA determines that supervision by a physician is necessary for safe administration of the drug.[69] Almost all drugs begin as Rx-only, and after at least five years of being on the market, may become eligible for an OTC switch.[70] Most current OTC drugs were once Rx-only, and virtually all future OTC drugs will be the result of an Rx switch.[71] By allowing the drug to be on the market for a few years while still requiring a prescription, safety data can continue to be gathered by the FDA and patients monitored for any adverse effects.[72] Despite having been on the market since the nineteenth century, oral contraceptives still may not be sold OTC in the United States.[73]

An OTC drug is defined as one that is "safe and effective for use by the general public without seeking treatment by a health professional."[74] Generally, OTC drugs are held to the same safety standards as their Rx-only counterparts.[75] The FDA considers three factors in determining whether a drug may be sold OTC, though it has never clearly articulated specific rules in making these determinations.[76] The three factors

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[66] *Id.*

[67] *See* §§301, 351-360(n), *supra* note 65; *see also What Does FDA Do?, supra* note 64.

[68] 21 U.S.C. §301, §351-360(n) (2012) (Congress may pass a law that requires the FDA to "prioritize review" of a certain drug, but it does not have the authority to decide the status of any drug); *see* Allowing Greater Access to Safe and Effective Contraception Act, S. 1438, 114th Cong. (2015); Affordability is Access Act, S. 1532, 114th Cong. (2015).

[69] *See* 21 U.S.C. §353(b)(1) (2012) ("because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, [it] is not safe for use except under the supervision of a practitioner licensed by law to administer such drug").

[70] Peter Barton Hutt et al., 960 FOOD AND DRUG LAW CASES AND MATERIALS (Foundation Press 4th ed. 2014).

[71] *Id.*

[72] *Id.*

[73] Donovan, *supra* note 3.

[74] Food and Drug Administration, *Drug Applications for Over-the-Counter (OTC) Drugs*, U.S. DEPT. OF HEALTH AND HUMAN SERVICES, http://www.fda.gov/drugs/developmentapprovalprocess/howdrugsaredeveloped andapproved/approvalapplications/over-the-counterdrugs/default.htm (last visited Oct. 9 2016).

[75] *Id.*

[76] Food, Drug, and Cosmetic Act, 21 U.S C. § 353(b)(1) (1938); Peter Barton Hutt, *A Legal Framework*

are: (1) the toxicity of the drug, (2) potential harmful effects of the drug moving to OTC status, and (3) "the method of use and collateral measures necessary to use" the drug.[77]

The first factor is toxicity.[78] Generally for a drug to pass this factor, it must have a low risk of misuse.[79] Any drug can be misused and result in toxicity,[80] so this possibility is not enough to show that a drug is too toxic for OTC status.[81] However, drugs with a "low margin of safety" that must be monitored closely to ensure effectiveness without compromising patient safety should remain Rx-only.[82] For the second factor, the FDA has discretion to decide what constitutes "other potential harmful effects," which includes, for example, the possibility of package tampering or black market sales.[83] The third and broadest factor, "method of use," includes issues other than safety.[84] Under "method of use," the FDA considers the ability of laypersons to self-diagnose and self-treat, adequate labeling of the drug, and broad social policy.[85] This "method of use" factor will be discussed in more depth shortly, as it presents a larger obstacle than the other factors to making oral contraceptives available OTC.

Although the FDA can technically move an Rx-only drug to OTC status in four manners,[86] most OTC switches since the 1980s have occurred by the original NDA filer (the drug company or "sponsor") of a drug submitting a supplemental application (SNDA) to the FDA for consideration to make a switch.[87] This SNDA includes additional

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for Future Decisions on Transferring Drugs from Prescription to Nonprescription Status 37 FOOD DRUG COSMETIC LAW JOURNAL 427 (1982) (These factors were added as part of the Durham-Humphrey Amendments of 1951).

[77] Hutt, *supra* note 76.

[78] *Id.*

[79] McIntosh, *supra* note 50 at 426.

[80] Hutt et al., *supra* note 70 at 427; *see Drug Applications for Over-the-Counter (OTC) Drugs*, FDA.GOV, http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/Over-the-CounterDrugs/default.htm (2015).

[81] Hutt, *supra* note 76.

[82] *Id.*

[83] *Id.*

[84] *Id.*

[85] *Id; see* DeLap, *12 Principles of OTCness*, NDMA EXECUTIVE NEWSLETTER 3 (Nov. 20, 1998).

[86] Hutt, *supra* note 70 at 960-62 (First, the FDA can initiate notice-and-comment rulemaking after receiving a petition for a switch or on its own initiative. Second, a drug company can put a drug that already has a monograph straight into the OTC market. Third, the original NDA filer can submit an SNDA to the FDA for consideration to make a switch. Fourth, once a name-brand drug is "off patent," the generic version of it can be submitted for a switch by anyone, not just the drug sponsor).

"label comprehension" and "actual use" studies that indicate the drug is safe enough for OTC status.[88]

B. Oral Contraceptives Meet FDA Requirements for an OTC Switch

Medical and health professionals agree that oral contraceptives are safe enough to be sold OTC.[89] They would easily pass the FDA's requirements for making a switch if the central concern here was safety and effectiveness.[90]

Today, birth control pills no longer pose the same health concerns that they once did[91] because the strength of oral contraceptives has decreased dramatically from thirty years ago.[92] The first pill available to the market in 1960, "Enovoid," contained a large excess of hormones to prevent pregnancy, which increased health risks.[93] Enovoid contained 10,000 micrograms of progestin and 150 micrograms of estrogen, while today's pills contain 50-150 micrograms of progestin and 20-50 micrograms of estrogen.[94]

Further, it is now common knowledge that there is no connection between the results of a pap smear and the safety or effectiveness of birth control usage.[95] However, many doctors continue to require annual pap smears to write a birth control prescription to women.[96] Thus, the argument that the pill is not safe for women without them seeing a physician loses much of its merit. In addition to being safe when taken as directed, oral contraceptives do not have a high potential for misuse,[97] so the FDA's toxicity and "potential for harmful effects" factors would easily be satisfied.[98]

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[87] *Id.; see also* 21 U.S.C. §353(b)(3) (2012).

[88] 21 U.S.C. §353(b)(3) (2012); *see* Scout Richters, *The Moral Interception of Oral Contraception Potential Constitutional Claims Against the FDA's Prescription Requirement for A Progestin-Only Birth Control Pill*, 22 J.L. & POL'Y 393, 414 (2013); Donovan, *supra* note 3.

[89] McIntosh, *supra* note 50 at 426-427; *see* Mac Dougall, *supra* note 4; *Comm. Opinion*, *supra* note 15.

[90] *See* Mcintosh, *supra* note 50 at 426-28.

[91] *See* Jacque Wilson, *Physicians: Birth control should be sold without a prescription*, CNN.COM (2012), http://www.cnn.com/2012/11/20/health/birth-control-over-the-counter/ ("[A] large body of evidence documents the safety and effectiveness of the pill").

[92] *See* Planned Parenthood, *The Birth Control Pill*: *A History*, PLANNED PARENTHOOD (2013), www.plannedparenthood.org.

[93] *Id.*

[94] *Id.*

[95] *See Comm. Opinion*, *supra* note 15.

[96] *Id.*

[97] *See* Mcintosh, *supra* note 50 at 426-28.

The third factor is more complicated, which encompasses the ability of a woman to self-diagnose and self-treat, as well as "broad social policy."[99] In the context of oral contraceptives, this means women must be able to take the pill "without a health care provider's instructions"[100] and must be able to identify whether birth control pills pose any "particular, individual risk"[101] to pass muster. Studies have shown that American women "in all likelihood…would self-prescribe and use oral contraceptives on their own without issue in the large majority of cases."[102] Women are able to self-screen at least as well as their doctors, and therefore should be able to determine for themselves if the pill is right for them.[103] Thus, self-diagnosis and self-screening abilities would likely pass the FDA's test.[104] The real issue lies in the "broad social policy" factor that the FDA takes into account, where politics and Big Pharma interests potentially seep into the analysis.

C. Why Oral Contraceptives Nonetheless Remain Rx-Only

Despite the safety of oral contraceptives and their likelihood of passing muster with the FDA, the pills remain Rx-only for two central reasons: lack of financial incentives and political repercussions. Big Pharma has big reasons not to support a switch, as it could lose millions. The FDA is still dealing with a huge mistake it made with Plan B,[105] an emergency contraceptive, and is moving at a snail's pace in considering any regular-use birth control switch.

1. Big Pharma's Skin in the Game

Big Pharma is profiting greatly from the ACA contraceptives mandate,[106] since

98 *Id.*

99 Hutt et al., *supra* note 70 at 960-62.

100 Mac Dougall, *supra* note 4 at 224-25.

101 *Id.*

102 *Id.*

103 Mcintosh, *supra* note 50 at 427.

104 *See* Mac Dougall, *supra* note 4 at 224-25.

105 *See* Lisa Heinzerling, *The FDA's Plan B Fiasco: Lessons for Administrative Law*, 102 GEORGETOWN L. J. 928, 939 (2014). The incident and its ramifications for regular-use birth control is discussed in detail in part II.

106 Peter Schweizer, *Big Pharma's Role in the Contraception Debate*, THE DAILY BEAST (March 3, 2012),

consumers currently pay the same amount for expensive name-brand contraceptives as they would for generics.[107] Contraceptive pills are currently "the most lucrative product segment in the contraceptive drugs market," which is "majorly driven by the presence of favorable government initiatives and regulatory framework."[108] The mandate does not allow health insurance companies to have copays or deductibles for name brand contraceptives, so the drugs are paid for in their entirety by insurance companies.[109] The consumer sees no price difference, so expensive brand names have seen a rise in demand.[110] This fact makes the odds of Big Pharma supporting an OTC switch slim to none, since consumers cannot afford to pay as much for oral contraceptives as can insurance companies.[111]

Nap Hosang, CEO of Pelagius and Professor of Public Health at UC Berkeley, further commented that the huge markup of birth control pills is another way Big Pharma will lose money if the pill goes OTC.[112] The pills cost less than $10/pack to make, but are sold for $25-60 per pack, which is at least a 150% markup.[113] When the pills are made OTC, their price will also go down, but the increase in market will likely not be enough to make up for the decrease in profit because there are a fixed number of women in the market, around 30 million.[114]

Another contributing factor is that generic oral contraceptives have led the market since 2014 and are projected to have the greatest amount of growth going into 2023.[115] There are not many NDA (original sponsor) filers still active for birth control pills;[116] almost all birth control sold currently is generic.[117] Companies that own the generics

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http://www.thedailybeast.com/articles/2012/03/02/peter-schweizer-big-pharma-s-role-in-the-contraception-debate.html.

[107] *Id.*

[108] Globe Newswire, *Contraceptives Market Size to Exceed $33 Billion by 2023: Global Market Insights, Inc.*, GLOBE NEWSWIRE (May 19, 2016), https://globenewswire.com/news-release/2016/05/19/841462/0/en/Contraceptives-Market-size-to-exceed-33-Billion-by-2023-Global-Market-Insights-Inc.html.

[109] Schweizer, *supra* note 106.

[110] *Id.*

[111] Hosang, *supra* note 57; *see also* Schweizer, *supra* note 106.

[112] Hosang, *supra* note 57.

[113] *Id.*

[114] *Id.*

[115] *See* Transparency Market Research, *Oral Contraceptive Pills Market- Global Industry Analysis, Size, Share, Growth, Trends and Forecast 2015- 2023* (Dec. 23, 2015), http://www.transparencymarketresearch.com/oral-contraceptive-pills-market.html.

[116] Gangeskar, *supra* note 61; *see also* Hutt et al., *supra* note 70 at 960-62.

cannot petition the FDA to make them available OTC because those companies did not have to do the same safety studies that NDA filers had to.[118] Thus, only NDA holders of oral contraceptives may file SNDA's (supplemental applications) to the FDA, and there are very few NDA holders.[119] Filing an SNDA includes demonstrating proper use, comprehension of labels, and self-selection studies,[120] which are expensive and time-consuming, giving NDA holders even less of a financial incentive to file.[121]

However, there is a silver lining. The impending reform of the ACA could lose Big Pharma millions of dollars and target an entire market of women who will likely switch to cheaper generics if the contraceptives mandate is removed.[122] Perhaps this will keep the Trump administration from removing contraceptives from the mandate entirely. Alternatively, if the mandate is removed, Big Pharma will be forced to compete with generics, which would drive down the cost of the pill, making it more affordable for consumers.

Although Big Pharma currently has no incentive to petition for a switch, some venture-backed companies have purchased the rights to discontinued NDA oral contraceptives and are in the process of applying to the FDA to have them switched to OTC status.[123] Because they do not have shareholders that expect a large return like pharmaceutical companies do, they can more freely choose to do this.[124]

Even though the FDA made a statement that it is willing to meet with any pharmaceutical company who would like to make a switch for its product to OTC status (and appears to be doing so), original NDA holders are not likely to "tak[e] the bait" because of the disaster that was the emergency contraception incident.[125] Even if a company did decide to move forward with filing an SNDA, this is still

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117 Gangeskar, *supra* note 61. *see also* Hutt et al., *supra* note 70 at 960-62.

118 *See* Hutt et al., *supra* note 70 at 960-62 (When a company makes a generic version of a drug, it files an ANDA (rather than an NDA) to the FDA with a much easier threshold of passing. All that must be shown in the ANDA is that the generic drug has the same chemical composition as the name brand drug already on the market).

119 *See* Hutt et al., *supra* note 70 at 960-62.

120 *Id.*

121 *Id.*

122 *See* Schweizer, *supra* note 106.

123 Gangeskar, *supra* note 61; One of these companies is Pelagius, Inc., a new start-up (Hosang, *supra* note 57).

124 Hosang, *supra* note 57.

125 Wilson, *supra* note 91.

"uncharted territory" for the FDA because it has never approved a "chronic" over-the-counter drug before.[126] This is likely to take several years, as the FDA is going about the process in a very process-conservative and stringent way due to heavy oversight of this particular issue.[127]

2. FDA's Plan B Blunder

The Plan B incident is a big contributor to the FDA's lag. It occurred in 2001 and involved a citizen's petition by the Center for Reproductive Rights to the FDA to make Plan B and its generic equivalents OTC, while various SNDAs were filed simultaneously, also seeking nonprescription status.[128] The FDA finally agreed to make Plan B One-Step available OTC in 2013 after a heated district court ruling against it.[129] The controversy began when the FDA Commissioner Margaret Hamburg announced that the FDA had found Plan B One-Step to be safe and effective for OTC status for all ages.[130] Very shortly after, the Secretary of Health and Human Services unprecedentedly demanded that Hamburg deny nonprescription status to Plan B One-Step to girls under the age of seventeen.[131] The FDA, five days later, denied the citizen petition.[132]

The petitioner returned to court, which held the Secretary's actions to be "arbitrary, capricious, unreasonable, and made in bad faith."[133] It was a huge, drawn-out disaster for the FDA, because its decision to deny the petition was very obviously motivated by politics, which the FDA, as an independent agency, is supposed to be immune from.[134] Because this occurred only a few years ago, and because the social stigma surrounding regular-use birth control is in the same vein as that of Plan B, it is likely that the FDA will not be eager to make a decision on the status of regular-use birth control.[135]

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[126] *Id.*

[127] Gangeskar, *supra* note 61.

[128] *See* Tummino v. Hamburg (*Tummino II*), 936 F. Supp. 2d 162, 197 (E.D.N.Y. 2013); Heinzerling, *supra* note 105.

[129] Heinzerling, *supra* note 105.

[130] *Id.*

[131] *Id.*

[132] *Id.*

[133] Tummino II, *supra* note 128; Heinzerling, *supra* note 105.

[134] *See* Mac Dougall, *supra* note 4 at 233 ("political pressures").

[135] *See generally*, Heinzerling, *supra* note 105 (The FDA will likely be subject to substantial public

D. Why Should We Care?

Women have been fighting for OTC access for several years,[136] and it has become abundantly clear that if real progress is to be made, it must be made by the states. This section argues that increasing access to oral contraceptives is vitally important, particularly right now in our current political climate.

1. The Importance of Access

Women want control over their medical decisions,[137] and more women would take oral contraceptives if they were made OTC.[138] Currently, women have to go through either a doctor or a pharmacist to obtain a prescription for access to birth control pills.[139] For some women working multiple jobs or who are uninsured, the prescription requirement severely impedes access,[140] as seeing a doctor often requires time off of work and is expensive without insurance.[141]

Further, prescriptions from a doctor often entail invasive tests and procedures.[142] These tests are not only medically unnecessary but are absolutely irrelevant to determining the safety of oral contraceptives for a particular woman.[143] Their irrelevance make these tests incredibly paternalistic, and in a sense hold birth control hostage. In addition to being coercive, studies indicate that these tests also deter women from taking oral contraceptives.[144]

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oversight with this heavily political issue, and will thus go about this process in a very cautious and process-specific way, if at all. Plan B one-step did become available OTC to women of all ages after Judge Korman overturned the FDA decision to restrict OTC access to women ages 17 and older, and gave the FDA 30 days to comply); Tummino v. Hamburg (*Tummino II*), 936 F. SUPP. 2d 162, 197 (E.D.N.Y. 2013).

136 *See* Mac Dougall, *supra* note 4 at 233.

137 Grossman, *supra* note 10.

138 *Id.*

139 *See Comm. Opinion*, *supra* note 15.

140 *See* Mac Dougall, *supra* note 4 at 217.

141 *See Id.*

142 *Comm. Opinion*, *supra* note 15; Mcintosh, *supra* note 50 at 427.

143 *Comm. Opinion*, *supra* note 15 at 4 ("no medical or safety benefit to requiring routine pelvic examination"); Mcintosh, *supra* note 50 at 427 ("[S]creening patients … should have no impact on the decision to initiate hormonal contraception").

144 *Comm. Opinion*, *supra* note 15 at 4 ("no medical or safety benefit"); Mcintosh, *supra* note 50 at 427; Note that obtaining a prescription from a pharmacist still poses these same barriers, as women are still required to see a doctor (and thus are subject to these tests) every three years. *See* OR. ADMIN. R. 855-019-0410 (2015) (For example, a woman who visits the pharmacy to obtain and fill a birth control

By increasing access to oral contraceptives by making them available OTC, women who are most at-risk for unintended pregnancy are more likely to continue taking them, and women who currently are not taking them are more likely to start.[145] This includes adolescents, who face a greater risk of unintended pregnancy than older women in part because they have more barriers to access to oral contraceptives than other women.[146] Births to minors remains a huge issue in the United States, and "a low rate of contraceptive use is the greatest contributor to unintended pregnancies in this age group."[147] Low-income women, minority women, women aged 18-24, or women living with a partner are also at a high risk for unintended pregnancy.[148]

Several studies have indicated that women would rather not have to obtain a prescription for access, so long as the cost remains low.[149] If oral contraceptives are made more accessible to women, particularly at-risk women, the number of unwanted pregnancies in the United States would very likely decrease.[150]

In addition to a decrease in unwanted pregnancies, the economic impact that oral contraceptive use has had on women is overwhelmingly positive. Oral contraceptive use is correlated with a narrowed wage gap, an increased number of women obtaining higher educational degrees, an increased number of women in white-collar jobs, and in turn a more stimulated economy.[151] A 2013 study by the Guttmacher Institute

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prescription will still often be required to have had a pap smear within the last 3 years to get the prescription. Because that test is very uncomfortable and unnecessary, women often elect to simply avoid it, and thus, cannot get a prescription).

145 Grossman, *supra* note 10; Mac Dougall, *supra* note 4 at 230.

146 Barot, *supra* note 5 at 87.

147 Thomas K. McInerny, American Academy of Pediatrics, *Comments on Proposed Rules Regarding Contraception*: *Letter to Secretaries Sebelius and Lew and Acting Secretary Harris*, AMERICAN ACADEMY OF PEDIATRICS (April 8, 2013) ("There are more than 400,000 births to teen mothers each year in the United States, costing taxpayers…at least $10.9 billion annually").

148 Barot, *supra* note 5 (Low-income and minority women are at a higher risk due in part to various access issues including the price of the pill and the inability to take time off of work or childcare obligations to see a doctor and obtain the pill. Additionally, women of this particular age group or those who live with a partner are simply statistically more likely to have an unintended pregnancy, which could be improved if it were less of a hassle to obtain the pill).

149 Mac Dougall, *supra* note 4 at 230.

150 *Id.* at 238-39.

151 Jaclyn Trop, *50 years of legal birth control: how it changed the workplace for women*, FORTUNE (June 2015), http://fortune.com/2015/06/07/50-years-legal-birth-control-workplace/ ("The net savings totaled $13.6 billion in 2010, the institute reported. Contraceptive care at publicly supported centers helped women avert 2.2 million unintended pregnancies, 1.1 million unplanned births, 761,000 abortions and 164,000 preterm or low-birth-weight births, according to its 2010 report." Thus, women who avoid unintended pregnancy are

further supports these findings, as oral contraceptives were shown to have a profound positive impact on women's ability to support themselves, finish school, and keep or get a job.[152] Women are more likely than they used to be to enter the workforce and be self-sufficient, due in part to their ability to be in control of their reproductive health.[153]

Advocates of increasing access to oral contraceptives have been making the OTC argument for several years.[154] However, the push to make oral contraceptives available OTC has recently gained an incredible amount of support from women's health organizations,[155] the federal government,[156] and President Trump.[157] There is also more health data available now, as oral contraceptives have been on the market for many years,[158] which evidences the safety of making oral contraceptives available OTC.

When Plan B became over-the-counter it was not covered by insurance,[159] and in many states, is still not covered.[160] It sells for about $40 per pill,[161] which is out of the range of what many low-income women can afford. It is unclear what the cost of birth control would be if it were sold OTC, but could be considerably more than Plan B, as women take it every day. Thus, insurance coverage will have a huge impact on access, and a solution that would make oral contraceptives available virtually OTC and covered by insurance is one that should be seriously considered.

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more likely to finish school, and in turn more likely to obtain meaningful employment, than women who face unintended pregnancy).

[152] 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 (April 2013), https://www.guttmacher.org/sites/default/files/pdfs/pubs/journals/j.contraception.2012.08.012.pdf.

[153] *Id.*

[154] *See* Richters, *supra* note 88.

[155] Barot, *supra* note 5 at 86 ("[L]eading medical groups—including the American Medical Association, American College of Obstetricians and Gynecologists and American Academy of Family Physicians—have endorsed making the pill OTC").

[156] *See e.g.,* S. 1438 *supra* note 68; S. 1532, *supra* note 68.

[157] *See* Scutti, *supra* note 43; Howard, *supra* note 43.

[158] *See, e.g.,* Planned Parenthood, *supra* note 92 (Safety data continues to be obtained from all drugs on the market by various companies and the FDA, and oral contraceptives have been on the market a very long time).

[159] *See* Roseann Termini, *supra* note 34.

[160] Planned Parenthood, *Morning-After Pill (Emergency Contraception)* (2017), https://www.plannedparenthood.org/learn/morning-after-pill-emergency-contraception.

[161] The Emergency Contraception Website, *How to Get Emergency Contraception*, EC.PRINCETON.EDU (2016), http://ec.princeton.edu/questions/ec-ACA.html.

2. The Current Political Climate and State Backlash

The ACA's future is currently uncertain, as is the contraceptives mandate.[162] President Trump's vow to repeal and replace the ACA[163] has had many states worried about women's access to the pill,[164] despite the Republican failure to repeal Obamacare in March 2017.[165] California, Maryland, Vermont, and Illinois have enacted state laws since 2014 expanding on the ACA contraception mandate.[166] Other states such as New York, Minnesota, Colorado, Nevada,[167] and Massachusetts are pursuing similar efforts this year, "with Obamacare under mortal threat in Washington."[168]

The importance of insurance coverage in the issue of access will only grow in 2017, as the ACA may be eliminated altogether,[169] and will almost certainly be reformed in some way.[170] Without insurance coverage of oral contraceptives, the prescription issue of access will become much less important. Even if access were dramatically increased by an OTC switch, if the pills are not low-cost or covered by insurance, we will have simply traded one barrier for another.[171] Many states appear to be protecting some form of the contraceptive mandate,[172] and all remaining states should seriously consider following suit.

Ⅱ. State Pharmacy Prescriber Laws

States are responding to the lack of federal support for women's reproductive health issues. Some have responded by passing pharmacy prescriber laws, allowing some

[162] *See* Mincer, *supra* note 40; David Crary & Alison Noon, *States push to protect birth control despite failed GOP bill*, KSL.COM (Mar. 28, 2017), http://www.ksl.com/index.php?nid=151&sid=43659309&title=states-push-to-protect-birth-control-despite-failed-gop-bill.

[163] Mincer, *supra* note 40.

[164] *Id.*

[165] Crary, *supra* note 162.

[166] *Id.*

[167] Crary, *supra* note 162.

[168] Mincer, *supra* note 40.

[169] *Id.*

[170] *See* Tami Luhby, *Saving Obamacare is now up to Trump*, CNN.COM (March 25, 2017), http://money.cnn.com /2017/03/24/news/economy/trump-obamacare-collapse/index.html; Crary, *supra* note 162.

[171] *See Comm. Opinion*, *supra* note 15.

[172] *See* Crary, *supra* note 162; Mincer, *supra* note 40.

pharmacists to prescribe birth control. This part introduces state pharmacy prescriber laws and evaluates their intent as well as how they are playing out in practice. It then identifies the gap between what these laws were designed to do and how well they are doing it, and concludes with a recommendation of how to make the laws more effective.

A. Introduction to Pharmacy Prescriber Laws & Their Stated Intent

Though the FDA decides which drugs must be prescribed rather than available OTC, the states have the authority to decide who may prescribe,[173] as they designate who may be considered a "licensed practitioner."[174] In some states, prescribers are only licensed physicians, but recently other states have expanded this definition of "prescriber" to encompass pharmacists who have gone through additional training.[175] The intensity of the training requirement varies by state.[176] This new group of pharmacists creates a third category of drug availability that is somewhere between prescription and OTC, and informally known as "behind the counter" (BTC) status.[177]

Currently, due to recent legislation, two states allow pharmacists to prescribe birth control autonomously: Oregon and California.[178] A general requirement of both state laws is that the person seeking birth control from the pharmacist must take a "Self-Screening Risk Assessment Questionnaire," which is reviewed by the pharmacist.[179] The pharmacist subsequently has discretion to prescribe birth control pills "if appropriate."[180] Both

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[173] *See e.g.*, OR. ADMIN R. *supra* note 144 ("Prescriptive Authority"); California S. 493, Ch. 469.

[174] *See e.g.*, *Id.*

[175] *See e.g.*, OR. ADMIN R. *supra* note 144 ("Prescriptive Authority"); California S. 493, Ch. 469 ("'Advanced practice pharmacist' means a licensed pharmacist who has been recognized as an advance practice pharmacist… [and] "is entitled to practice advanced practice pharmacy"); *Id.* at Sec. 4.(c) ("The Legislature further declares that pharmacists are health care providers who have the authority to provide health care services").

[176] *See* OR. ADMIN R. *supra* note 144; California S. 493, Ch. 469.

[177] *See* Richters, *supra* note 88 at 396 (quoting Tummino v. Hamburg, 936 F. Supp. 2d 180, 183 (E.D.N.Y. 2013) (The FDA currently does not have another standard for "behind the counter" medications, and indeed that is not a "real" category but rather what pharmacist-prescribed birth control has been referred to as).

[178] OR. ADMIN R. *supra* note 144 ("Prescriptive Authority"); California S. 493, *supra* note 175; 2681 HBR, Washington 2016.

[179] OR. ADMIN R. *supra* note 144; California S. 493, *supra* note 175.

[180] OR. ADMIN R. *supra* note 144; *see* California S. 493, *supra* note 175 at 90 ("The standardized procedure or protocol shall require that the patient use a self-screening tool that will identify patient risk factors for use of self-administered hormonal contraceptives").

laws also require that birth control be covered by insurance the same way it would be covered if it had been prescribed by a doctor.[181] Neither state law requires pharmacies to offer these services, but rather pharmacists can choose whether they would like to participate.[182]

The stated intent of the Oregon law is to "remove barriers and provide timely access to care.[183]" Some limitations specific to the Oregon law are that: (1) a pharmacist cannot "[c]ontinue to prescribe and dispense [birth control] beyond three years from the initial prescription without evidence of a clinical visit;" (2) prescriptions are valid for one year only; and (3) a person must be at least 18 years old, or have "evidence of a previous prescription from a primary care practitioner or women's health care practitioner" for the birth control to be eligible for a pharmacist to prescribe birth control to her.[184]

The California law is more comprehensive than the Oregon law, and includes different restrictions. First, the requirements to become an "advanced practice" pharmacist (a pharmacist who may prescribe birth control) are more stringent, and include paying "an applicable fee" to the board.[185] California also allows participating pharmacists to charge "an administrative fee not to exceed ten dollars above the retail cost of the drug" for their time, although they cannot "directly charge a patient a separate consultation fee.[186]" Unlike the Oregon law, which imposes an age restriction on the consumer and requires her to be evaluated by a doctor within three years of receiving a prescription from the pharmacist, the California law does not have such limitations.[187]

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[181] OR. ADMIN R. *supra* note 144; 2013 Cal. Stat. Ch. 469; *see* Soumya Karlamangla, *What you need to know about California's new birth control law*, L.A. TIMES (April 8, 2016), http://www.latimes.com/local/lanow/la-me-ln-birth-control-law-20160408-story.html; Sarah Breitenbach, *States Start to Let Pharmacists Prescribe Birth Control Pills*, INVESTIGATEWEST (Feb. 18, 2016), http://invw.org/2016/02/18/states-start-to-let-pharmacists-prescribe-birth-control-pills/.

[182] Karen MacLean, *Certificate and Order for Filing, Permanent Administrative Rules*, CA BOARD OF PHARMACY (May 1, 2016); OR. ADMIN R. *supra* note 144; California Senate Bill No. 493, Ch. 469; *See also* Kelly O'Mara, *Law Allows Women to Obtain Birth Control Without Prescription, But Few Pharmacies Offer Service*, KQED NEWS (May 19, 2016), https://ww2.kqed.org/stateofhealth/2016/05/19/law-allows-women-to-obtain-birth-control-without-prescription-but-few-pharmacies-offer-service/.

[183] MacLean, *supra* note 182.

[184] OR. ADMIN R. *supra* note 144.

[185] 2013 Cal. Stat. Ch. 469.

[186] *Id.*

[187] *Id.*

There is also no discussion of how long the prescription will be valid, as opposed to Oregon's 3-year rule.[188] Also, the consultation fee is not covered in California by insurance, whereas in Oregon, the state's Medicaid program covers that fee.[189] Many other states have similar legislation pending that would allow pharmacists to prescribe oral contraception.[190]

Washington state has implemented a similar initiative, where doctors and pharmacists enter into a "collaborative drug therapy agreement," which allows about 40 pharmacies across the state to prescribe birth control.[191] The main difference with the Washington law as compared to those of Oregon and California is that pharmacists do not have the autonomy to make a decision themselves, but rather have to rely on an agreement with the state health officer or doctor that determines the scope of the pharmacists' authority.[192] The Washington restrictions are similar to those in the Oregon legislation; the woman must be at least eighteen years old and must have seen a doctor within the last 3 years.[193] The bill further states that "pharmacists are not compensated for these services, but will be in 2017."[194]

Many other states have implemented legislation designed to increase access in some way. Hawaii and Vermont recently passed legislation mandating that insurers cover 12-month supplies, as opposed to 3-month supplies, of birth control pills to consumers with a prescription.[195] Illinois, Vermont, and California disallow cost-sharing and require

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188 *Id.*

189 O'Mara, *supra* note 182.

190 *See e.g.*, New Jersey, http://www.njleg.state.nj.us/2016/Bills/A2500/2297_I1.PDF; Tennessee, http://www.tennessean.com/story/news/politics/2016/03/09/senate-approves-bill-let-pharmacists-prescribe-birth-control/81526340/; Missouri, https://www.illinoispolicy.org/missouri-lawmaker-proposes-bill-to-allow-pharmacists-to-prescribe-birth-control/; Hawaii, New Mexico and Alaska, https://www.pharmacist.com/birth-control-without-prescriptions-coming-soon-california-under-new-law (last visited April 14, 2017).

191 2016 Wash. Sess. Laws Ch. 132; Melissa Santos, *Want birth control prescribed by your pharmacist? Check for a sticker*, THE NEWS TRIBUNE (March 31, 2016), http://www.thenewstribune.com/news/politics-government/article69313722.html; Pam Belluck, *States Lead Effort to Let Pharmacists Prescribe Birth Control*, THE NEW YORK TIMES (Nov. 22, 2015), http://www.nytimes.com/2015/11/23/health/states-lead-effort-to-let-pharmacists-prescribe-birth-control.html?_r=0; Tennessee recently adopted similar legislation, *see* TENN. CODE ANN. 63 § 1 (2016).

192 2016 Wash. Sess. Laws Ch. 132.

193 *Id.*

194 *Id.*

195 The Henry J. Kaiser Family Foundation, Women's Health Policy, *Oral Contraceptive Pills*, KFF.ORG (2016), http://kff.org/womens-health-policy/fact-sheet/oral-contraceptive-pills/.

all insurers to cover in full all prescribed, FDA-approved contraceptives.[196] On January 1, 2018, the Maryland Contraceptive Equity Act will take effect, requiring insurers to cover OTC and Rx contraception equally, without cost-sharing.[197] It is the first state in the U.S. to pass this type of legislation.[198]

B. The Practicalities of Pharmacy Prescriber Laws

Currently on the state level, Oregon, California, and Washington's legislation allows behind-the counter-access to oral contraception.[199] However the legislation still falls short of expanding access to oral contraceptives the way it was designed to.[200] These laws essentially exchange gatekeepers, include different restrictions, and are not implemented uniformly since pharmacists are not incentivized to participate.

According to Hans Gangeskar, CEO of *Nurx*,[201] the California pharmacy prescriber law was a result of two years' worth of negotiation between the Pharmacy Board and Medical Board of California, and the political nature of contraceptives resulted in the law being much more restrictive than it was originally conceived to be.[202] Due to the law's restrictive nature, increased access is not happening in practice, even though the law "looks good on paper."[203] There are too many hoops that pharmacists have to jump through, including extra training that they are not compensated for, such as taking patients' blood pressure, etc.[204] According to Gangeskar, the movement of state prescriber laws are good for the fact that they are signaling something more

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[196] *Id.*

[197] *Id.* (This means that over-the-counter birth control, like Plan B, are completely covered by public insurance the same as prescription birth control is covered. Most co-payments for any birth control are also eliminated. Thus, if the pill were to become available OTC, Maryland's framework would ensure that the pills would still be covered by insurance, even if the ACA is repealed. Maryland is the first state in the country to offer this comprehensive coverage).

[198] *Id.*

[199] *See* Tony Yang, *Pharmacist-Prescribed Birth Control in Oregon and Other States*, 315 JOURNAL OF THE AMERICAN MEDICAL ASSOCIATION 1567, 1567 (2016).

[200] *See* Kelly O'Mara, *It's Still Hard To Get Birth Control Pills in California Without a Prescription*, NPR.ORG (May 26, 2016), http://www.npr.org/sections/health-shots/2016/05/26/478878991/its-still-hard-to-get-birth-control-pills-in-california-without-a-prescription.

[201] Nurx is a birth control prescription site and app, which is explained in more detail in Part III.

[202] Gangeskar, *supra* note 61.

[203] *Id.*

[204] *Id.*

needs to be done on a national level, but they are not doing much for increasing access, at least not in California.[205]

Washington's law is very similar to Oregon's, but is more restrictive since pharmacists do not have the same autonomy as pharmacists in Oregon do.[206] Oregon and Washington's legislation does not apply to women who are under 18 years old, and still requires a prescription from a doctor at least every three years.[207] As discussed in *Tummino v. Hamburg*, there is no medical reason for the age limit requirement.[208] The requirement that women have an exam within three years of obtaining a prescription has all of the same problems as the one-year prescription requirement. The CDC guidelines establishing how often pap smears are medically necessary has changed from annually to every three-years.[209] Thus, the state law in Oregon and Washington likely used that three-year mark to determine how often women can obtain birth control from the pharmacist. This determination is problematic because there is no medical connection between pap smears and birth control,[210] and thus the state prescriber laws should not require doctor visits based on this guidance. Further, undocumented women and teens are unable to benefit because of the identification and age requirements.[211] Thus, this legislation is only minimally increasing access to contraception in Oregon to women who were likely already able to get a prescription from a doctor before. Thus, "instead of providing OTC, easily accessible birth control for women, the new laws shift the burden of prescribing onto the pharmacy," which "stops short of fully alleviating the burden of prescription on women who seek access."[212]

The pharmacy prescriber legislation in both Oregon and California make it discretionary for pharmacists or pharmacies to participate.[213] Lack of participation

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[205] *Id.* (They do not appear to be increasing access much in other states, either).

[206] 2013 Cal. Stat. Ch. 469 *supra* note 185; OR. ADMIN R. *supra* note 144.

[207] 2013 Cal. Stat. Ch. 469 *supra* note 185; OR. ADMIN R. *supra* note 144.

[208] Tummino v. Hamburg, *supra* note 128.

[209] *Cervical Cancer Screening Guidelines for Average-Risk Women*, CDC.GOV, https://www.cdc.gov/cancer/cervical/pdf/guidelines.pdf (last visited Jan., 2017).

[210] *Comm. Opinion*, *supra* note 15; Jillian Henderson et al., *Pelvic Examinations and Access to Oral Hormonal Contraception*, 116 OBSTETRICS AND GYNECOLOGY 6 (2010), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3745305/.

[211] *See* 2013 Cal. Stat. Ch. 469 *supra* note 185; OR. ADMIN R. *supra* note 144.

[212] Tony Yang, *Pharmacist-Prescribed Birth Control in Oregon and Other States*, 15 JOURNAL OF THE AMERICAN MEDICAL ASSOCIATION 1567 (2016).

[213] *See* 2013 Cal. Stat. Ch. 469 *supra* note 185; OR. ADMIN R. *supra* note 144.

is particularly felt in California, where fewer than 100 pharmacies out of 7,000 have implemented this, despite the law having been in place for over eighteen months.[214] The relatively low level of participation is due in part to a lack of a workable compensation model for pharmacists, and thus it might not make economic sense for pharmacists to take part in prescribing birth control.[215] If a better compensation structure were in place to incentivize pharmacies and pharmacists to take part in prescribing, they would likely be more willing to do so.

C. How Pharmacy Prescriber Laws Could be Improved and Their Limits

The state pharmacist-prescriber laws are a step in the right direction, but in many ways just replace one gatekeeper, the physician, with another, the pharmacist.[216] Thus, no matter how much these laws can be improved to increase access, they will not eliminate unnecessary barriers completely. Access could still be increased by making two changes to those laws.

First, states should enact laws that give pharmacists more incentive to prescribe. It is voluntary that pharmacists participate in such prescribing,[217] so they need more of a reason to. By combining elements of the California and Oregon laws, this incentive would be stronger. Allowing pharmacists to charge a fee, as they are allowed to do in California,[218] which is required to be covered by state insurance, such as in Oregon,[219] would incentivize pharmacists at no cost to the consumer. Further, the extra courses or training that a pharmacist must take in order to become licensed[220] should be covered by the state as part of the pharmacists' training rather than by the pharmacists themselves.

Second, the requirement that women see a physician every three years in order to continue receiving prescriptions from pharmacists, and the requirement that birth control must have been originally prescribed by a physician, should be eliminated

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[214] O'Mara, *supra* note 200.

[215] *Id.* ("They have the authority to furnish birth control, but it didn't come with the requirement that they get paid for these services").

[216] *See* ACOG Statement on Pharmacist Prescribing Laws, *supra* note 60.

[217] *See* OR. ADMIN R. *supra* note 144; 2013 Cal. Stat. Ch. 469 *supra* note 185.

[218] *See* 2013 Cal. Stat. Ch. 469 *supra* note 185.

[219] *See* OR. ADMIN R. *supra* note 144.

[220] *See Id.*; 2013 Cal. Stat. Ch. 469 *supra* note 185.

from all state legislation. The three-year requirement is likely only part of the law because of CDC guidelines stating how often women should see a gynecologist for pap smears.[221] This has no relation to the safe use of birth control, and is merely a watered-down version of the current law that requires such appointments for every prescription.[222]

The requirement that a woman must first have obtained a prescription from a physician is also a barrier because it disadvantages lower-income women who do not have time to obtain a prescription, women without insurance, and teens who could not get a prescription from a physician.[223] The pharmacy-prescriber laws tend to help those women who already have the means to get a prescription be slightly less burdened, but do little else. By making these adjustments, the prescribing process would go faster and allow more women to participate.

Ⅲ. Birth Control Applications: A Work-Around

A relatively new phenomenon that is rapidly gaining popularity[224] is the use of birth control prescription phone apps and websites. Through these apps, a woman may obtain an oral contraception prescription from a physician licensed in their state by answering online questions or video chatting with them online.[225] There are at least six of these apps: *Lemonaid*, *Nurx*, *Prjkt Ruby*, *Maven*, *Planned Parenthood Care*, and *Virtuwell*,[226] and they are regulated by state telehealth laws.[227] This part defines

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[221] *See* OR. ADMIN R. *supra* note 144 (requiring patients to have obtained a prescription from a doctor every 3 years in order to get a prescription from the pharmacist); *Cervical Cancer Screening Guidelines for Average-Risk Women*, *supra* note 209.

[222] *See Comm. Opinion*, *supra* note 15; Henderson, *supra* note 210.

[223] *See Comm. Opinion*, *supra* note 15; Henderson, *supra* note 210.

[224] *See e.g.*, Editorial Board, *Need a birth control prescription? There's an app for that.*, THE WASHINGTON POST (Aug. 21, 2016), https://www.washingtonpost.com/opinions/need-a-birth-control-prescription-theres-an-app-for-that/2016/08/21/26224bd8-5fdd-11e6-8e45-477372e89d78_story.html?utm_term=.c5910a7822e8 (highlighting that a site called "Nurx" is available in CA, NY and WA as of Aug 21, 2016); Nurx, https://www.nurx.com (the site is available in California, New York, Washington DC, Pennsylvania, Illinois, Washington, Florida, Michigan, New Jersey, Minnesota & Missouri) (last visited April 14, 2017).

[225] Editorial Board, *supra* note 224.

[226] *See* Belluck, *supra* note 2.

[227] *See* Telehealth Resource Center, *Food and Drug Administration and State Regulations,* http://www.telehealth

telehealth and explores its regulatory framework as well as how birth control apps might fit into that framework. This part concludes with a discussion of insurance issues that arise in the telehealth context.

A. Telehealth: Definition and Regulatory Framework

Broadly speaking, telehealth has been around for over 125 years, beginning with a physician listening to the cough of an infant over the telephone to discover whether the child had croup.[228] Telehealth has since evolved and expanded with advances in technology.[229] Today, "telehealth" or "telemedicine"[230] is defined differently in every state.[231]

The Telehealth Advancement Act of 2011 defines telehealth as:

> The mode of delivering health care services and public health via information and communication technologies to facilitate the diagnosis, consultation, treatment, education, care management, and self-management of a patient's health care while the patient is at the originating site and the health care provider is at a distant site.[232]

In the petitioner's brief for the recent Supreme Court case *Whole Women's Health v. Hellerstedt*,[233] telehealth was described to be a situation "where a physician is at one geographical location, a patient is at a different geographical location, and the

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resourcecenter.org/toolbox-module/food-and-drug-administration-and-state-regulations (last visited Nov. 4 2016) ("In addition to FDA regulations, telemedicine providers must also consider State regulations. What is commonplace in one State may be illegal in another"); Telehealth Resource Center, *Telehealth and Prescribing*, http://www.telehealthresourcecenter.org/toolbox-module/telehealth-and-prescribing (last visited Nov. 4, 2016).

[228] Jennifer Little, *Into the Future: The Statutory Implications of North Carolina's Telepsychiatry Program*, 93 N.C. L.R. 864, 868 (2015) (Technology and health have been intertwined for a very long time; this is not a new concept).

[229] *Id.*

[230] Telehealth and telemedicine are used interchangeably, but for clarity this comment will only refer to telehealth.

[231] *See* Food and Drug Administration and State Regulations, *supra* note 227 (This is not an issue, however, because it contributes to telehealth remaining a product of state law, thus shielding it from federal regulation and the politics associated with federal regulations).

[232] A.B. 415 § 6 (Ca. 2011).

[233] Brief for Petitioner at 13, *Whole Women's Health v. Hellerstedt*, 136 S. Ct. 2292 (2016) (No. 15-274) (formerly *Whole Women's Health v. Cole*).

two communicate through a secure audio-visual connection."[234] Telehealth regulation is a complex and uncertain area of law, because technology is advancing faster than what the law can keep up with.[235] Much of its regulation thus remains to be seen. Each state defines telehealth differently, regulates it differently, and currently no federal regulation of telehealth exists.[236]

There are now four distinct groups of telehealth modalities, as defined by the National Telehealth Policy Resource Center: live video, store-and-forward, remote patient monitoring, and mobile health (mHealth).[237] Live video telehealth includes two-way interactions between a physician and a patient using "audiovisual telecommunications technology" or "real-time" technology used for consultative, treatment, or diagnostic services.[238] Store-and-forward telehealth includes situations where recorded health history is transmitted through a "secure electronic communications system to a practitioner" who then uses it to evaluate the patient "outside of a real-time or live interaction."[239] Remote patient monitoring refers to personal health data transmitted from the patient in one location "via electronic communication technologies" to the physician in another location, "for use in care and related support."[240] Finally, Mobile Health (mHealth) refers to "health practice" that is supported by mobile communications like cell phones, laptops and tablets.[241]

B. Birth Control Applications

Birth control apps are a type of telehealth, but it is unclear how exactly they fit into the telehealth regulatory scheme. The apps could conceivably fall into multiple of the four telehealth modalities.[242] *Maven* and *Planned Parenthood Care* apps require video visits with a doctor, as some state telehealth regulations require face-to-face,

234 *Id.*

235 *See* Center for Connected Health Policy, *What is Telehealth?*, http://cchpca.org/what-is-telehealth (last visited Nov. 4, 2016).

236 *Id.*

237 *See Id.*

238 *Id.*

239 *Id.*

240 *What is Telehealth?, supra* note 235.

241 *Id.*

242 *See* Belluck*, supra* note 2.

real-time interaction.[243] Others only require patients to fill out online questionnaires about their health,[244] which are then reviewed by a doctor who decides whether a prescription is appropriate.[245] Thus, birth control apps have aspects of mHealth, store-and-forward, and live video telehealth modalities.

Another difference between these apps is how insurance coverage factors in. This often depends on whether the app ships the pills directly to the patient, or if the patient picks the pills up from a local pharmacy.[246] *Nurx*, *Planned Parenthood Care*, and *Prjkt Ruby* ship directly when permitted to do so by state law, and *Lemonaid, Maven, and Virtuwell* send prescriptions to local pharmacies.[247] One benefit to the latter is the ability to use insurance to pay for the birth control the same way the patient would if the prescription was written at a physical doctor's office.[248] Often this means the pill would be free to consumers because the ACA mandates that no out-of-pocket costs can be paid by the consumer for birth control if they have insurance coverage.[249] *Nurx*, *Planned Parenthood Care* and *Virtuwell* accept insurance directly, and some states allow Medicaid to be used for these prescriptions.[250] If a patient does not have insurance or wants to just file a claim afterwards, *Lemonaid*, *Prjkt Ruby*, and *Maven* charge between $15-20 per visit.[251]

In all states, an established patient-provider relationship is required, to varying degrees, for physicians to legally prescribe anything.[252] States vary widely on their interpretation

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[243] *See Id.*

[244] *See Id.*

[245] *See Id.*

[246] *See Id.*

[247] *See* Belluck, *supra* note 2.

[248] *See Id.*

[249] 42 U.S.C. § 300gg-13, *supra* note 41; *see* Belluck, *supra* note 2 (This assumes insurance coverage remains widely available under the ACA. If a significant number of women lose this coverage, telehealth applications will likely be directly affected).

[250] *See* Belluck, *supra* note 2 (The differences in the apps can be attributed to their location in different states. Each state defines and regulates telehealth differently, and these apps operate under those regulations); *see State Telehealth Laws and Medicaid Program Policies: A Comprehensive Scan of the 50 States and District of Columbia*, PUBLIC HEALTH INSTITUTE CENTER FOR CONNECTED HEALTH POLICY (March 2016) [hereinafter *A Comprehensive Scan*].

[251] *See Id.* (*Lemonaid* charges $15 for a consultation that includes the birth control prescription sent to a pharmacy. *Prjkt Ruby* charges $20 per pack of pills and "donates 25 cents of that to a nonprofit that supports contraceptive access for women in developing countries." *Maven* charges $18 for a ten-minute consultation and donates $1 from every appointment to its foundation which "provides appointments for low-income women").

[252] *A Comprehensive Scan*, *supra* note 250.

of what this requires of online prescribers.[253] The American Health Lawyers Association created a Health Law Practice Guide, which established nationwide guidelines for telehealth provider-patient relationships.[254] These guidelines include verifying the location of the patient, validating the provider's identity and credentials, and obtaining informed consent[255] from the patient regarding the use of telehealth technology.[256] However, these only serve as a floor and do not restrict states from adding additional requirements.[257]

Some states require an initial in-person meeting with the physician, and most states will not allow prescriptions to be given based only on an online questionnaire or phone call.[258] If the state allows, physicians can choose whether to participate in telehealth,[259] how often women must come in for an exam in order to obtain birth control, and the brand of birth control prescribed.[260] For example, California allows online prescribing telehealth applications,[261] Oregon explicitly prohibits it altogether,[262] and New York is silent.[263] State medical and pharmacy boards decide whether online prescribing through telehealth may be allowed in the state and to what extent.[264]

Many states, such as New York, have not issued any guidance as to their requirements for allowed online prescribing.[265] Thus, birth control apps may operate in those states, since they may operate in any state that does not expressly forbid such prescribing,[266] so long as their clinicians only prescribe in states where they are licensed.[267] Private

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[253] *A Comprehensive Scan*, *supra* note 250; Telehealth and Prescribing, *supra* note 227.

[254] 3 Health L. Prac. Guide § 46:18 (2016).

[255] *Id.*

[256] *Id.*

[257] *See* Telehealth and Prescribing, *supra* note 227.

[258] *Id*.

[259] *See* Telehealth Resource Center, *Cross-state Licensure*, http://www.telehealthresourcecenter.org/toolbox-module/cross-state-licensure (last visited Nov. 4, 2016).

[260] *See* Federation of State Medical Boards, *Internet Prescribing Language, State-by-State Overview*, https://www.fsmb.org/Media/Default/PDF/Advocacy/InternetPrescribinglaw.pdf (last visited April 14, 2017).

[261] *A Comprehensive Scan*, *supra* note 250.

[262] *A Comprehensive Scan*, *supra* note 250 (In Oregon,"[w]riting prescriptions based only on an internet sale or consult is prohibited").

[263] *Id.*

[264] *Id.*

[265] *A Comprehensive Scan*, *supra* note 250.

[266] *Id.*

[267] *See Cross-State Licensure*, *supra* note 259 ("A practitioner must be licensed, or follow state reciprocity rules, prior to working in a state").

companies and nonprofits who run these apps "require no legislative approval [to prescribe] since clinicians still write the prescriptions."[268]

It is unclear when and if the FDA will regulate birth control apps, but it currently does not have any official regulations for eHealth applications.[269] Thus, assuming at least some of these birth control apps fall into the eHealth modality, they will not be regulated by the FDA. However, the National Telehealth Policy Resource Center has issued some guidance as to the FDA's probable regulation of eHealth generally.[270] In this guidance, the NTPRC states "[w]hen equipment or software is intended for use in the diagnosis or treatment of a disease or other condition, the FDA considers the equipment or software to be a medical device."[271]

Under the FDCA,[272] medical devices have their own regulatory scheme put in place by the FDA.[273] Thus, "[t]he FDA intends to apply its oversight to those medical apps that are medical devices, and whose functionality could pose a risk to the patient's safety if the mobile app did not function as intended."[274] However, "the FDA will exercise 'enforcement discretion' on mobile medical apps that pose a low risk to patients."[275] So although the FDA has the right to regulate these apps, it is currently choosing not to, as the apps pose a low risk of harm to consumers.[276] This is potentially a great thing for birth control apps; they are either not considered to be medical devices, in which case the FDA has no authority to regulate them, or they are considered to be medical devices that the FDA has decided not to regulate. Thus, either way, the states are free to allow apps in whatever capacity they see fit.

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[268] Belluck, *supra* note 2.

[269] Center for Connected Health Policy, *The FDA & Mobile Medical Applications*, http://www.cchpca.org/sites/default/files/resources/FDA%20and%20Medical%20Apps_0.pdf (last visited April 14, 2017) ("merely provides the FDA's current thinking on the topic").

[270] *Id.*

[271] Food and Drug Administration and State Regulations, *supra* note 227.

[272] 21 U.S.C. §201(h) (2012) (The Food, Drug & Cosmetic Act).

[273] The National Telehealth Policy Resource Center, *mHealth Laws and Regulations*, http://cchpca.org/mhealth-laws-and-regulations (last visited Nov. 4 2016).

[274] Center for Connected Health Policy, *supra* note 269.

[275] *See The Basics: mHealth and the FDA*, Telehealth Resource Center (2016); 21 CFR §807.65 (listing the exemptions from device enforcement).

[276] Center for Connected Health Policy, *supra* note 269 ("The FDA intends to apply its oversight to those medical apps that are medical devices, and whose functionality could pose a risk to the patient's safety if the mobile app did not function as intended." This lack of regulation allows birth control app companies more flexibility in creating their apps).

C. Insurance & Regulatory Issues

Insurance coverage of oral contraceptives plays a crucial role in women's ability to access them. Despite its flaws,[277] the ACA grants access to many women who otherwise may not be able to afford the pill, so insurance coverage is a chief concern when contemplating an OTC switch.[278] Currently the ACA only includes birth control that is prescribed.[279] This is not an issue with state prescriber laws or select telehealth birth control apps, since physicians still prescribe. However, other telehealth apps are not covered by insurance because of state law restrictions on insurance coverage of online prescribing or telehealth generally.[280] States vary widely in their approach to public insurance coverage of telehealth, which is problematic for women who want to use a birth control app but reside in states whose laws forbid it.

In the 2016 legislative season, forty-four states have introduced over 150 pieces of telehealth-related legislation that address various aspects of reimbursement.[281] Currently, thirty-three jurisdictions have laws in place that govern the reimbursement policies of private payers in regards to telehealth, and not all of them mandate reimbursement.[282] On the other hand, some states require the reimbursement amount to be identical to the amount that would have been reimbursed had the service been rendered in a physical location.[283]

Forty-seven states' public insurance programs provide some kind of reimbursement for telehealth.[284] Most states require that reimbursable telehealth services be limited to rural or underserved areas, though this trend is decreasing.[285] The most prominently

[277] Although the ACA mandates that women must have access to birth control of every type at no out-of-pocket costs if they have insurance coverage, access is still unequal, and for many, the pill is still difficult to obtain. *See* Mac Dougall, *supra* note 4 at 215.

[278] *Id.* ("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").

[279] 42 U.S.C. § 300gg-13, *supra* note 41.

[280] *See A Comprehensive Scan*, *supra* note 250.

[281] *Id.*

[282] *Id.*

[283] *Id.*

[284] *A Comprehensive Scan*, *supra* note 250 (the three states that do not provide any reimbursement are MA, RI, and UT).

[285] *Id.*

reimbursed telehealth modality is the "live video" type, with all states except Massachusetts, Rhode Island, and Utah offering some form of reimbursement.[286] Further, states can have restrictions on the type of service, type of provider, and location of the patient in determining public reimbursements.[287]

Store-and-forward services are only reimbursed by a few state Medicaid Programs,[288] and of those that do, some have further limitations, such as in California where reimbursement is limited to "teledermatology, teleophthalmology, and teledentistry."[289] Remote Patient Monitoring (RPM) is reimbursed with restrictions in only sixteen states, and the most common restriction is to exclude all but home health agencies.[290] It is unclear how eHealth might be reimbursed.

Thus, the category of telehealth modality birth control apps fall under is crucial in determining whether public or private insurance will cover their services, and therefore how much they are increasing access. The apps vary widely, but those that include a "live video" option have a better chance of being covered. Many store-and-forward services are also covered. For example, *Nurx*[291] includes store-and-forward services, sometimes uses live-video interaction, and is covered by Medi-Cal.[292]

Ⅳ. Recommendation: Legitimize Telehealth

Although an OTC switch is unlikely to occur for several years, if it all, oral contraceptive access can be expanded state by state by embracing birth control apps. These apps are the best alternative for increasing access and allow the pills to be sold virtually OTC. States can make these apps more available by adopting a regulatory

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286 *Id.*

287 *Id.*

288 *Id.* (Alaska, Arizona, California, Illinois, Minnesota, Mississippi, New Mexico, Virginia, Washington).

289 *Id.*

290 *A Comprehensive Scan*, *supra* note 250 (Reimbursements of some level given in public program in Alabama, Alaska, Colorado, Illinois, Indiana, Kansas, Louisiana, Maine, Minnesota, Mississippi, New York, South Carolina, Texas, Utah, Vermont, and Washington).

291 *See* Nurx, https://www.nurx.com (last visited April 14, 2017).

292 Cal. Dept. of Health Care Services, *Medi-Cal Part 2 General Medicine Manual, Telehealth*. p. 1 (Dec. 2013).

scheme for telehealth modeling that of California.

A. Birth Control Apps Provide the Best Alternative to OTC Access

Although birth control apps still technically require a prescription for access to oral contraceptives,[293] they are faster, more convenient, and in many cases, much cheaper than physically going in to see a physician.[294] They do not require unnecessary tests[295] and they effectively move oral contraceptives to virtually OTC status.

The increase of access to WiFi in recent years makes access to telehealth resources widely available to most anyone. According to President Obama in 2015, "98% of Americans are connected to high-speed wireless Internet."[296] Even fast-food chains now have free WiFi in their restaurants,[297] and low-income individuals often own smart phones, allowing them access to the Internet.[298] Thus, birth control applications are widely available to most everyone, though they are still subject to state telehealth limitations.

Unlike the state prescriber laws, birth control apps do not require that women see a physician prior to getting a prescription. There is also sufficient variety among the apps that allows access for women of different circumstances. For example, some apps do not have an age limit[299] or require insurance coverage,[300] while other apps allow insurance coverage.[301] They are also widely available to women who otherwise

293 *See* Pam Belluck et al., *Which Birth Control App or Website Should You Use?*, N. Y. TIMES, (June 19, 2016), http://www.nytimes.com/interactive/2016/health/birth-control-options-apps.html?_r=0.

294 *Id.*

295 *See e.g.*, Nurx, *supra* note 291.

296 Chris Evans, *98 Percent of Americans Are Connected to High-Speed Wireless Internet*, OBAMAWHITEHOUSE.ARCHIVES.GOV (March 24, 2015), https://obamawhitehouse.archives.gov/blog/2015/03/23/98-americans-are-connected-high-speed-wireless-internet.

297 *See e.g.* Katie O'Neill, *The Wendy's Company Chooses Boingo Wireless as Wi-Fi Service Provider*, BOINGO.COM (last updated 2017), http://www.boingo.com/press-releases/the-wendys-company-chooses-boingo-wireless-as-wi-fi-service-provider-2/.

298 *See* Rebecca Ungarino, *For more poor Americans, smartphones are lifelines*, CNBC.COM (April 1, 2015), http://www.cnbc.com/2015/04/01/for-more-poor-americans-smartphones-are-lifelines.html (Many states offer free smartphones to those desperately in need); *see* The Federal Communications Commission, *Lifeline Program for Low-Income Consumers* (last updated January 19, 2017), https://www.fcc.gov/general/lifeline-program-low-income-consumers.

299 *See* Belluck et al., *supra* note 296.

300 *Id.*

301 *Id.*

would be without access, such as teenagers and undocumented women.[302] Thus, by increasing access to these apps to women of every state, access to contraception will dramatically increase.

Those on the fence about the use of birth control apps in lieu of a doctor's visit have argued that women miss out on "education" and "risk assessment" that doctors provide.[303] However, the very small percentage[304] of women who cannot safely take oral contraceptives can easily self-screen for any safety issues.[305] Further, women who should not take oral contraceptives for safety reasons typically only discover this after taking the pill and having something go wrong.[306] Thus women's ability to see a doctor and obtain a prescription does not make the pill any safer for them to take.[307]

Because telehealth as a means of medical care is not accepted in every state,[308] women's ability to obtain oral contraceptives through these apps depends directly on what state they live in. Additionally, those states that do accept telehealth as a legitimate means of care differ on what constitutes an appropriate patient-provider relationship, as is required in every state for physicians to prescribe.[309] Currently, birth control prescription apps are available to women in 47 states[310] where telehealth and online prescribing are not prohibited. Of those 47 states, 24 only provide for one option, *Prjkt Ruby*, which does not accept any form of insurance.[311] Although there is much to accomplish in ensuring these apps reach women in every state, the number of states that now allow at least one of these apps to operate has more than doubled since early 2016.[312] Thus, the popularity of these apps is indeed growing.

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302 *See* Colino, *supra* note 1.

303 Jessica Roy, *You can get birth control from an app – but should you?*, L.A. TIMES (June 21, 2016), http://www.latimes.com/health/la-he-birth-control-app-telehealth-20160621-snap-story.html.

304 Barot, *supra* note 5 at 86.

305 *See* Barot, *supra* note 5 at 86; Mac Dougall, *supra* note 4.

306 *See* Mac Dougall, *supra* note 4; *see generally* Part I.

307 *See generally* Part I.

308 *See* Food and Drug Administration and State Regulations, *supra* note 227.

309 *See A Comprehensive Scan*, *supra* note 250.

310 Beth Skwarecki, *These Online Services Offer Birth Control Without Visiting a Doctor*, LIFEHACKER.COM (Dec. 27, 2016), http://vitals.lifehacker.com/these-online-services-offer-birth-control-without-visit-1790510793.

311 *Id.*

312 *See supra* note 225, showing the growth of the availability of birth control apps from 2016-2017.

B. The California Model: A Workable Solution

The states should follow the California model by first deeming telehealth a legitimate means of providing care.[313] The Telehealth Advancement Act of 2011[314] states that "[i]t is the intent of the Legislature to recognize the practice of telehealth as a legitimate means by which an individual may receive health care services from a health care provider without in-person contact with the health care provider."[315] Many California Codes were reformed by the Telehealth Advancement Act of 2011,[316] which other States should use as a model to reform their own legislation. [317]

Additionally, California's public insurance, Medi-Cal, reimburses "live video" as well as some "store-and-forward" telehealth services across a wide array of medical specialties,[318] which encompasses some birth control apps.[319] Other states should adopt similar legislation. However, states should go even further than reimbursing only these types of telehealth services (although this is a great start) by explicitly requiring oral contraceptives to be covered by public insurance, regardless of telehealth modality, so long as the prescription is valid. California is currently considering similar legislation.[320]

It is unclear what patient-provider relationship requirements exist in California to allow online prescribing,[321] but California law does not prohibit online prescribing, thus allowing birth control apps to operate in the state. Currently, five birth control apps operate in California, which is the most of any state.[322] Three of these five have a live-video or live-chat[323] option to speak to a physician prior to prescribing,[324]

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[313] Telehealth Advancement Act of 2011, A.B. 415 § 6 (Ca. 2011) (adding Section 1374.13 to the Health and Safety Code).

[314] *Id.*

[315] *Id.*

[316] *Id.*

[317] *Id. at* § 1-8 (The Act revised parts of California's Business and Professions Code, Health & Safety Code, Insurance Code, and Welfare & Institutions Code).

[318] Cal. Dept. of Health Care Services, *supra* note 293.

[319] Prkjt Ruby, https://www.prjktruby.com (last visited April 14, 2017); Virtuwell, https://www.virtuwell.com (last visited April 14, 2017) (interactive, rules-based interview); Nurx, *supra* note 291 (store-and-forward).

[320] S.B. 960, 2015-2016 Sess. (Cal. 2016) (This bill would allow Medi-Cal reimbursement specifically for reproductive healthcare store-and-forward telehealth modalities); *See* Center for Connected Health Policy, *CA Legislation: SB 960: Store and Forward Reimbursement* http://www.cchpca.org/ca-legislation-sb-960-store-and-forward-reimbursement (last visited April 14, 2017).

[321] *See A Comprehensive Scan*, *supra* note 250.

[322] Skwarecki, *supra* note 310.

and the remaining two, *Planned Parenthood Care* and *Lemonaid*, require patients to take a picture of themselves along with filling out a questionnaire, since "state regulations require [they] see who [they] are treating."[325]

Most other states also do not prohibit such prescribing, provided patients have an opportunity to consult with a physician by more than just an online questionnaire.[326] Thus, not much needs to be done legislatively to "online prescribing" to allow birth control apps to flourish. States may simply stay silent regarding online prescribing for the time being.[327]

Conclusion

Oral contraceptives are safe, effective, and widely used by women in the United States to prevent pregnancy. However, there are several unnecessary barriers between women and obtaining the pill, the largest being the requirement of a prescription and cost. These requirements disadvantage poor, young, and uninsured women most, and these women are at the highest risk for unintended pregnancy. Although the best option for increasing access to the pill would be for it to be available OTC, birth control apps are moving the nation in the right direction. By making them more uniformly available in the United States, access to birth control would be increased for thousands of women who currently lack access for various reasons.

With every additional state that jumps on board, access will be increased. Birth control apps do not require federal legislative approval and they are not federally regulated, so they are largely shielded from the current political climate. It is up to state legislation and medical boards to legitimize telehealth in a way that birth control apps may service women in their jurisdiction. As evidenced by the explosion of pharmacy

323 It is unclear exactly how live-chat factors into the state regulatory scheme.

324 Prkjt Ruby, *supra* note 319; Nurx, *supra* note 291; Virtuwell, *supra* note 319 (interactive, rules-based interview).

325 *See* Planned Parenthood, https://www.plannedparenthood.org/get-care/birth-control-online/california (last visited April 14, 2017); Lemonaid, https://www.lemonaidhealth.com/services/birth-control-pills (last visited April 14, 2017).

326 A *Comprehensive Scan*, *supra* note 250.

327 *Id.*

prescriber laws and statements made by state officials vowing to protect women's rights in the face of federal failure to do so,[328] many states appear eager to protect reproductive rights in some way. States could drastically increase access to oral contraceptives by adopting the California model, which would allow birth control apps to have a further reach. The companies that created such apps are largely women's rights advocates who are looking to increase the number of states that they service. All states must do is grab the helping hand reaching out to them.

Received: April 15, 2017
Revised: June 05, 2017
Accepted: June 24, 2017

[328] *See e.g.*, Alexandra Sifferlin, *How These States Are Fighting to Protect Women's Rights*, TIME.COM (Feb. 8, 2017), http://time.com/4663777/states-protect-reproductive-rights/.