

# DAY ONE PROJECT

## **Federal Approval of Over-the-Counter Birth-Control Pills**

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August 2021

## Summary

Women have a right to contraception, regardless of circumstance. But this right has recently come under threat. Starting in 2016, multiple federal and state regulations pulled critical funding to reproductive and family-planning services. The COVID-19 crisis amplified the challenges Americans face while attempting to receive basic healthcare resources like birth-control pills. To reverse this worrying trend and ensure universal access to contraception in the United States, the federal government should approve over-the-counter (OTC) birth-control pills — thereby removing the need for a prescription to protect women’s health and prevent unintended pregnancies.

Specifically, the Biden-Harris Administration should commission the Food and Drug Administration (FDA) to create an OTC Monograph for oral contraceptives (i.e., birth-control pills). An OTC Monograph is a rulebook established by the FDA that gives specific instructions on the manufacture, distribution and marketing of non-prescription, OTC drugs. Circumstances are right for this action. 2020’s Coronavirus Aid, Relief, and Economic Security (CARES) Act established the OTC Monograph Reforms, creating a new and efficient process to produce OTC drugs. The CARES Act also provided the FDA’s Department of Non-prescription Drugs with \$110 million over five years<sup>1</sup> to produce more OTC drugs. Oral contraceptives are ideal OTC candidates, having been proven safe and effective for 60 years. It is time for the United States to follow the example set by more than 100 countries to date and provide women with OTC birth-control pills.

## Challenge and Opportunity

American women seeking access to birth-control pills face a range of barriers. Obtaining birth-control pills requires women to schedule an appointment, go to the doctor, receive a prescription, and then pick up their pills at a pharmacy. This process is onerous and time-consuming, especially for the millions of women living in areas with few local health-service centers.<sup>2</sup>

Limited access to birth control is a key reason why unintended pregnancy rates are higher in the United States than in other developed countries.<sup>3</sup> In 2011, 45% of U.S. pregnancies were unintended,<sup>4</sup> and nearly half of these were unwanted. Rates of unintended pregnancies are highest among low-income women, cohabiting women, and women of color.<sup>5</sup> In addition to directly imposing adverse consequences on

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<sup>1</sup> Kochanowski, B.; Spangler, D.C. (2020). [OTC monograph reform is now law: What’s next](#). Regulatory Affairs Professionals Society, April 7.

<sup>2</sup> Power to Decide. (n.d.). [Birth Control Access](#).

<sup>3</sup> Guttmacher Institute. (2019). [Unintended Pregnancy in the United States](#). January.

<sup>4</sup> U.S. Centers for Disease Control and Prevention. (2021). [Unintended Pregnancy](#). June 28.

<sup>5</sup> Finer, L.B.; Zolna, M.R. (2016). Declines in Unintended Pregnancy in the United States, 2008–2011. *New England Journal of Medicine*, 374: 843–852.

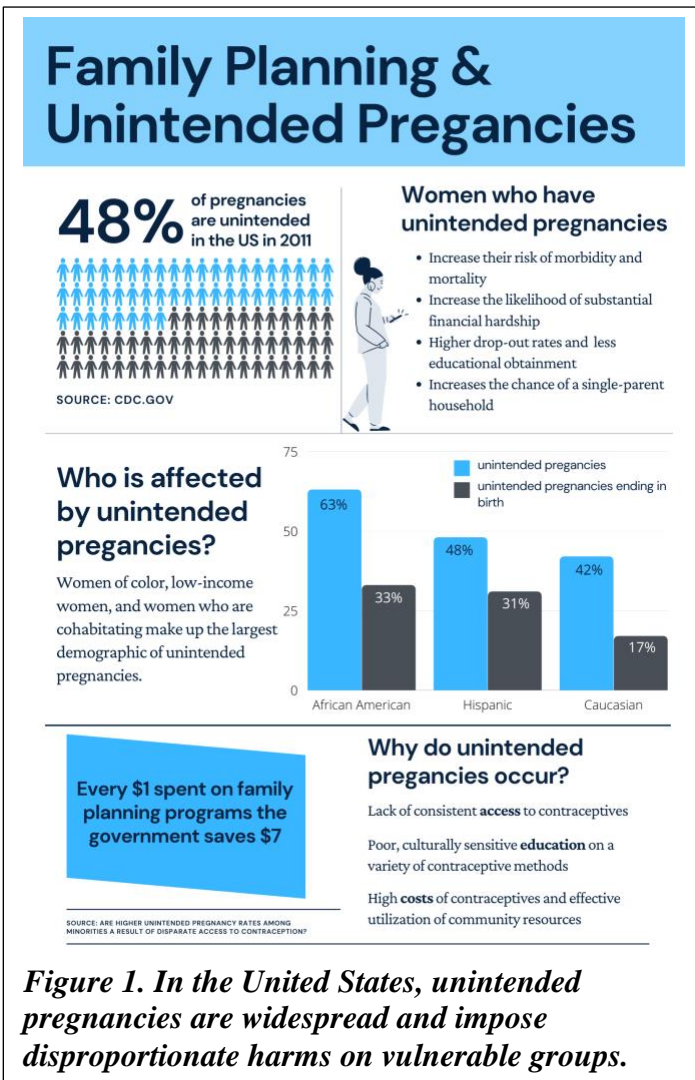
mothers and their families, these pregnancies have spill over burdens that are borne by American taxpayers. The federal government pays about 68% of the costs associated with unintended pregnancies (e.g., prenatal care, delivery, termination) through Medicare. These costs totalled \$21 billion in 2010.<sup>6</sup>

Eliminating the prescription requirement for birth-control pills is an important way to address the medical, financial, and social effects of unintended and unwanted pregnancies.

Researchers anticipate that approving over-the-counter (OTC) birth-control pills would reduce unintended pregnancies by 7–25%.<sup>7</sup> Though the safety of OTC pills historically posed a concern, this is no longer the case. OTC birth control pills are approved in more than 100 countries and are demonstrably less toxic than other approved OTC drugs. The American College of Obstetricians and Gynaecologists has publicly stated it “supports making contraceptives available over-the-counter,”

additionally the American Academy of Family Physicians and the American Medical Association have issued similar public statements of support.<sup>8</sup> Politicians from both sides of the aisle agree that birth control should be OTC.<sup>9</sup> The two major obstacles that stand in the way of transitioning from prescription to OTC birth control in the United States are securing FDA approval and getting the pharmaceutical industry to buy into the switch.

The FDA permits prescription drugs to transition to OTC status via (1) a New Drug Application (NDA), (2) an OTC Drug Monograph, or (3) a Citizen Petition (Appendix A). The NDA pathway process costs \$2.9 million per submission<sup>10</sup> and would take a



<sup>6</sup> Guttmacher Institute. (2015). [Public Costs from Unintended Pregnancies and the Role of Public Insurance Programs in Paying for Pregnancy-Related Care: National and State Estimates for 2010](#). February.

<sup>7</sup> Foster, D.G.; et al. (2015). Potential public sector cost-savings from over-the-counter access to oral contraceptives. *Contraception*, 91(5): 373–379.

<sup>8</sup> The American College of Obstetricians and Gynecologists. (2019). [Over-the-Counter Access to Hormonal Contraception](#). Committee Opinion Number 788, October.

<sup>9</sup> Hellmann, J. (2019). [Democrats roll out proposal requiring insurance to cover birth control](#). *The Hill*, June 13.

<sup>10</sup> Innovative Science Solutions. (2020). [NDA vs. OTC Monograph: Which Pathway is Right for You?](#) June 22.

considerable amount of time to implement for each of the more than 100 FDA-approved birth-control pills. Plan B-Step — an emergency contraceptive — is the closest example of a prescription-to-OTC transition related to birth control that occurred through an NDA. The approval process for Plan-B Step was initiated in April 2003 and a decision was expected in February of 2004, but process delays meant that Plan B-Step didn't get placed on shelves until the summer of 2013. Along the way, the pharmaceutical industry witnessed a series of battles between the FDA and its advisory committees, resignations of key FDA staff, state-led lawsuits, and numerous FDA-rejected petitions from both citizens and industry.<sup>11</sup> In part due to the FDA's handling of Plan B-Step, companies that manufacture prescription-based birth control are wary of attempting to convert their products to OTC status. In 2016, HRA Pharma (in partnership with the non-profit Ibis Reproductive Health) became the first company to attempt to transition a standard birth-control pill to OTC status via the NDA pathway.<sup>12</sup> But in the five years that have elapsed since HRA Pharma announced its intention to pursue this goal, there have been no further updates.

An OTC monograph for oral contraceptives would provide industry with a straightforward way to manufacture and distribute OTC birth control pills. Though the original OTC monograph process was over-burdened and inefficient,<sup>13</sup> the CARES Act recently triggered much-needed process reforms. The OTC Reforms specified in the CARES Act ensure set timelines and costs for approval of OTC drugs. Once established, an OTC monograph allows companies to produce a certain class of OTC drugs without FDA pre-market approval, encouraging beneficial competition. An OTC monograph for birth control would provide industry with stronger incentives to produce OTC birth-control pills and reduce the costs of doing so. The result would be increased availability and affordability of birth control for all American women.

## Plan of Action

The Biden-Harris administration should direct the FDA to (1) file an order to create an OTC Drug Monograph category for oral contraceptives, and (2) conduct outreach to drug companies to encourage submissions of candidate OTC birth-control pills. The administration should also work with Congress to pass legislation expanding the Affordable Care Act (ACA) to cover OTC birth-control pills. More detail on each of these steps is provided below.

### Step 1: Create an OTC Drug Monograph category for oral contraceptives

The FDA should file an order to create an OTC Drug Monograph category for oral contraceptives. An OTC monograph serves as a rulebook for different classes of OTC drugs, including a list of Generally Recognized As Safe and Effective (GRASE) ingredients, approved ways to administer GRASE ingredients, approved dosages of GRASE ingredients, and more. Following the monograph allows industry to

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<sup>11</sup> Wood, S.F. (2014). Inappropriate Obstructions to Access: The FDA's Handling of Plan B. *AMA Journal of Ethics*, April.

<sup>12</sup> Ibis Reproductive Health. (2016). [Ibis announces groundbreaking partnership with HRA Pharma to move a birth control pill over the counter](#). December.

<sup>13</sup> U.S. Food and Drug Administration. (2021). [Over-the-Counter \(OTC\) Drug Review | OTC Monograph Reform in the CARES Act](#). April 27.

manufacture, distribute, and market OTC drugs without pre-market FDA approval. Appendix B provides more information on the cost and time associated with achieving GRASE status and summarizes active ingredients that would need to be deemed GRASE for an OTC monograph to cover the wide range of prescription-based birth-control pills already on the market.

## **Step 2: Conduct outreach to drug companies to encourage submissions of candidate OTC birth-control pills.**

The FDA (and supporting advisors) should design an outreach program to (1) notify the pharmaceutical industry of the nascent opportunity to manufacture OTC birth-control pills and (2) encourage them to do so. The FDA can also invite industry and other stakeholders to suggest edits to the oral-contraceptive monograph, including edits that would expand the monograph to include newly developed active ingredients and accompanying information on administration and dosage. Finally, the FDA can consider establishing incentives for drug companies that produce OTC birth-control pills. The FDA could, for instance, waive the fee for companies to request approval of new active ingredients for a particular OTC monograph therapeutic category: a fee that currently stands at \$500,000 per ingredient request. The FDA could also provide extended exclusivity terms for first movers.

## **Step 3: Expand ACA coverage to include OTC birth-control pills**

The Affordable Care Act (ACA) currently covers all forms of prescription-based birth-control pills. The ACA does not, however, guarantee coverage of OTC birth-control pills when and if they become available. The Affordability Is Access Act<sup>14</sup> is an example of legislation that has already been proposed to ensure coverage of OTC birth control. The Biden-Harris Administration should work with Congress to advance and enact such legislation.

## **Conclusion**

The switch from prescription-based to OTC birth-control pills is long overdue. A broad coalition of stakeholders recognizes that OTC birth-control pills are safe, effective, and important. Recent reforms to the FDA's OTC Drug Monograph process, coupled with CARES Act funding to increase the number and types of available OTC drugs, have created the ideal conditions for the United States to finally embrace OTC birth control. The Biden-Harris Administration should seize this opportunity to reduce unintended pregnancies, increase societal cost savings, foster equitable healthcare outcomes, and empower all American women to make the health choices that are right for them.

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<sup>14</sup> [H.R.3296 - Affordability is Access Act.](#)

## Appendix A

Comparison of processes for transitioning prescription drugs to OTC status.<sup>15</sup> The citizen petition process works by allowing the public to instigate a change to the FDA healthy policy by instigating changes to the NDA or OTC Monograph process.

New Drug Application (NDA)	Over-the-Counter (OTC) Monograph process
Pre-market approval required	No pre-market approval required
Confidential filing	Public process
Specific to drug product	Specific to active ingredient (within an OTC therapeutic category)
May require a user fee	May require a user fee
Potential for marketing exclusivity	No marketing exclusivity
Mandated FDA review timelines	Reformed FDA review timelines
May require clinical studies <ul style="list-style-type: none"> <li>• Label comprehension</li> <li>• Actual use</li> </ul>	May require clinical studies <ul style="list-style-type: none"> <li>• Label comprehension and actual use studies not required</li> </ul>
Approved labelling is unique to the drug	Labelling is defined by the OTC monograph. Once marketed, FDA can review the complete labelling at any time to determine whether it is truthful or misleading
Approved NDA is your “license” to market	Final monograph is open to anyone
Trade name reviewed prior to marketing	No review of trade name prior to marketing. Once marketed, FDA can review the trade name at any time

<sup>15</sup> U.S. Food and Drug Administration. (n.d.). [Differences: NDA Process and OTC Monograph Process](#).

## Appendix B

For an OTC monograph on birth-control pills to cover the wide range of prescription-based birth-control pills currently on the market (including progestin-only pills as well as estrogen/progestin combination pills), each of the active ingredients summarized in the table below would need to be deemed GRASE. The OTC Reforms specified in the CARES Act require a separate Tier 1 OTC monograph order request (OMOR) for each ingredient proposed for a new OTC monograph therapeutic category. Under the FY 2021 Tier 1 OMOR fee rate of \$500,000 per request, approving each of the ingredients in the table would cost a total of \$3.5 million in OMOR fees. Under the timeline laid out by the FDA for Tier 1 OMORs, the maximum time for approval of each ingredient would be approximately 17.5 months under normal circumstances and 22.5 months if public comment is numerous or substantive.<sup>16</sup>

Active ingredient	Types of pills that use ingredient	Hormone
Ethinyl Estradiol	Combination	Estrogen
Levonorgestrel	Combination	Progestin
Norgestrel	Combination, Progestin-Only	Progestin
Desogestrel	Combination	Progestin
Drospirenone	Combination	Progestin
Norgestimate	Combination	Progestin
Norethindrone	Combination, Progestin-Only	Progestin

## Frequently Asked Questions

### 1. What has been done in the past to make OTC birth-control pills available in the United States?

The first attempt to make OTC birth-control pills available in the United States occurred in 1993, in the form of a meeting organized by a group of industry experts and researchers.<sup>17</sup> The FDA cancelled the meeting because the agenda was too broad and never rescheduled it afterwards.

Senators Cory Gardner (R-CO) and Kelly Ayotte (R-NH) proposed a bill to incentivize manufacturers to submit applications for OTC birth-control pills for women over 17 years of age.<sup>18</sup> This bill included fast-track options for applications and a waiver for the application filing fee. Additionally to this proposal, Senator Ayanna Pressley (D-MA) proposed a bill to require the Affordable Care Act to also cover OTC birth-control pills.<sup>19</sup>

<sup>16</sup> U.S. Food and Drug Administration. (n.d.). [Over-the-Counter Monograph Use Fee Program Performance Goals and Procedures - Fiscal Years 2018-2022](#). Table II.B.1.d: Timelines for Innovation OMORs (Industry-Initiated Over-the-Counter Monograph Order Requests OMORs for Monograph Changes).

<sup>17</sup> Dekhtyar, A. (1997). [A Difficult Proposition: Oral Contraceptives' Switch from Prescription to Over-the-counter Status](#). Third Year Paper, Harvard University.

<sup>18</sup> S.1438 - 114th Congress (2015-2016): [Allowing Greater Access to Safe and Effective Contraception Act.](#)"

<sup>19</sup> H.R.3296 - 116th Congress (2019-2020): [Affordability Is Access Act.](#)"

Neither of these bills passed, and similar bills in subsequent years were also stalled in Congress.

In December 2016, Ibis Reproductive Health and HRA Pharma jointly announced<sup>20</sup> that they would take the necessary steps to apply for OTC status for a progesterone-only birth-control pill. The outcome of this submission is still pending.

The emergency contraceptive Plan B-Step is the drug closest to standard birth-control pills to receive OTC approval. The NDA application for transitioning Plan B-Step from prescription to OTC status was first submitted in 2003. This initial application was rejected and a revised application was submitted in 2006. The approval process was scheduled to take only a year to finish, but was ultimately not completed until 2013.<sup>21</sup>

## **2. How much does the government spend on issues related to birth control, unintended pregnancies, and family planning?**

In 2010, the federal government spent around \$21 billion to pay for medical costs associated with unintended pregnancies. Medicaid paid for about 68% of all unintended pregnancies, compared with only about 38% of planned births. In the same year at the state level, 19 states exceeded \$400 million in public expenditures related to unintended pregnancies. Texas spent an astonishing \$2.9 billion on the issue.<sup>22</sup>

In 2010, public investments in family-planning services saved taxpayers \$13.6 billion by helping women avoid unintended pregnancies as well as other negative reproductive outcomes. Phrased in another way, taxpayers save more than \$7 for every dollar they invest into family-planning resources and services.<sup>23</sup>

In addition to financial costs, there are a number of other indirect costs associated with unintended pregnancies. High rates of unintended pregnancies among women ages 15–24 years directly affect the ability of those women to complete their educations, build their careers, and ultimately reach their earning potential.<sup>24</sup>

Children born through unintended pregnancies also have poorer health and educational outcomes.<sup>25</sup> Around 40% of infants born after unintended conception begin life with unmarried parents and commonly grow up in single-parent households. Long-standing research shows that children who grow up in single-parent households face increased risk of joblessness post-graduation as well as increased risk of entering the criminal-justice system.<sup>26</sup>

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<sup>20</sup> Ibis Reproductive Health. (2016). Ibis announces ground-breaking partnership.

<sup>21</sup> ProCon/Encyclopaedia Britannica. (2018). [History of OTC Birth Control](#). December 19.

<sup>22</sup> Guttmacher Institute. (2015). *Public Costs from Unintended Pregnancies*.

<sup>23</sup> Guttmacher Institute. (2015). [Unintended Pregnancies Cost Federal and State Governments \\$21 Billion in 2010](#). March 2.

<sup>24</sup> National Conference of State Legislatures. (2016). [Unplanned Pregnancy and Future Opportunities](#). June.

<sup>25</sup> Ibid.

<sup>26</sup> National Conference of State Legislatures. (2016). [Unplanned Pregnancy and Future Opportunities](#). June.



### **3. What is an OTC Drug Monograph category? What is an OTC Monograph?**

An OTC Drug Monograph category is a type of therapeutic class (e.g., analgesics or antacids). OTC Monograph categories are used to organize approved labelling and ingredients for a class of therapeutics — a more efficient option, where appropriate, than listing out specifications for individual drug products individually.

For each category, an OTC Drug Monograph is developed and published in the Federal Register. OTC drug monographs serve as rulebooks for different classes of therapeutics, specifying acceptable ingredients, doses, formulations, and labelling for drug products by therapeutic class. Once the final monograph for a category is published, companies can make and market an OTC product in that category without securing FDA pre-approval. The FDA's review of OTC drugs is handled by the Office of Non-prescription Drugs.

### **4. Why is it better to create an OTC Monograph for oral contraceptives instead of having companies request approval of OTC birth-control pills through the NDA prescription-to-OTC process?**

Currently there is no established pathway for a prescription-based birth-control pill to transition to OTC status. Over 100 birth-control pills are approved by the FDA for prescription use. The NDA prescription-OTC pathway seemed to be the best way to achieve the transition, which is why Ibis Reproductive Health and HRA Pharma submitted their pill through that process. However, the NDA pathway for transitioning prescription-based birth control to OTC status — as evidenced by the Ibis/HRA example — demonstrates the lengthy timeframes and inefficiencies this process has for just one pill approval. Previously, the OTC Drug Review process has been notorious for being overburdened and inefficient, particularly when attempting to create a new drug category. But this has changed since the OTC Monograph Reforms. The demonstrated challenges of the NDA pathway coupled with the recent OTC Reforms have created a valuable opportunity to establish oral contraceptives as an OTC therapeutic category.

Focusing on the OTC Monograph process as the preferred pathway for transitioning prescription-based birth-control pills to OTC status will likely enable quicker approval and distribution of OTC birth-control pills, ensure long-term affordability of OTC birth control, and provide more opportunities for innovations to improve health outcomes for women. To wit:

- The NDA process costs around \$2.9 million per drug application. The OTC Monograph process costs up to \$500,000 for each ingredient added to a new therapeutic category. Since there are roughly seven different common ingredients for both progestin-only and progestin/estrogen combination pills, the cost of establishing an OTC Monograph broad enough to cover most prescription-based birth-control pills on the market today would be roughly equivalent to the cost of securing NDA approval for just one or two individual drug products.

- The standard NDA approval process takes around 6–10 months per drug product. Establishing a new OTC Monograph category takes longer up front (up to 22.5 months), but ultimately provides an expedited pathway for transitioning the ~100 existing prescription-based birth-control pills to OTC status.
- OTC monographs produce competitive drug markets—and hence affordable drugs—by allowing more companies to distribute drug products without regulatory pre-approval. OTC drugs also tend to be considerably cheaper than prescription drugs because they are marketed directly to consumers and pricing isn't influenced by a third-party (e.g. doctors, insurers, etc.).
- An OTC monograph for birth-control pills would open the door to new innovations that could further benefit consumers. For example, the OTC monograph would make it easier for a company to produce a birth-control pill including herbal supplements that reduce PMS/PMDD symptoms.

## 5. What are the biggest changes introduced by the OTC Monograph Reforms instituted by the CARES Act?

The OTC monograph drug-review process was created in 1972. The purpose of the process was to establish the Generally Recognized as Safe and Effective (GRASE) conditions for each OTC therapeutic drug class in the form of OTC monographs or rulebooks that drug manufacturers could follow. Initially, the process included a three-phase public-notice-and-comment rulemaking proceeding that, when completed, resulted in a new final monograph published in the Code of Federal Regulations (Figure 2).

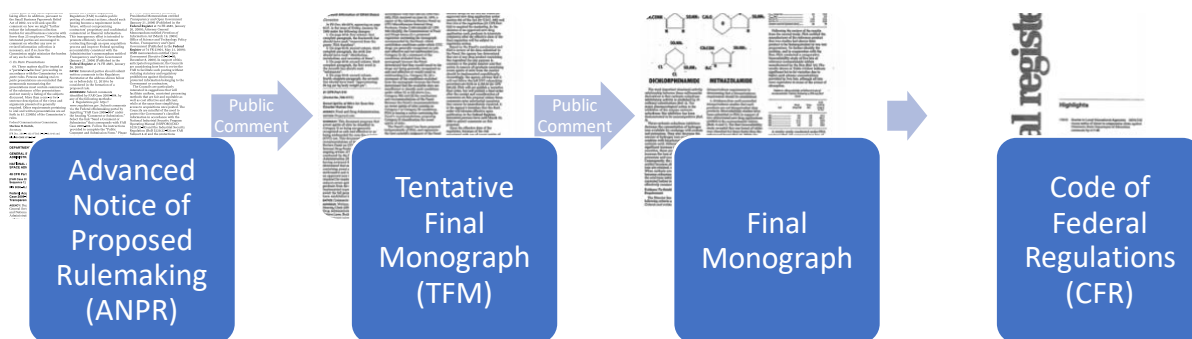


Figure 2. Steps of the original OTC monograph drug-review process.

The OTC monograph's multistep rulemaking process was burdensome and the FDA lacked appropriate resources available to carry out the public comment and rulemaking stages efficiently. Final monographs were hard to establish—so hard that there still exist Tentative Final Monographs that were proposed in the 1970s but were never finalized. Final OTC monographs were also challenging to amend even when OTC drugs posed direct threats to public safety.

2020's Coronavirus Aid, Relief, and Economic Security Act (CARES Act) finally modernized the OTC monograph process through the OTC Monograph Reforms. The biggest change was that the public-notice-and-comment rulemaking proceeding was replaced with a process based on administrative orders. The FDA now has the authority to issue an administrative order that adds, removes, or changes GRASE conditions for an OTC drug monograph. This order can be initiated by the FDA or by industry. The OTC Monograph Reforms also created an expedited administrative-order process to authorize the FDA to quickly address any safety issues related to any OTC products. Figure 3 illustrates the amended OTC monograph process. The OTC Monograph Reforms also established the Over-The-Counter Monograph Drug User Fee Program (OMUFA), which clearly sets out the performance goals, costs, and timelines for the OTC Monograph process.

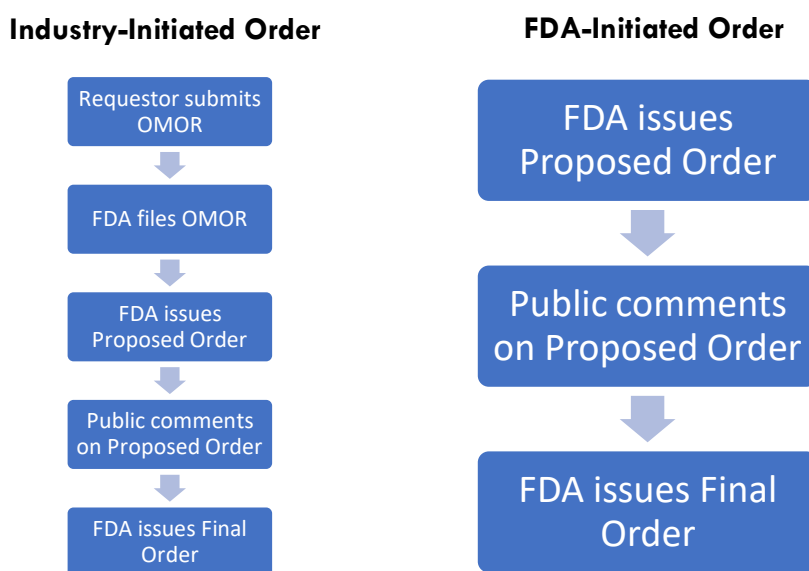


Figure 3. Steps of the OTC monograph drug-review process, as amended by the 2020 CARES Act OTC Monograph Reforms.

## 6. What does the medical community think about OTC birth control pills?

Doctors and medical associations are largely in support of over-the-counter birth control. As mentioned in this memo, the American College of Obstetricians and Gynecologists, the American Academy of Family Physicians, American Medical Association, and the American Public Health Association have all issued public statements in favour of OTC birth control. The American Medical Association (AMA) convened on 2017 Annual Meeting quoted saying “That our AMA condemn age-based, cost-based, and other non-medical barriers to contraceptive drug access; that our AMA adopt policy supporting equitable access to OTC contraception including those forms of contraception recommended for OTC sale.”

The major concerns that healthcare providers have cited with respect to OTC birth control are a potential decrease in preventative screenings, changes to the patient-

provider relationship, and loss of revenue.<sup>27</sup> There are straightforward responses to each of these concerns. In terms of preventative screenings and patient-provider relationship, the COVID-19 crisis shifted expectations around how birth-control prescriptions are issued. The majority of birth-control prescriptions are now issued through telehealth services. In many states, patients are no longer coming into the office to receive a birth-control prescription. Patients are still engaging in preventative screenings like PAP smears or STI/STD checks — these screenings have simply been decoupled from the receipt of birth control. Patients still participate in other in-person medical visits that give provider opportunities to build rapport; rapport can also be built via existing telemedicine as well. In terms of revenue, as stated by AMA, the priority of decision-making should be oriented towards equitable access to contraception and the removal of cost-based barriers. Though revenue will likely be lost for individual doctors, the greater benefits and savings that OTC birth control will provide to Americans should be seen as the priority initiative and concern.

## **7. How will doctors educate patients about birth-control pills if OTC pills are available?**

Availability of OTC birth-control pills will not preclude patients from asking their doctors about birth control during routine check-ups, telemedicine consultations, and in the course of receiving other essential healthcare services. But research indicates that consumers of all educational and socioeconomic backgrounds can successfully use a simple checklist in lieu of a doctor's consultation to determine whether birth control is an appropriate form of contraception for them.<sup>28</sup> The rise of telehealth companies in response to the COVID-19 pandemic has already begun to empower patients to request specific types of birth-control pills from their providers instead of relying on doctors to make the decision. Availability of OTC birth control may actually improve consumer knowledge of birth control by increasing public visibility. In a competitive marketplace, drug companies are more likely to launch educational campaigns targeted at a diverse range of people as a way to increase sales of their product.

## **8. How will creating OTC birth control pills affect pricing?**

All female contraceptives, including all birth-control pills, are currently covered under the Affordable Care Act (ACA). However, insurance companies are not required to cover OTC non-prescription drugs. Some fear that transitioning birth-control pills to OTC status will therefore make birth control *less* affordable and accessible for consumers. One solution to this problem is to make birth-control pills available on both a prescription and an OTC basis. A second solution, as proposed in this memo, is to pass legislation expanding the ACA to include OTC birth control.

If either or both of these solutions is put into place, OTC birth-control pills are almost certain to be less expensive than prescription-based birth-control pills. An OTC drug

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<sup>27</sup> The American College of Obstetricians and Gynecologists. (2019). Over-the-Counter Access.

<sup>28</sup> The American College of Obstetricians and Gynecologists. (2019). [Over-the-Counter Access to Hormonal Contraception](#). Committee Opinion Number 788, October.

market imposes lower regulatory burdens on companies,<sup>29</sup> provides more opportunities for companies to market their products to consumers, and provides more opportunities for companies to innovate within certain drug classes. These benefits combine to create a competitive environment that is attractive to industry and yields long-term lower costs for consumers.

## **9. Will ingredients in birth-control pills be deemed Generally Recognized as Safe and Effective (GRASE) for over-the-counter use?**

In the United States, the FDA has yet to assign GRASE status to the seven active ingredients used in most birth-control pills. Achieving GRASE status for these ingredients is an important prerequisite for an OTC monograph for birth-control pills. However, it seems likely that active ingredients in birth-control pills meet the criteria for GRASE status. These criteria are as follows:

- Criterion I. The particular drug product must have been subjected to adequate and well-controlled clinical investigations that establish the product as safe and effective.
- Criterion II. The aforementioned investigations must have been published in scientific literature available to qualified experts.
- Criterion III. Experts must agree, based on the scientific literature, that the drug product in question is safe and effective for its intended uses. At a minimum, the general acceptance of a product as GRASE must be supported by the same quality and quantity of scientific and/or clinical data necessary to support the approval of a New Drug Application.

Birth-control pills are one of the best-studied types of pharmaceuticals in the world. About 100 hormonal birth-control pills have already been approved by the FDA through the NDA process. Additionally, OTC birth-control pills show no significant toxicity level if overdosed and are not addictive.

## **10. What is the biggest health concern associated with birth-control pills?**

Combination progestin/estrogen birth-control pills can increase a user's risk of blood clots slightly. Overall, the risk is quite small — less than the increased risk of blood clots posed by pregnancy and considerably lower than the risk of blood clots women face post-partum. Progestin-only birth-control pills present no additional risk for blood clots. Birth-control also presents a slight increase risk of cervical cancer. However, it also offers several health protective effects such as reduced risk of ovarian and endometrial cancer.

## **11. How would establishing an OTC monograph for birth-control pills encourage companies to submit their pills for OTC approval?**

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<sup>29</sup> Michele, T.M. (2020). [An Exciting New Chapter in OTC Drug History: OTC Monograph Reform in the CARES Act](#). U.S. Food and Drug Administration, August 6.

Pharmaceutical companies care about risk mitigation, costs, timeframes, exclusivity, and potential revenue opportunities. The OTC monograph process addresses many of these. The OTC monograph tells companies exactly what drug formulations the FDA will accept or reject and the exact cost, timeframes, and exclusivity guidelines for companies that are first to file. As discussed above, the OTC monograph process also allows companies to make micro-innovations on products covered by the monograph. All of these benefits will likely encourage companies that produce prescription-based birth-control pills to consider using the OTC monograph process to transition to OTC.

## **12. Why should the federal government take action on this issue rather than state and local governments?**

Federal approval (via the FDA) is needed to transition drug products from prescription to OTC status. State governments can stop or limit the distribution of drug products but lack the authority to approve drugs for local distribution.

Absent widespread federal approval of OTC birth control, some state governments have taken steps to expand access to birth control. 13 states allow pharmacists to prescribe oral contraceptives, meaning that women don't have to go to the doctor for a prescription. But since the societal and economic impacts of unintended pregnancies affect all Americans, it is appropriate that expanded access to birth control be addressed at the federal level.

## **13. How would an OTC birth-control pill increase health equity?**

Unintended pregnancies disproportionately affect low-income women and women of color. The National Latina Institute for Reproductive Health reports that Latinas strongly support OTC birth-control pills because the OTC option will greatly reduce systemic barriers like poverty, immigration status, and language that currently prevent a large portion of the Latina community from obtaining birth-control pills.<sup>30</sup> Research has also shown that African-American women, Asian-American women, and young women alike prefer the convenience and privacy of getting birth-control pills OTC.<sup>31</sup> OTC birth-control pills also reduce the burden of purchase for women. When OTC birth-control pills become available, partners, family members, and other invested individuals will be able to purchase those pills just as they can already purchase emergency contraception or condoms.

## **14. What would a less ambitious — but still impactful — version of the proposal in this memo look like?**

To start gaining traction and interest, the administration could focus only on Steps 1 and 2 of the proposal in this memo — i.e., creating an OTC Drug Monograph category

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<sup>30</sup> National Latina Institute for Reproductive Justice. (2012). [Over-the-counter birth control will benefit Latina health](#). November 20.

<sup>31</sup> Baum, S.; et al. (2016). Perspectives among a Diverse Sample of Women on the Possibility of Obtaining Oral Contraceptives Over the Counter: A Qualitative Study. *Womens Health Issues*, 26(2): 147–52.

for oral contraceptives and conducting outreach to pharmaceutical companies, but temporarily setting aside the politically difficult task of expanding the ACA to include OTC birth-control pills.

Another option would be to expedite OTC approval of HRA Pharma's progestin-only birth-control pill as a starting point. Approving even a single OTC birth-control pill would set a valuable precedent for transitioning a birth-control drugs from prescription to OTC status via the NDA process. However, it is important to recognize that transitioning multiple birth-control drugs via this pathway will be much more expensive and time-consuming than establishing an OTC monograph.

A final option would be to establish an OTC monograph for progestin-only birth-control pills. This approach would involve approval of fewer active ingredients than an OTC monograph that also covers progestin/estrogen combination pills, and might also spark less concern given that progestin-only pills lack some of the risks (e.g., of blood clots) that estrogen-containing pills do. Depending on consumer demand and manufacturer interest, the monograph could be expanded over time to also cover combination pills.

## **15. Is there bipartisan agreement around use of OTC birth-control pills?**

There is widespread agreement among American women that birth control is morally acceptable and widespread use of contraception among sexually active women. In 2015–2017, 64.9% of the 72.2 million women aged 15–49 in the United States were actively using a form of contraception.<sup>32</sup> 99% of sexually active women aged 15–44 in the United States report using at least one contraceptive method during their lifetime.<sup>33</sup> Two-thirds of young Republicans agree that “every adult woman should have access to affordable, effective birth control because it gives people a chance to build families on their own terms.”<sup>34</sup>

Bipartisan support for OTC birth control extends to Congress. In 2019, Republican Senator Joni Ernst (R-IA) introduced a bill offering a way to fast-track transition of hormonal contraceptive pills from prescription to OTC status.<sup>35</sup> Democratic Representative Ayanna Pressley (D-MA) introduced a separate bill mandating insurance coverage without cost-sharing for OTC birth-control pills.<sup>36</sup> The upshot is that OTC birth control isn't controversial in and of itself—rather, the question of who should pay for it creates the most division. Interestingly, 60% of young Republicans hold a negative view of the ACA, but half of all young Republican women say they support the ACA enforcing the coverage of OTC birth control pills by insurers.<sup>34</sup>

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<sup>32</sup> Daniels, K.; Abma, J.C. (2018). [Current Contraceptive Status Among Women Aged 15–49: United States, 2015–2017](#). U.S. Centers for Disease Control and Prevention, National Center for Health Statistics. NCHS Data Brief No. 327. December.

<sup>33</sup> Daniels, K.; Mosher, W.D.; Jones, J. (2013). [Contraceptive Methods Women Have Ever Used: United States, 1982–2010](#). U.S. Centers for Disease Control and Prevention, National Center for Health Statistics. National Health Statistics Reports, Number 62. February.

<sup>34</sup> Anderson, K.S. (2015). [Young Republicans, Birth Control, and Public Policy](#). The National Campaign to Prevent Teen and Unplanned Pregnancy. March.

<sup>35</sup> [S.930 - Allowing Greater Access to Safe and Effective Contraception Act](#).

<sup>36</sup> [H.R. 3296 - Affordability is Access Act](#).

## About the Authors



**Erika Cheung** is the Executive Director of Ethics in Entrepreneurship, a non-profit organization with the mission to embed ethical questioning, culture, and systems in start-up ecosystems worldwide. Erika began her career working as a medical researcher in the biotechnology industry, and is most famously known for being a key whistle-blower reporting the medical-diagnostic company Theranos to health regulators. Erika went on to help launch a technology accelerator in Hong Kong supporting early-stage technology investments across the Asia-Pacific (APAC) region. She continues to advise and support the development of biotechnology and healthcare initiatives across the APAC region.

## About the Day One Project



The Day One Project is dedicated to democratizing the policymaking process by working with new and expert voices across the science and technology community, helping to develop actionable policies that can improve the lives of all Americans, and readying them for Day One of the next presidential term. For more about the Day One Project, visit [dayoneproject.org](https://dayoneproject.org).

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