



Dr. Robert M. Califf
c/o U.S. Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993-0002

April 4, 2022

Dear Dr. Califf:

Congratulations on your appointment as Commissioner of the Food and Drug Administration. We wish you all the best in your new job.

During your tenure, the FDA likely will be evaluating two applications to bring oral contraceptives over the counter, and we expect more to follow. Removal of unnecessary prescription barriers to oral contraception has strong support in the science and data. As leaders within the reproductive health, rights, and justice movements, we urge you to lead the FDA in fulfilling its mission to advance public health and innovation and to follow the evidence to ensure timely review and science-based decision-making that will maximize benefits.

Over-the-counter birth control pills are safe, and a common-sense, science-based approach to addressing an important health equity and reproductive justice issue facing our communities.

Over sixty years of research and data show that oral contraception is safe and effective. However, due to pervasive and systemic inequities, significant barriers to access remain for communities who bear the greatest share of these inequities: people of color, particularly Black, Latinx, AAPI, and Indigenous peoples, people who live in rural areas, those working to make ends meet, immigrants, LGBTQ+ folks, and young people. Increasing access to over-the-counter birth control would allow people to make decisions with dignity and respect – about their own bodies, lives and reproductive health and well-being, including when and whether to have children.

We urge you to continue to stand behind the scientific, evidence-based approach for FDA review and approval of drugs, including Rx-to-OTC switches, which takes the importance of benefits to people's health and wellbeing into account.¹

The potential benefits here are enormous and have been documented through decades of research and data on the benefits of birth control access for all.² Health care providers and major medical organizations have voiced their support for over-the-counter birth control pills for people of all ages. The American College of Obstetricians and Gynecologists supports over-the-counter access to hormonal contraception without age restrictions,³ and medical organizations such as the American Academy of Family Physicians support making birth control pills available over the counter as safe, effective, and beneficial to overall health and well-being.⁴ The public support reflects the benefits of access as well: seventy percent of women of reproductive age are in favor of making birth control available over the counter without a prescription.⁵

Birth control pills are one of the most widely-used and extensively studied medicines on the market today, and the research supports the safety and benefits of over-the-counter birth control pills with no age restriction.⁶ Consistent with the FDA's standards for over-the-counter status, birth control pills have: 1) no significant toxicity if overdosed, 2) the pills are non-addictive, 3) users can self-diagnose conditions for appropriate use, 4) users can safely take the medication without a clinician's screening⁷. Simply put, the pill is safe, and decades of documentation demonstrate low prevalence of contraindications for people of all ages, particularly for young people.⁸

In fact, we know that millions of young people safely use oral contraceptives every day, and for years, emergency contraception has been available over the counter to all ages without issue. Additionally, adolescents face unique barriers to contraceptive access, including lack of transportation and financial resources, needing time off from school, and fear that confidentiality

¹ Overall standards for approval of both new drugs and Rx-to-OTC switches include an assessment of the safety margin that the benefits of access outweigh the risks. See U.S. Food and Drug Administration. Development & Approval Process | Drugs. October 2019, and FDA Presentation-Regulatory Approaches for Prescription to OTC Switch, July 2015, and . Available [here](#) and [here](#) .

² Joint Economic Committee. The Economic Benefits of Birth Control and Access to Family Planning. February 2020. Available [here](#).

³ American College of Obstetricians and Gynecologists. October 2019. Over-the-Counter Access to Hormonal Contraception. Available [here](#).

⁴ American Academy of Family Physicians. Over-the-Counter Oral Contraceptives. Available [here](#).

⁵ Kaiser Family Foundation. April 2021. Women's Sexual and Reproductive Health Services: Key Findings from the 2020 KFF Women's Health Survey. Available [here](#).

⁶ Journal of Adolescent Health. October 2016. Over-the-Counter Access to Oral Contraceptives for Adolescents. 60 (217) 634-640. Available [here](#)

⁷ OCs OTC Working Group. July 2015. OCs Moving the birth control pill over the counter in the United States. Available [here](#).

⁸ Journal of Adolescent Health. October 2016. Over-the-Counter Access to Oral Contraceptives for Adolescents. 60 (217) 634-640. Available [here](#)

will be breached. These access issues could be lessened with over-the-counter access to the pill. Organizations that work directly with young people hear countless stories about the hurdles and barriers youth often face to be able to afford and access birth control. Access to over-the-counter birth control will prevent interruption in use, and will help people of all ages have healthier reproductive lives. The evidence shows that access to contraception is an important contributor to overall health and wellbeing.⁹

You have a critical opportunity to address health equity and make a positive impact on the health and wellbeing of people capable of pregnancy across the United States. We urge you to ensure timely review of applications for over-the-counter oral contraceptives, based on the data, and ensure a science- and evidence-based process that considers the long history of safety, efficacy and benefits of access to oral contraception.

Again, we congratulate you on your new role as Commissioner and appreciate your attention to this critical reproductive health care issue.

Sincerely,

Undersigned by members of the [Oral Contraceptives \(OCs\) Over-the-Counter \(OTC\) Working Group](#)

OCs OTC Working Group Steering Committee Members

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⁹ Office of Disease Prevention and Health Promotion, Office of the Assistant Secretary for Health, Office of the Secretary, U.S. Department of Health and Human Services. January 2022. Family Planning. Available [here](#).

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Contraceptive Access Initiative (CAI)
Essential Access Health
Healthy Teen Network
Ibis Reproductive Health
Illinois Caucus for Adolescent Health (ICAH)
ICAN - IL Contraceptive Access Now
Indigenous Women Rising
In Our Own Voice: National Black Women's Reproductive Justice Agenda
Ipas
Jacobs Institute of Women's Health
Jane's Due Process
Legal Voice
Michigan Organization on Adolescent Sexual Health (MOASH)
NARAL Pro-Choice America
National Association of Nurse Practitioners in Women's Health (NPWH)
National Center for Lesbian Rights
National Family Planning & Reproductive Health Association
National Health Law Program
National Organization for Women
National Women's Health Network
Nurses for Sexual & Reproductive Health
NY Birth Control Access Project
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Additional Supporters

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