

Congress of the United States
Washington D.C. 20515

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

March 7, 2022

Dear Dr. Califf:

Congratulations on your appointment as Commissioner of Food and Drugs. We look forward to working with you in your new role.

As you may know, over-the-counter oral contraceptives (OCs) will be a key issue on FDA's agenda this year. You are taking the helm at a time when FDA is evaluating two oral contraceptive products seeking over-the-counter status. As Members of Congress who have long been leaders on reproductive rights and justice issues, we ask for your ongoing commitment to advance public health and follow the science and data in all decisions, including the timely review of the oral contraception applications and the evidence regarding its safety and efficacy.

This is a critical issue for reproductive health, rights, and justice. Despite decades of proven safety and effectiveness, people still face immense barriers to getting birth control due to systemic inequities in our healthcare system. These barriers are disproportionately borne by people of color, immigrants, LGBTQ+ people, low-income individuals, young people, and people in rural communities – individuals who have faced and continue to face the greatest inequities. FDA has an important role to play in removing unnecessary barriers to provide individuals greater control over their reproductive lives and health.

Birth control pills are one of the most studied medicines on the market today and they meet FDA's standards for over-the-counter statusⁱ. Additionally, evidence supports the safety and benefits of over-the-counter birth control pills with no age restriction, and adolescent sexual and reproductive health experts support access for people of all ages.ⁱⁱ The pill is safe: the prevalence of contraindications is low for all people, and in many cases, lower for young people.

Over-the-counter birth control pills are widely supported by health care providers and the general public for all people of reproductive age. The American College of Obstetricians and Gynecologists supports over-the-counter access to hormonal contraception without age restrictionsⁱⁱⁱ. Medical organizations including 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.^{iv} There is broad public support as well – 70% of women of reproductive age are in favor of making birth control available over the counter without a prescription.^v

This year poses a significant opportunity to ensure that FDA prioritizes science over politics, particularly when it comes to reproductive health. We were encouraged to hear your commitment to following the science during your December 14, 2021 hearing in the Senate HELP Committee. We urge FDA to review applications for over-the-counter birth control pills without delay and based solely on the data and defend against political interference during the review processes. The health and well-being of people capable of pregnancy across America is at stake.

Again, we congratulate you on your new role as Commissioner and look forward to working with you on this critical issue.

Sincerely,



Barbara Lee
Member of Congress
Co-Chair, Pro-Choice Caucus



Diana DeGette
Member of Congress
Co-Chair, Pro-Choice Caucus



Ayanna Pressley
Member of Congress



Judy Chu
Member of Congress

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Jake Auchincloss
Member of Congress

_____/s/_____

Nanette Diaz Barragán
Member of Congress

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Karen Bass
Member of Congress

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Suzanne Bonamici
Member of Congress

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Julia Brownley
Member of Congress

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Salud Carbajal
Member of Congress

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Katherine Clark
Member of Congress

_____/s/_____

Yvette D. Clarke
Member of Congress

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Steve Cohen
Member of Congress

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Gerald E. Connolly
Member of Congress

_____/s/_____
Rosa L. DeLauro
Member of Congress

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Mark DeSaulnier
Member of Congress

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Lizzie Fletcher
Member of Congress

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Lois Frankel
Member of Congress

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Kaiiali'i Kahele
Member of Congress

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Daniel T. Kildee
Member of Congress

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Ann Kirkpatrick
Member of Congress

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Brenda Lawrence
Member of Congress

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Carolyn B. Maloney
Member of Congress

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Betty McCollum
Member of Congress

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Grace Meng
Member of Congress

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Marie Newman
Member of Congress

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Chris Pappas
Member of Congress

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Suzan DelBene
Member of Congress

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Adriano Espaillat
Member of Congress

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Bill Foster
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Jimmy Gomez
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Ro Khanna
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Derek Kilmer
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Rick Larsen
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Andy Levin
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Kathy Manning
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James P. McGovern
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Gwen Moore
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Eleanor Holmes Norton
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Ed Perlmutter
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Chellie Pingree
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Katie Porter
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Deborah K. Ross
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Jan Schakowsky
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Jackie Speier
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Mark Pocan
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Jamie Raskin
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Mary Gay Scanlon
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Adam B. Schiff
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Albio Sires
Member of Congress

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Marilyn Strickland
Member of Congress

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David Trone
Member of Congress

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Debbie Wasserman Schultz
Member of Congress

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Nikema Williams
Member of Congress

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

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

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

^{iv} American Academy of Family Physicians. Over-the-Counter Oral Contraceptives. Available [here](#).

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