

September 8, 2021

The Honorable Janet Woodcock
Acting Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993-0002

Dear Acting Commissioner Janet Woodcock:

We write as public health professionals, scientists, social justice advocates, business leaders, and members of civil society to urge the Food and Drug Administration (FDA) to prioritize the completion of the review process to make already common and safe formulations of oral contraceptives available over-the-counter (OTC). The evidence of the benefits of OTC availability is strong, and the public health and medical community urges the FDA to follow the science and approve an OTC oral contraceptive.

The FDA's mandate to protect public health by ensuring the safety, efficacy and security of human drugs is critical. In the case of OTC medications, the FDA's Center for Drug Evaluation and Research (CDER) evaluates if a drug's benefits outweigh the risks, assures proper labeling, and assesses if OTC drugs are safe and effective for the general public without seeking treatment by a health professional. At least two pharmaceutical companies are currently in discussions with the FDA about applications to switch existing formulations to OTC status.

[Oral contraceptives meet the accepted medical and regulatory criteria for OTC access.](#)

They have a [strong, proven safety record](#) after 60 years in the marketplace, and are [widely available OTC outside of the U.S.](#) Studies of oral contraceptives demonstrate a strong safety profile that compares favorably – and in some cases, it could be argued, better – to many medications already available OTC in the U.S. Research also shows that women can understand how to properly take oral contraceptives and [screen for potential risks on their own](#), just as they do for pain medications, allergy medications, and even the cold medications they give their children.

Leading U.S. medical associations endorse the availability of an OTC oral contraceptive. They include the [American Academy of Family Physicians](#) and the American College of Obstetricians and Gynecologists (ACOG) Committee on Gynecologic Practice; the latter [supports an OTC oral contraceptive](#) “without age restrictions.” Their positions align with the [WHO's Consolidated Guideline on Self-Care Interventions for Health, and its recommendation](#) that governments expand availability of contraceptive methods through places other than healthcare facilities, “with or without prescription.” More than 100 organizations, including 19 health care provider professional associations, have indicated their support of OTC access to oral contraceptives by signing on to the [Oral Contraceptives OTC Working Group's Statement of Purpose](#).

The Centers for Disease Control and Prevention (CDC) identified family planning as one of the [10 great public health achievements](#) of the 20th century. A [new CDC analysis](#) shows that nearly a third of women of child-bearing age in the U.S. did not always use contraceptives during sexual encounters, and it was often due to gaps in access to effective birth control. Access to contraception is critical for people to exercise their rights to bodily autonomy and sexual and reproductive health. Correct and consistent contraceptive use dramatically reduces unintended and teen pregnancy and can help to improve health and social outcomes. A series of studies by the CDC, Guttmacher Institute, and Columbia University have demonstrated that teen pregnancy

rates in the U.S. have declined dramatically since 1991, primarily because of improved contraceptive use. Still, [nearly half](#) of all pregnancies in the U.S. are unintended, with the highest rates among adolescents and young adults, underserved racial and ethnic groups, and women with lower income and education levels. Unintended pregnancy resulting from unmet contraception needs [increases the risk](#) for negative maternal and infant outcomes and creates a significant socioeconomic burden to families, health systems, and society.

A vast body of scientific evidence from more than three decades supports that women and families have better health and quality of life when contraception is made more easily accessible. In recent years, the practice of providing [more oral contraceptive packs at a time](#) to women has been shown to be associated with increased continuation of pill use, and decreases in pregnancy test use, pregnancies, and cost per client.

OTC access to oral contraceptives is critical for people of all demographic groups, including adolescents and young adults. Requiring a prescription for oral contraceptives is a significant obstacle for young people to access the care that they need and want. Young people should have the resources they need to take care of their health and plan their futures, including access to all current and any future FDA-approved OTC birth control pills. Research shows that there is [no scientific basis](#) for imposing an age restriction on birth control pills available over the counter—oral contraceptives are safe and highly effective for adolescents and contraindications are rarer among this age group compared to adult women. Research also shows that increasing access to birth control does not lead to more frequent sexual activity. Furthermore, experts on adolescent health support OTC access to birth control pills including the American Academy of Pediatrics, American Medical Association, and the Society for Adolescent Health and Medicine. Ensuring young people have equal access to OTC birth control pills would not only give them more options to prevent unintended pregnancy, but also greater control over their sexual and reproductive health and lives.

Increased access to effective and preferred contraceptive methods is especially critical in the wake of the COVID-19 pandemic. [National survey data](#) from 2020 show that one in three women of reproductive age in the U.S. had to delay or cancel a reproductive health visit or had trouble accessing family planning services and methods because of the pandemic; [27 percent](#) of women worry more than before about affording or obtaining contraceptives. These negative impacts adversely affected people at greatest risk for reduced access to quality timely care, effective methods, and worse outcomes: Black, Indigenous, Latinx, AAPI, and other people of color, as well as LGBTQI, gender-expansive and gender non-binary folks, and people working to make ends meet.

Evidence-based advocacy and policy efforts including those from professional medical and scientific groups, [those most likely to use OTC oral contraceptives](#), and the public at large support making oral contraceptives available over the counter: 70% of reproductive-aged women [agree that policy-makers and regulatory bodies should ensure oral contraceptives be made available](#) for over-the-counter access.

The FDA has a unique opportunity to champion an imperative advancement in sexual and reproductive health and well-being at a critical time, coming on the heels of the detrimental impact of the pandemic. We urge the agency to prioritize following the evidence and medical consensus and move forward with this long overdue initiative.

Sincerely,

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