

May 8, 2023

Dockets Management Staff (HFA-305)
Food and Drug Administration
U.S. Department of Health and Human Services

Re: Joint Meeting of the Nonprescription Drugs Advisory Committee and the Obstetrics, Reproductive and Urologic Drugs Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments (Docket No. FDA-2022-N-1959)

The Jacobs Institute of Women's Health at The George Washington University Milken Institute School of Public Health appreciates the opportunity to comment on the Joint Meeting of the Nonprescription Drugs Advisory Committee and the Obstetrics, Reproductive and Urologic Drugs Advisory Committee as the advisory committees consider HRA Pharma's application for Opill to be made available over the counter. We write to register our strong support for this application.

The mission of Jacobs Institute of Women's Health is to identify and study aspects of healthcare and public health, including legal and policy issues, that affect women's health at different life stages; to foster awareness of and facilitate dialogue around issues that affect women's health; and to promote interdisciplinary research, coordination, and information dissemination, including publishing the peer-reviewed journal *Women's Health Issues*. We represent an interdisciplinary group of affiliated faculty members who are experts in research, health policy, and medical care related to women's health.

Research shows that women with access to contraception are more likely achieve their preferred family size and spacing,¹ attain higher levels of education,² and earn higher wages.³ However, access to contraception is uneven, and those with low incomes – who, because of structural racism, are disproportionately likely to be Black – are disproportionately likely to face barriers.⁴ Adolescents and

¹ Kavanaugh ML & Anderson RM. (2013). Contraception and Beyond: The Health Benefits of Services Provided at Family Planning Centers. Guttmacher Institute. <https://www.guttmacher.org/sites/default/files/pdfs/pubs/health-benefits.pdf>

² Yeatman S, Flynn JM, Stevenson A, Genadek K, Mollborn S, & Menken J. (2022). Expanded Contraceptive Access Linked to Increase in College Completion among Women in Colorado. *Health Affairs*, 41(12):1754-1762. <https://pubmed.ncbi.nlm.nih.gov/36469823/>

³ Bailey MJ. (2006). More Power to the Pill: The Impact of Contraceptive Freedom on Women's Life Cycle Labor Supply. *The Quarterly Journal of Economics*, 121(1):289-320. <https://academic.oup.com/qje/article-abstract/121/1/289/1849021>

⁴ Kavanaugh ML, Pliskin E, & Hussain R. (2022). Associations between unfulfilled contraceptive preferences due to cost and low-income patients' access to and experiences of contraceptive care in the United States, 2015-2019. *Contraception*, <https://doi.org/10.1016/j.conx.2022.100076>

young people are another critical vulnerable group, and even young people who have access to no-cost contraception from school-based or community health clinics have reported having unprotected sex because of barriers such as having a hard time reaching the clinic.⁵ Making another effective form of contraception available without a prescription will increase options for people who face barriers to obtaining prescription methods, and thereby reduce current disparities in access. A recent survey with a Black, Indigenous, and people of color (BIPOC) sample found that those who experienced challenges to accessing contraception in the past were more likely than those who did not experience such challenges to indicate that they would use an over-the-counter oral contraceptive.⁶

The safety and efficacy of Opill are already well established, and there is also compelling evidence that it is appropriate for over-the-counter distribution. Only a small proportion of reproductive-aged women (1.6% in a recent study) have contraindications to progestin-only pills, and women can accurately self-screen for these contraindications.⁷ Women and other pregnancy-capable individuals have also shown high comprehension of nearly all clinical safety and efficacy messages provided on a prototype label for a combined oral contraceptive; in a study of pregnancy-capable individuals aged 12-49 that tested comprehension of 11 of these messages, 95% of participants understood 10 of the messages, and 89% understood the other one.⁸ Among participants in a progestin-only pill trial, 83% reported likelihood of future use, and those likely to use the progestin-only pill in the future were more likely to be Hispanic/Latinx and Black and have public insurance.⁹

Given the substantial benefits of over-the-counter availability of hormonal contraception and the evidence of label comprehension and suitability for most of the pregnancy-capable population, the Jacobs Institute of Women's Health supports HRA Pharma's application for over-the-counter distribution of Opill.

Thank you for this opportunity to comment for this docket. If you have any questions, please contact Jacobs Institute managing director Liz Borkowski at 202-994-0034 or borkowsk@gwu.edu.

⁵ Nathan SF, Berglas NF, Kaller S, Mays A, & Biggs MA. (2023). Reasons for Having Unprotected Sex Among Adolescents and Young Adults Accessing Reproductive Health Services. *Women's Health Issues*. <https://doi.org/10.1016/j.whi.2022.11.006>

⁶ Key K, Wollum A ... Baum SE. (2023). Challenges accessing contraceptive care and interest in over-the-counter oral contraceptive pill use among Black, Indigenous, and people of color: An online cross-sectional survey. *Contraception*. <https://doi.org/10.1016/j.contraception.2023.109950>

⁷ White K, Potter JE, Hopkins K, Fernández L, Amastae J, & Grossman D. Contraindications to progestin-only oral contraceptive pills among reproductive-aged women. *Contraception*, 86(3):199-203.

⁸ Grindlay K, Key K, Bradford RD, Amato C, Blanchard K, & Grossman D. (2022). Perspectives on Sexual and Reproductive Health. <https://doi.org/10.1363/psrh.12214>

⁹ Grindlay K, Key K, Zuniga C, Wollum A, Blanchard K, & Grossman D. (2022). Interest in Continued Use After Participation in a Study of Over-the-Counter Progestin-Only Pills in the United States. *Women's Health Reports*. <https://doi.org/10.1089/whr.2022.0056>

