



State of California
Office of the Attorney General

ROB BONTA
ATTORNEY GENERAL

November 3, 2022

Via Federal eRulemaking Portal

Robert M. Califf, M.D.
Commissioner of Food and Drugs
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-002

RE: Over the Counter Approval of Opill/ 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.

Dear Dr. Califf:

As the Attorneys General of the States of California, Colorado, Connecticut, Hawai'i, Illinois, Iowa, Maine, Maryland, Massachusetts, Minnesota, Michigan, Nevada, New Jersey, New Mexico, New York, North Carolina, Oregon, Pennsylvania, Rhode Island, Vermont, and Washington we write in response to the pending application from HRA Pharma, SA to make Opill the first birth control pill available over-the-counter (OTC), i.e., without a prescription. We urge the Food and Drug Administration (FDA) to approve OTC birth control bills that meet applicable safety and efficacy standards, which will improve access to birth control for millions of people in in this country. Now, more than ever, ensuring access to birth control is crucial.

A. Access to Birth Control Confers Significant Benefits

The benefits of using birth control are universal. As the American College of Obstetricians and Gynecologists explained, the benefits of birth control “are widely recognized and include improved health and well-being, reduced global maternal mortality, health benefits of pregnancy spacing for maternal and child health, female engagement in the workforce, and economic

self-sufficiency for women.”¹ Stated differently, birth control allows people to time and space their pregnancies, affording them greater control over their life choices, such as to pursue educational and work opportunities.² Further, studies show that access to birth control before the age of 21 significantly reduces the probability that a woman will subsequently experience poverty, reduces the likelihood of a first birth before 22, increases the number of women in the paid labor force, and raises the number of annual hours worked.³ And the children of women who have access to birth control are less likely to live in poverty and more likely to have higher education attainment.⁴

Given these benefits, it is no surprise that 99% of U.S. women who have been sexually active report having used some form of birth control and nearly 72% of U.S. women use more than one type of birth control in their lifetime.⁵

One of the most obvious benefits of birth control is the ability to avoid an unintended pregnancy, which has many risks and potentially adverse health outcomes. Sadly, the United States is the “the most dangerous wealthy country in which to give birth,” especially for racial minorities, low-income women, and women living in rural locations.⁶ In fact, a recent report

¹ *Access to Contraception*, Am. College of Obstetricians and Gynecologists (ACOG), Committee on Health Care for Underserved Women (Jan. 2015), <https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2015/01/access-to-contraception> (reaffirmed 2022).

² Adam Sonfield, et al., *The Social and Economic Benefits of Women’s Ability to Determine Whether and When to Have Children*, Guttmacher Inst. (March 2013), <https://www.guttmacher.org/report/social-and-economic-benefits-womens-ability-determine-whether-and-when-have-children>.

³ *The Economic Benefits of Birth Control and Access to Family Planning*, Joint Economic Committee, House of Representatives (Feb. 2020), https://www.jec.senate.gov/public/_cache/files/bb400414-8dee-4e39-abd3-c2460fd30e7d/the-economic-benefits-of-birth-control-and-access-to-family-planning.pdf (citing Stephanie P. Browne & Sara LaLumia, *The effects of contraception on female poverty*, J. of Policy Analysis and Management (2014), http://lanfiles.williams.edu/~sl2/Browne_LaLumia_ELA.pdf and Martha J. Bailey, *More power to the pill: the impact of contraceptive freedom on women’s life cycle labor supply*, 121 Quarterly J. Econ. 289-320 (2006), <https://www.jstor.org/stable/pdf/25098791.pdf>).

⁴ *Id.* (citing Martha J. Bailey, Olga Malkova, & Johannes Norling, *Do family planning programs decrease poverty? Evidence from public census data*, 60 CESifo economic studies 312-37 (2014), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4206087/>; see also Martha J. Bailey, *Fifty years of family planning: new evidence on the long-run effects of increasing access to contraception*, National Bureau of Economic Research (2013), https://www.brookings.edu/wp-content/uploads/2016/07/2013a_bailey.pdf).

⁵ *Access to Contraception*, ACOG, *supra* n. 1; Brittini Frederiksen, et al., *Women’s Sexual and Reproductive Health Services: Key Findings from the 2020 KFF Women’s Health Survey*, Kaiser Family Foundation (Apr. 21, 2021), <https://www.kff.org/womens-health-policy/issue-brief/womens-sexual-and-reproductive-health-services-key-findings-from-the-2020-kff-womens-health-survey/>.

⁶ Claire Suddath, *A Very Dangerous Place to Be Pregnant Is Getting Even Scarier*, Bloomberg (Aug. 4, 2022), <https://www.bloomberg.com/news/features/2022-08-04/texas-pregnancy-care-worsens-as-maternity-wards-close?leadSource=uverify%20wall>; Christine Dehlendorf, et al., *Disparities in Family*

found that maternity care is decreasing, affecting nearly 7 million people and creating maternal care deserts.⁷ Pregnant people in such deserts face an even higher risk of poor health outcomes. In 2020, roughly 900 women died of pregnancy-related causes and two-thirds of such deaths are preventable.⁸

Denying a person a wanted abortion may have negative developmental and socioeconomic consequences for that person's existing children, including higher levels of depression and anxiety and a decline in psychological well-being.⁹ Further, those with unintended pregnancies are more likely to experience serious complications from the end of pregnancy including eclampsia, more likely to stay tethered to abusive partners, more likely to suffer anxiety and loss of self-esteem in the short term, less likely to have aspirational life plans for the coming year, and more likely to experience poor physical health for the years after the pregnancy.¹⁰ And many risks and adverse health outcomes associated with unintended pregnancy attach to the children born of those pregnancies, including an increased likelihood of preterm birth and low birth weight.¹¹ Further, an unintended pregnancy negatively impacts the individual's existing children, with a study finding that the existing children had lower mean child development scores and were more likely to live in poverty.¹²

Planning, 202 Am. J. Obstetrics & Gynecology 214-20 (Mar. 2010), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2835625/> (explaining that minority and low-income women are at a greater risk of facing barriers to family planning services and of unintended pregnancy).

⁷ Rachel Treisman, *Millions of Americans are Losing Access to Maternal Care*, NPR (Oct. 12, 2022), <https://www.npr.org/2022/10/12/1128335563/maternity-care-deserts-march-of-dimes-report>.

⁸ *Id.*

⁹ Pamela Herd, et al., *The Implications of Unintended Pregnancies for Mental Health in Later Life*, 106 Am. J. Public Health 421-29 (Mar. 2016), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4815713/>.

¹⁰ Diana Foster, et al., *The Turnaway Study*, Advancing New Standards in Reproductive Health (ANSIRH), University of California San Francisco (2020), <https://www.ansirh.org/research/ongoing/turnaway-study>.

¹¹ Joan Rosen Bloch et al., *Pregnancy Intention and Contraceptive Use at Six Months Postpartum Among Women With Recent Preterm Delivery*, 41 J. Obstetric, Gynecologic & Neonatal Nursing 389-97 (May 2012) <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3409429/> (“Adverse outcomes associated with unintended pregnancy include child health and development issues, relationship instability, and low birth weight and prematurity.”).

¹² Diana Greene Foster, et al., *Effects of Carrying an Unwanted Pregnancy to Term on Women's Existing Children*, J. of Pediatrics (Oct. 30, 2018), [https://www.jpeds.com/article/S0022-3476\(18\)31297-6/fulltext](https://www.jpeds.com/article/S0022-3476(18)31297-6/fulltext).

Access to OTC birth control is more important than ever.¹³ Since the Supreme Court's decision in *Dobbs v. Jackson Women's Health Organization*, No. 19-1392, 597 U.S. ____ (2022), uncertainty surrounding reproductive healthcare has caused great confusion and created dangerous situations for pregnant people.¹⁴ For instance, determinations of when an abortion is allowed under certain state laws has "become fraught with uncertainty and legal risk," forcing doctors to "significantly alter the care they provide to women whose pregnancy complications put them at high risk of harm."¹⁵ However, any failure to provide, or delays in providing, necessary abortion care puts the pregnant patient's life or health at risk.¹⁶ In the aftermath of the *Dobbs* decision, even the ability to access birth control has been fraught with uncertainty, resulting in reduced access to family planning and healthcare.¹⁷

B. Many People Face Barriers to Obtaining Birth Control

The barriers to obtaining birth control would be vastly diminished through access to OTC birth control. One-third of adult U.S. women who have ever tried to obtain prescription contraception reported access barriers.¹⁸ These barriers include challenges in getting an appointment or getting to a clinic, required clinic visits, time required for clinic visits, restrictions on the number of packs of prescription contraception purchased monthly, and the

¹³ Caroline Kitchener & Susan Svrluga, *U. of Idaho may stop providing birth control under new abortion law*, Wash. Post (Sept. 26, 2022), <https://www.washingtonpost.com/politics/2022/09/26/u-idaho-may-stop-providing-birth-control-under-new-abortion-law/>.

¹⁴ Frances Stead Sellers & Fenit Nirappil, *Confusion post-Roe spurs delays, denials for some lifesaving pregnancy care*, Wash. Post (July 16, 2022), <https://www.washingtonpost.com/health/2022/07/16/abortion-miscarriage-ectopic-pregnancy-care/>; see also *State of Texas, et al. v. Xavier Becerra, et al.*, No. 5:22-cv-185 (N.D. Tex.); *United States of America v. The State of Idaho*, No. 1:22-cv-00329 (D. Idaho).

¹⁵ J. David Goodman & Azeen Ghorayshi, *Women Face Risks as Doctors Struggle With Medical Exceptions on Abortion*, N.Y. Times (Jul. 20, 2022), <https://www.nytimes.com/2022/07/20/us/abortion-save-mothers-life.html>.

¹⁶ See, e.g., Reuters Fact Check, *Fact Check-Termination of pregnancy can be necessary to save a woman's life, experts say*, Reuters (Dec. 27, 2021), <https://www.reuters.com/article/factcheck-abortion-false/fact-check-termination-of-pregnancy-can-be-necessary-to-save-a-womans-life-experts-say-idUSL1N2TC0VD> (discussing, for example, that placental abruption presents a risk of hemorrhage, which left untreated, threatens the pregnant women's life and that preeclampsia if not treated quickly can result in the pregnant person's death); *Facts Are Important: Understanding Ectopic Pregnancy*, ACOG, <https://www.acog.org/advocacy/facts-are-important/understanding-ectopic-pregnancy> (2022) (advising that "[a]n untreated ectopic pregnancy is life threatening; withholding or delaying treatment can lead to death").

¹⁷ Oriana Gonzalez, *Post-Dobbs birth control fight heads to college campuses*, Axios (Oct. 2, 2022), <https://www.axios.com/2022/09/30/dobbs-ro-abortion-university-birth-control>.

¹⁸ Kate Grindlay & Daniel Grossman, *Prescription Birth Control Access Among U.S. Women at Risk of Unintended Pregnancy*, 25 J. Womens Health 249-54 (Mar. 2016), <https://pubmed.ncbi.nlm.nih.gov/26666711/>.

limited time frame for purchase before the prescription expired deterred consistent use.¹⁹ Further, one-third of birth control users say they have missed taking their birth control because they were unable to get their next supply in time.²⁰

Transgender and gender nonbinary individuals face unique barriers in accessing reproductive health care, including birth control. They are more likely to be uninsured, experience discrimination and mistreatment in health care settings, and have providers refuse care.²¹ These barriers are compounded by the gendered environments where sexual and reproductive care are provided, including care related to contraception and pregnancy.²²

All of these barriers would be reduced, or eliminated, if the FDA were to make safe, effective birth control available OTC. In fact, studies have already shown that allowing birth control pills to be available OTC would increase the use of contraception, resulting in up to a 25% decrease in the number of unintended pregnancies.²³

C. Consumers Have Been Safely Using Birth Control for Decades

Birth control pills have been used safely for decades. For example, Opill, a progestin-only pill, has been used in the United States since it was FDA-approved for prescription use in 1973.²⁴ Birth control pills are the most popular non-permanent birth control method in the United States.²⁵ Nearly 37% of all women ages 18-49 have used the birth control pill in last year, with few side-effects, most of which are mild.²⁶

The nation's major medical associations agree that birth control pills should be available OTC. According to the American College of Obstetricians and Gynecologists, OTC access to

¹⁹ Amanda Dennis & Daniel Grossman, *Barriers to contraception and interest in over-the-counter access among low-income women: a qualitative study*, 44 *Perspectives Sexual & Reprod. Health* 84-91 (Mar. 2012).

²⁰ Fredricksen, et al., *Women's Sexual and Reproductive Health Services: Key Findings from the 2020 KFF Women's Health Survey*, *supra* n. 5.

²¹ Moseson, et al., *The Imperative for Transgender and Gender Nonbinary Inclusion: Beyond Women's Health*. *Obstet Gynecol.* 135(5) 1059-1068 (May 2020), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7170432/>.

²² *Id.*

²³ *Id.*; Diana G. Foster et al., *Potential public sector cost-savings from over-the-counter access to oral contraceptives*, 91 *Contraception* 373-79 (May 2015), <https://pubmed.ncbi.nlm.nih.gov/25732570/>.

²⁴ *FDA Receives First Application for Over-The-Counter Birth Control Pill*, Kaiser Health News (July 11, 2022) <https://khn.org/morning-breakout/fda-receives-first-application-for-over-the-counter-birth-control-pill/>.

²⁵ *Contraceptive Use in the United States by Method*, Guttmacher Institute (May 2021) <https://www.guttmacher.org/fact-sheet/contraceptive-method-use-united-states>.

²⁶ Fredricksen, et al., *Women's Sexual and Reproductive Health Services: Key Findings from the 2020 KFF Women's Health Survey*, *supra* n. 5; Danielle Cooper et al., *Oral Contraceptive Pills*, StatPearls (May 2022), <https://www.ncbi.nlm.nih.gov/books/NBK430882/>.

progestin-only birth control pills is “generally safe.”²⁷ Likewise, the American Medical Association explained that providing patients with OTC access to birth control was an “easy call,” particularly given that “the health risks of pregnancy vastly outweigh those of oral contraceptive use.”²⁸ The American Association of Family Physicians also voiced its support for OTC access, explaining that birth control pills are “widely considered to be safe and effective medications.”²⁹

No examinations or tests are needed before starting progestin-only pills.³⁰ Studies show that progestin-only birth control carries no or minimal risk of blood clots.³¹ And very few women will have contraindications to progestin-only birth control.³² Moreover, women are able to self-screen for these contraindications, as they do with other OTC medications. Indeed, studies show that women are more likely to report contraindications than health care providers.³³ Finally, studies show that most women would still obtain reproductive health preventative screenings from medical providers if birth control pills were made available OTC.³⁴

In a time when reproductive rights have been curtailed across the country, we urge the FDA to take this step to provide expanded access to birth control—an essential medication that ensures that people across this country can achieve meaningful autonomy over their futures and their lives. The Attorneys General of California, Colorado, Connecticut, Hawai’i, Illinois, Iowa,

²⁷ *Over-the-Counter Access to Hormonal Contraception*, ACOG (Oct. 2019) <https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2019/10/over-the-counter-access-to-hormonal-contraception>

²⁸ *AMA urges FDA to make oral contraceptive available Over-the-Counter*, Am. Med. Ass’n (June 15, 2022), <https://www.ama-assn.org/press-center/press-releases/ama-urges-fda-make-oral-contraceptive-available-over-counter>.

²⁹ *Over-the-Counter Oral Contraceptives*, Am. Acad. Fam. Physicians (2019), <https://www.aafp.org/about/policies/all/otc-oral-contraceptives.html#:~:text=The%20AAFP%20supports%20over%2Dthe,methods%20approved%20by%20the%20FDA.>

³⁰ *Progestin Only Pills*, Centers for Disease Control and Prevention (Feb. 1, 2017), <https://www.cdc.gov/reproductivehealth/contraception/mmwr/spr/progestin.html>.

³¹ *Over-the-Counter Access to Hormonal Contraception*, *supra* n. 27.

³² *Id.*

³³ *Id.*

³⁴ Kristine Hopkins et al., *Reproductive health preventive screening among clinic vs. over-the-counter oral contraceptive users*, 86 *Contraception* 376-82 (Oct. 2012), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4418512/>.

Robert M. Califf, M.D.

November 3, 2022

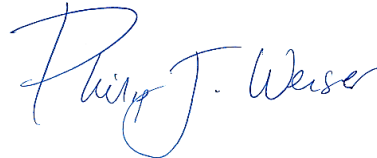
Page 7

Maine, Maryland, Massachusetts, Minnesota, Michigan, Nevada, New Jersey, New Mexico, New York, North Carolina, Oregon, Pennsylvania, Rhode Island, Vermont, and Washington urge the FDA to make birth control pills that meet applicable safety and efficacy standards available OTC.

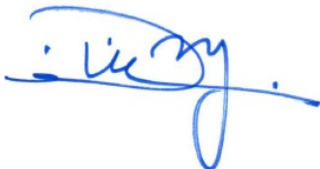
Sincerely,



ROB BONTA
California Attorney General



PHILIP J. WEISER
Colorado Attorney General




WILLIAM TONG
Connecticut Attorney General



HOLLY T. SHIKADA
Hawaii Attorney General



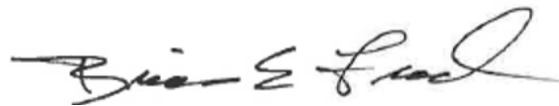
KWAME RAOUL
Illinois Attorney General



TOM MILLER
Iowa Attorney General



AARON M. FREY
Maine Attorney General



BRIAN E. FROSH
Maryland Attorney General



MAURA HEALY
Massachusetts Attorney General



KEITH ELLISON
Minnesota Attorney General



DANA NESSEL
Michigan Attorney General



AARON D. FORD
Nevada Attorney General



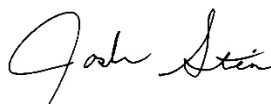
MATTHEW J. PLATKIN
New Jersey Attorney General



HECTOR BALDERAS
New Mexico Attorney General



LETITIA JAMES
New York Attorney General



JOSH STEIN
North Carolina Attorney General



ELLEN F. ROSENBLUM
Oregon Attorney General



JOSH SHAPIRO
Pennsylvania Attorney General



PETER F. NERONHA
Rhode Island Attorney General



SUSANNE R. YOUNG
Vermont Attorney General



BOB FERGUSON
Washington Attorney General