Exhibit K

The American College of Obstetricians and Gynecologists
WOMEN'S HEALTH CARE PHYSICIANS

October 6, 2021

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

Re: U.S. Food and Drug Administration's review of the risk evaluation and mitigation strategy for mifepristone

Dear Acting Commissioner Woodcock:

On behalf of the American College of Obstetricians and Gynecologists (ACOG), representing more than 60,000 physicians and partners dedicated to advancing women's health, we write to express our strong support for the review of the risk evaluation and mitigation strategy (REMS) for mifepristone currently underway at the U.S. Food and Drug Administration (FDA). ACOG supports efforts to improve access to quality women's health care and, given the decades of research and data reinforcing the safety of this medication, urges the FDA to remove the REMS and Elements to Assure Safe Use (ETASU) requirements for mifepristone.

Mifepristone has been used by over 3 million women in the United States since FDA approval in 2000 and robust evidence exists regarding the safety of mifepristone for medication-induced abortion.[1,2,3,4*] The REMS and ETASU requirements for mifepristone are inconsistent with those for other medications with similar safety profiles, and create barriers to access without demonstrated improvements to patient safety or outcomes. These medically unnecessary requirements restricting access to mifepristone interfere with the ability of obstetrician–gynecologists and other health care professionals to deliver the highest quality care for their patients. In addition to being supported by researchers, clinicians, and more than twenty years of data, removing the REMS and ETASU requirements for mifepristone is consistent with FDA's mission to ensure the safety and efficacy of medications and help "…the public get the accurate and science-based information they need to use medical products…"[5]

ACOG is the premier professional membership organization for obstetrician-gynecologists and produces practice guidelines for women's health clinicians based on the best available science and evidence. As referenced in ACOG Practice Bulletin 225, *Medication Abortion Up to 70 Days of Gestation*, medication abortion is a safe and effective method of providing abortion. The REMS restrictions for mifepristone do not make care safer, are not based on medical evidence or need, and create barriers to patient access to medication abortion.[6, 7, 8] Abortion is an essential component of comprehensive health care and is a time-sensitive service for which a delay of several weeks, or in some cases days, may increase the risks or

[*] Recent evidence also supports the use of mifepristone to improve the safe and effective medical management of early pregnancy loss.
See Schreiber CA, Creinin MD, Atrio J, Sonalkar S, Ratcliffe SJ, Barnhart KT. Mifepristone pretreatment for the medical management of early pregnancy loss. N Engl J Med 2018;378:2161-70. Available at: https://www.nejm.org/doi/full/10.1056/NEJMoa1715726. Retrieved July 9, 2018; and
Westhoff CL. A Better medical regimen for the management of miscarriage. N Engl J Med 2018;378:2232-3. Available at: https://www.nejm.org/doi/full/10.1056/NEJMe1803491. Retrieved July 9, 2018.

potentially make it completely inaccessible.[9] Furthermore, research conducted during the COVID-19 pandemic, when enforcement of the in-person dispensing requirement for mifepristone was suspended, demonstrates the safety of providing abortion through telehealth contact and mailed medications.[10,11] Additionally, recent data suggests that patients offered telemedicine with mailed medications had abortions earlier than those without this option.[12] Removing the REMS and ETASU on mifepristone will improve access to medication-induced abortion and enhance patient care.

ACOG is pleased that the FDA is conducting a thorough review of the REMS restrictions for mifepristone and urges the FDA to remove the medically unnecessary REMS and ETASU restrictions that hinder access to medication abortion. Thank you for your attention to this critical issue. We are available to answer any questions.

Sincerely,

Maureen G. Phipps, MD, MPH, FACOG
Chief Executive Officer
American College of Obstetricians and Gynecologists

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[1] Improving Access to Mifepristone for Reproductive Health Indications. Position Statement. American College of Obstetricians and Gynecologists. June 2018. Available at https://www.acog.org/clinical-information/policy-and-position-statements/position-statements/2018/improving-access-to-mifepristone-for-reproductive-health-indications.
[2] Cleland K, Smith N. Aligning mifepristone regulation with evidence: Driving policy change using 15 years of excellent safety data. *Contraception*. 2015;92(3):179-181. doi:10.1016/j.contraception.2015.06.016.
[3] Sixteen Years of Overregulation: Time to Unburden Mifeprex. *N Engl J Med*. 2017;376(8):790-794.
[4] Song LP, Tang SY, Li CL, Zhou LJGYK, Mo XT. Early medical abortion with self-administered low-dose mifepristone in combination with misoprostol. *J Obstet Gynaecol Res*. 2018;44(9):1705-1711. doi:10.1111/jog.13716.
[5] U.S. Food and Drug Administration. FDA Mission. Available at https://www.fda.gov/about-fda/what-we-do. Retrieved September 20, 2021.
[6] Medication abortion up to 70 days of gestation. ACOG Practice Bulletin No. 225. American College of Obstetricians and Gynecologists. Obstet Gynecol 2020;136:e31–47.
[7] Grossman D, Grindlay K, Altshuler AL, Schulkin J. Induced abortion provision among a national sample of obstetrician-gynecologists. Obstet Gynecol 2019;133:477–83.Raymond EG, Blanchard K, Blumenthal PD, Cleland
[8] Raymond EG, Blanchard K, Blumenthal PD, Cleland K, Foster AM, Gold M, et al. Sixteen years of overregulation: time to unburden mifeprex. Mifeprex REMS Study Group. N Engl J Med 2017;376:790–4.
[9] Joint Statement on Abortion Access During the COVID-19 Outbreak. March 18, 2020. Available at https://www.acog.org/news/news-releases/2020/03/joint-statement-on-abortion-access-during-the-covid-19-outbreak.
[10] Chong E, Shochet T, Raymond E, Platais I, Anger H, Raidoo S, et al. Expansion of a direct-to-patient telemedicine abortion service in the United States and experience during the COVID-19 pandemic. Contraception 2021.
[11] Kerestes C, Murayama S, Tyson J, Natavio M, Seamon E, Raidoo S, et al. Provision of medication abortion in Hawai‘i during COVID-19: Practical experience with multiple care delivery models. Contraception 2021.
[12] Aiken A, Lohr P, Lord J, Ghosh N, Starling J. Effectiveness, safety and acceptability of no-test medical abortion provided via telemedicine. British J Obstet Gynecol 2021.