November 7, 2025

Martin Makary, MD, MPH
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993-002

Re: Comment in Opposition to Citizen Petition FDA-2025-P-3288-0001

Commissioner Makary,

Commenters the American College of Obstetricians and Gynecologists ("ACOG"), Society of Family Planning, and Society for Maternal-Fetal Medicine submit this comment in opposition to citizen petition FDA-2025-P-3288-0001, regarding the U.S. Food and Drug Administration's ("FDA") regulation of mifepristone (NDA 020687, ANDA 091178, ANDA 216616). For the reasons stated herein, Commenters request that FDA deny the petition in full, and, in particular, that FDA (1) approve any currently pending or forthcoming application to add a miscarriage indication to mifepristone's label, and (2) remove entirely the Risk Evaluation and Mitigation Strategy ("REMS") for mifepristone, including the three Elements to Assure Safe Use ("ETASU"), or, in the alternative, at a minimum, refrain from taking any action that would increase restrictions on or further decrease access to mifepristone.

1. **FDA should approve any currently pending or forthcoming application to add a miscarriage indication to mifepristone's label.**

As fully explained in the 2022 citizen petition filed by ACOG and 48 other medical, research, and reproductive health organizations, mifepristone is a "safe and essential part of the most effective regimen for miscarriage management."[1] For the reasons explained in that petition, which Commenters adopt in full, FDA should approve any currently pending or forthcoming application to add a miscarriage indication to mifepristone's label and should modify or eliminate the mifepristone REMS for this indication.

2. **The scientific evidence supports *eliminating* the REMS and ETASU for mifepristone, rather than adding further restrictions.**

As explained in multiple currently pending citizen petitions and comments thereto, a substantial body of robust scientific evidence demonstrates that the current REMS and ETASU for mifepristone are not medically justified, unduly burden patients, and do not satisfy the statutory

[1] Citizen Petition from Am. College of Obstetricians & Gynecologists et al., FDA-2022-P-2425-0001, at 2 (Oct. 4, 2022), https://www.regulations.gov/document/FDA-2022-P-2425-0001.

requirements under federal law for imposing such restrictions.[2] As such, there is no basis to support the Petition's requests to retain the REMS and ETASU, increase restrictions on mifepristone by adding or reinstating additional REMS, ETASU, or restrictive conditions of use, or suspend or withdraw mifepristone's approval. The Petition should be denied in full.

Sincerely,

Sandra E. Brooks, MD, MBA, FACOG
American College of Obstetricians and Gynecologists

Amanda Dennis, DrPH, MBE
Society of Family Planning

Sindhu K. Srinivas, MD, MSCE
Society for Maternal-Fetal Medicine

[2] *See, e.g.*, Citizen Petition from Am. College of Obstetricians & Gynecologists, FDA-2025-P-0377-0001 (Jan. 31, 2025), https://www.regulations.gov/document/FDA-2025-P-0377-0001; Citizen Petition from Massachusetts, et al., FDA-2025-P-1576-0001 (June 5, 2025), https://www.regulations.gov/document/FDA-2025-P-1576-0001; Citizen Petition from Washington, et al., FDA-2025-P-3287-0001 (Aug. 20, 2025), https://www.regulations.gov/document/FDA-2025-P-3287-0001; Comment from National Abortion Federation, FDA-2025-P-0377-0010 (Mar. 18, 2025), https://www.regulations.gov/comment/FDA-2025-P-0377-0010; Comment from Planned Parenthood Federation of America, FDA-2025-P-0377-0018 (May 28, 2025), https://www.regulations.gov/comment/FDA-2025-P-0377-0018; Comment from Guttmacher Institute, FDA-2025-P-0377-0012, at 2 (Apr. 8, 2025), https://www.regulations.gov/comment/FDA-2025-P-0377-0012; Comment from UCSF Bixby Center for Global Reproductive Health, FDA-2025-P-0377-0015 (Apr. 22, 2025), https://www.regulations.gov/comment/FDA-2025-P-0377-0015; Comment from UCLA Law Center on Reproductive Health, Law, and Policy et al. on behalf of 263 Reproductive Health Researchers, FDA-2025-P-0377-0230 (Aug. 27, 2025), https://www.regulations.gov/comment/FDA-2025-P-0377-0230; Comment from Reproductive Freedom for All, FDA-2025-P-0377-0016, at 1–3 (May 1, 2025), https://www.regulations.gov/comment/FDA-2025-P-0377-0016; Comment to Supplement Citizen Petition No. FDA-2025-P-0377-0001 from Am. College of Obstetricians & Gynecologists, et al., (Nov. 7, 2025) (on file with FDA).