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Kristi Hamrick, Chief Media & Policy Strategist
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1000 Winchester Street, Suite 301
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January 3, 2023

Re: Docket No. FDA-2022-P-3209

Dear Ms. Hawkins and Ms. Hamrick:

This letter responds to your citizen petition submitted to the Food and Drug Administration (FDA or Agency) on December 13, 2022, on behalf of Students for Life of America and other signatories (Petition). In the Petition, you request that the "2021 and 2016 modifications to mifepristone's REMS be reversed and the REMS as they were in 2011 be restored." Specifically, you request that:

(1) FDA reverse the 2021 and 2016 modifications to the risk evaluation and mitigation strategy (REMS) for mifepristone[1] by requiring that:

a. "Mifepristone only be administered, in a regimen with misoprostol, for the termination of intrauterine pregnancy, for up to 49 days (7 weeks) gestation" (Petition at 1).
b. "Mifepristone only be administered by or under the supervision of a physically present physician" (Petition at 1).
c. "the use of Mifepristone and misoprostol for the termination of pregnancy necessitate three office visits by the patient" (Petition at 1).

[1] Mifepristone products for medical termination of intrauterine pregnancy through 70 days gestation are subject to a single, shared system REMS known as the Mifepristone REMS Program. We note that on December 16, 2021, FDA completed its review of the Mifepristone REMS Program and determined, among other things, that the REMS must be modified to remove the in-person dispensing requirement and add pharmacy certification. On December 16, 2021, FDA sent REMS Modification Notification letters to the applicants for Mifeprex and the approved generic version of Mifeprex, Mifepristone Tablets, 200 milligrams. Following receipt of these letters, the applicants prepared proposed REMS modifications and submitted them to FDA. On January 3, 2022, FDA approved the REMS modifications.

(2) "Mifepristone use should be contraindicated for patients who do not have convenient access to emergency medical care," and "[t]his use should be as limited as possible" (Petition at 1).

(3) "Telehealth should not be an option to all women, but only to women in absolute need under extreme circumstances that would make access to a medical care facility impracticable, with a substantial risk that the woman would die without immediate administration of Mifepristone" (Petition at 1).

(4) "To alter the Mifepristone REMS, a formal study should be required" (Petition at 1).

The actions you request in your Petition are the same or substantially the same as the actions requested in the March 29, 2019 citizen petition submitted by the American Association of Pro-Life Obstetricians and Gynecologists (AAPLOG) and the American College of Pediatricians (ACP) (FDA-2019-P-1534) (AAPLOG/ACP petition), which were addressed in FDA's December 16, 2021 response to that petition.[2] Your Petition does not provide any new data or evidence beyond what was provided in support of the AAPLOG/ACP Petition. FDA carefully considered the information submitted in the AAPLOG/ACP Petition and issued a detailed response. The December 16, 2021 citizen petition response is available at regulations.gov.

For the reasons explained above, we deny your Petition.

Sincerely,

Patrizia A. Cavazzoni -S

Digitally signed by Patrizia A. Cavazzoni -S
Date: 2023.01.03 09:41:02 -05'00'

Patrizia Cavazzoni, M.D.
Director
Center for Drug Evaluation and Research

[2] Available at https://www.regulations.gov/document/FDA-2019-P-1534-0016.