**Date:** 00/00/2018

**Removing REMS Categorization on Mifepristone**

**Introduced by:** [Name(s) and State Chapter]

**WHEREAS,** the Food and Drug Administration (FDA) uses the Risk Evaluation and Mitigation Strategies (REMS) classification to impose restrictions on only the most dangerous drugs with known or suspected serious complications or contraindications,[[1]](#footnote-1) [[2]](#footnote-2) and

**WHEREAS,** althoughthe current FDA label for mifepristone was modified in 2016 to reflect more evidenced-based dosing and gestational limits,[[3]](#footnote-3) [[4]](#footnote-4) the label still includes a REMS classification requiring three provisions to “assure safe use,”[[5]](#footnote-5) including that 1) mifepristone be dispensed in a healthcare setting under supervision from 2) a provider who is registered and has signed a provider agreement with the pharmaceutical distributor, and 3) the patient sign an FDA-approved Patient Agreement Form, and

**WHEREAS,** the American Academy of Family Physicians (AAFP) “supports a woman's access to reproductive health services and opposes non-evidence-based restrictions on medical care and the provision of such services,”[[6]](#footnote-6) and

**WHEREAS,** the REMS restrictions on mifepristone are not based on scientific evidence[[7]](#footnote-7) [[8]](#footnote-8) [[9]](#footnote-9) [[10]](#footnote-10) [[11]](#footnote-11) and cause significant barriers to accessing abortion care,[[12]](#footnote-12) (such as landlords whose leases don’t allow abortions to be done on site, managers who won’t allow stocking of mifepristone, and colleagues who object to provision), and

**WHEREAS**, stocking Mifepristone in the office causes an upfront expense and financial burden which can be difficult for small practitioners to bear, further decreasing access for patients who might prefer to go to their own physician, and

**WHEREAS,** there are 16 years of data proving an outstanding safety record of mifepristone,7-11 including a 0.05% risk of major complications,11 and

**WHEREAS,** other drugs with higher complication rates, such as acetaminophen, aspirin, loratadine, and sildenafil, do not have REMS restrictions,[[13]](#footnote-13) [[14]](#footnote-14) [[15]](#footnote-15) [[16]](#footnote-16) and

**WHEREAS,** the REMS classification contributes to delays in care,7, [[17]](#footnote-17) thereby increasing second-trimester and surgical abortions, both of which have increased complication rates, and

**WHEREAS,** the REMS classification creates a barrier to safe and effective off-label uses of mifepristone, such as for anti-corticoid treatment of Cushing's disease, term labor induction, and miscarriage management,[[18]](#footnote-18) and

**WHEREAS**the American Congress of Obstetricians and Gynecologists (ACOG) “believes that a Risk Evaluation and Mitigration Strategy (REMS) is no longer necessary for mifepristone, given its history of safe use. The REMS requirement is inconsistnt with requitements for other drugs with similar or greater risks, specially in light of the significant benet that mifepristone proves to patient,”19 now, therefore be it

**RESOLVED**, that the [Your State Academy] engage in advocacy and lobbying efforts to overturn the Risk Evaluation and Mitigation Strategies (REMS) classification on mifepristone; and be it further

**RESOLVED,** that the [Your State Academy] submit a resolution to the 2018 AAFP Congress of Delegates calling on the AAFP also to endorse the principle that the Risk Evaluation and Mitigation Strategies (REMS) classification on mifepristone is not based on scientific evidence and limits access to abortion care; and be it further

**RESOLVED,** that the [Your State Academy] codify as policy its decision to join the American Civil Liberties Union Foundation lawsuit against the U.S. Department of Health and Human Services and the U.S. Food and Drug Administration seeking to end the Risk Evaluation Mitigation Strategies (REMS) classification on mifepristone by endorsing the principle that the REMS classification on mifepristone is not based on scientific evidence and limits access to abortion care and be it further

**RESOLVED,** that the [Your State Academy] submit a resolution to the 2018 AAFP Congress of Delegates calling on the AAFP to engage in advocacy and lobbying efforts to overturn the Risk Evaluation and Mitigation Strategies (REMS) classification on mifepristone and also join the ACLU lawsuit against the FDA.

1. <https://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm184128.pdf> [↑](#footnote-ref-1)
2. <https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM521504.pdf> [↑](#footnote-ref-2)
3. <https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/020687s020lbl.pdf> [↑](#footnote-ref-3)
4. Greene MF, Drazen JM. A new label for mifepristone. *N Engl J Med*. 2016;374(23):2281-2282. [↑](#footnote-ref-4)
5. Approved Risk Evaluation and Mitigation Strategies (REMS): Mifeprex (mifepristone). Silver Spring, MD: Food and Drug Administration, March 29, 2016. https://www.accessdata.fda.gov/scripts/cder/rems/index.cfm?event=IndvRemsDetails.page&REMS=35 [↑](#footnote-ref-5)
6. Reproductive Health Services. Leawood, KS: American Academy of Family Physicians, 2014.

   <http://www.aafp.org/about/policies/all/reproductivehealth-services.html> [↑](#footnote-ref-6)
7. Mifeprex REMS Study Group. Sixteen years of overregulation: time to unburden Mifeprex. *N Engl J Med.* 2017;376(8):760-794. [↑](#footnote-ref-7)
8. Hausknecht R. Mifepristone and misoprostol for early medical abortion: 18 months experience in the United States. *Contraception*. 2003;67(6):463-465. [↑](#footnote-ref-8)
9. Upadhyay UD, Desai S, Zlidar V, et al. Incidence of emergency department visits and complications after abortion. *Obstet Gynecol*. 2015;125(1):175-183. [↑](#footnote-ref-9)
10. Zane S, Creanga AA, Berg CJ, Pazol K, et al. Abortion-related mortality in the United States, 1998–2010. *Obstet Gynecol*. 2015;126(2):258–265 [↑](#footnote-ref-10)
11. Weitz TA, Taylor D, Desai S et al. Safety of aspiration abortion performed by nurse practitioners, certified nurse midwives, and physician assistants under a California legal waiver, *Am J Public Health.* 2013;103(3):454–461. [↑](#footnote-ref-11)
12. Sheldon WR, Winikoff B. Mifepristone label laws and trends in use: recent experiences in four US states. *Contraception.* 2015;92(3):182-185 [↑](#footnote-ref-12)
13. 13 Ostapowicz G, Fontana R, Schiodt F, et al. Results of a prospective study of acute liver failure at 17 tertiary care centers in the United States. *Ann Intern Med*. 2002;137(12):947-954. [↑](#footnote-ref-13)
14. 14 McNeil Consumer & Specialty Pharmaceuticals. Aspirin and other OTC NSAIDs: background information for Nonprescription Drugs Advisory Committee Meeting. September 20, 2002. [↑](#footnote-ref-14)
15. 15 US Food and Drug Administration. Executive summary on risk issues draft presented at joint meeting of the Nonprescription Drugs Advisory Committee and the Pulmonary Allergy Drugs Advisory Committee. May 11, 2001. [↑](#footnote-ref-15)
16. 16 Lowe G, Costabile RA. 10-year analysis of adverse event reports to the Food and Drug Administration for phosphodiesterase type-5 inhibitors. *J Sex Med*. 2012;9(1):265-270. [↑](#footnote-ref-16)
17. 17 Grossman DA, Grindlay K, Buchacker T, Potter JE, Schmertmann CP. Changes in service delivery patterns after introduction of telemedicine provision of medical abortion in Iowa. *Am J Public Health* 2013;103(1):73-78. [↑](#footnote-ref-17)
18. 18 Dzuba IG, Grossman D, Schreiber CA. Off-label indications for mifepristone in gynecology and obstetrics. *Contraception*. 2015:92(3):203-205

    19 https://www.acog.org/About-ACOG/News-Room/Statements/2016/ACOG-Statement-on-Medication-Abortion [↑](#footnote-ref-18)