AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 504
(A-18)

Introduced by: Medical Student Section

Subject: Ending the Risk Evaluation and Mitigation Strategy (REMS) policy on Mifepristone (Mifeprex)

Referred to: Reference Committee E
(Douglas W. Martin, MD, Chair)

Whereas, The Food and Drug Administration (FDA) often regulates medications by associating them with a drug-specific Risk Evaluation and Mitigation Strategy (REMS), with the goal of ensuring a drug’s benefits outweigh its potential risks;¹ and

Whereas, The FDA REMS policy states that “Mifeprex© must be dispensed to patients only in certain healthcare settings, specifically clinics, medical offices, and hospitals” and prevents the distribution of mifepristone (Mifeprex©) through retail pharmacies;² and

Whereas, A woman is 14 times more likely to die from pregnancy-related complications than taking mifepristone for a medical abortion;³ and

Whereas, The estimated mortality rate of Mifeprex© is 0.00063% based on data from 3 million women in the United States who have used the medication for abortion;⁴ and

Whereas, The FDA’s REMS for Mifeprex© impedes the provision of Mifeprex©, even after over a decade of safe use, without offering any demonstrated or even reasonably likely advantage;¹ ⁴ and

Whereas, American College of Obstetricians and Gynecologists and the New England Journal of Medicine, among other prominent organizations, have called for the removal of the Mifeprex REMS given the drug’s history of safe use;¹ ⁴ therefore be it

RESOLVED, That our American Medical Association support efforts urging the Food and Drug Administration to lift the Risk Evaluation and Mitigation Strategy on mifepristone. (New HOD Policy)

Fiscal Note: not yet determined

Received: 04/26/18

RELEVANT AMA POLICY

The Evolving Culture of Drug Safety in the United States: Risk Evaluation and Mitigation Strategies (REMS) H-100.961

Our AMA urges that:

1. The Food and Drug Administration (FDA) issue a final industry guidance on Risk Evaluation and Mitigation Strategies (REMS) with provisions that: (a) require sponsors to consult with impacted physician groups and other key stakeholders early in the process when developing REMS with elements to assure safe use (ETASU); (b) establish a process to allow for physician feedback regarding emerging issues with REMS requirements; (c) clearly specify that sponsors must assess the impact of ETASU on patient access and clinical practice, particularly in underserved areas or for patients with serious and life threatening conditions, and to make such assessments publicly available; and (d) conduct a long-term assessment of the prescribing patterns of drugs with REMS requirements.

2. The FDA ensure appropriate Advisory Committee review of proposed REMS with ETASU before they are finalized as part of the premarket review of New Drug Applications, and that the Drug Safety and Risk Management Advisory Committee fulfills this obligation for drugs that are already on the market and subject to REMS because of new safety information.

3. To the extent practicable, a process is established whereby the FDA and sponsors work toward standardizing procedures for certification and enrollment in REMS programs, and the common definitions and procedures for centralizing and standardizing REMS that rely on ETASU are developed.

4. REMS-related documents intended for patients (e.g., Medication Guides, acknowledgment/consent forms) be tested for comprehension and be provided at the appropriate patient literacy level in a culturally competent manner.

5. The Food and Drug Administration (FDA) issue a final industry guidance on Risk Evaluation and Mitigation Strategies (REMS) with provisions that: (a) urge sponsors to consult with impacted physician groups and other key stakeholders early in the process when developing REMS with elements to assure safe use (ETASU); (b) establish a process to allow for physician feedback regarding emerging issues with REMS requirements; and (c) recommend that sponsors assess the impact of ETASU on patient access and clinical practice, particularly in underserved areas or for patients with serious and life threatening conditions, and to make such assessments publicly available.

6. The FDA, in concert with the pharmaceutical industry, evaluate the evidence for the overall effectiveness of REMS with ETASU in promoting the safe use of medications and appropriate prescribing behavior.

7. The FDA ensure appropriate Advisory Committee review of proposed REMS with ETASU before they are finalized as part of the premarket review of New Drug Applications, and that the Drug Safety and Risk Management Advisory Committee fulfills this obligation for drugs that are already on the market and subject to REMS because of new safety information.

8. To the extent practicable, a process is established whereby the FDA and sponsors work toward standardizing procedures for certification and enrollment in REMS programs, and the common definitions and procedures for centralizing and standardizing REMS that rely on ETASU are developed.

9. REMS-related documents intended for patients (e.g., Medication Guides, acknowledgment/consent forms) be tested for comprehension and be provided at the appropriate patient literacy level in a culturally competent manner.

10. The FDA solicit input from the physician community before establishing any REMS programs that require prescriber training in order to ensure that such training is necessary and meaningful, requirements are streamlined and administrative burdens are reduced.

Citation: (CSAPH Rep. 8, A-10; Reaffirmed: Res. 917, I-10; Appended: CSAPH Rep. 3, I-12)

See also:

*Physician Awareness and Education About Pharmaceutical and Biological Risk Evaluation and Mitigation D-100.971*

*Pregnancy Termination H-5.983*

*Policy on Abortion H-5.990*

*Abortion H-5.995*

*Medical Training and Termination of Pregnancy H-295.923*

*Freedom of Communication Between Physicians and Patients H-5.989*