FDA issues

AMA urges that FDA modify risk reduction plans

The AMA wrote Food and Drug Administration (FDA) Commissioner Margaret Hamburg, MD, to express concern about the manner in which FDA has been implementing the Risk Evaluation and Mitigation Strategies (REMS) provisions of a 2007 law and to recommend improvements. The AMA believes that REMS should support physician decision-making and help promote safe prescribing without erecting barriers to delivery of appropriate care.

The FDA has not required manufacturers to obtain input from practicing physicians on “elements to assure safe use” when such elements are included in REMS; however, nor has it outlined methods to assess the impact of REMS on patient access to needed drugs.

In its letter, the AMA recommended (PDF) that the FDA: require this type of consultation with specialty societies and practicing physicians; ensure that manufacturers evaluate the impact of REMS on patient access and clinical practice; provide for review of proposed REMS by the FDA Advisory Committees; and reduce the administrative burdens associated with REMS.

In response to the concerns expressed by AMA and other stakeholders, the FDA convened a public meeting on July 27–28, 2010, and reopened the comment period on its draft guidance on REMS. Dr. Sandra Fryhofer of the AMA Council on Science and Public Health represented the AMA at the public meeting.

FDA plans for opioids

Last year the FDA announced an initiative to work with manufacturers of extended-release and high-potency opioids to develop a Risk Evaluation and Mitigation Strategy or REMS.

In meetings, testimony at public hearings and comment letters, AMA has urged the agency to: ensure that the REMS does nothing to impair patient access to needed pain medications; seek a REMS focused primarily on educating physicians and patients; provide positive incentives rather than penalties; allow substantial opportunities for physician involvement in designing the educational programs; avoid restricted distribution; and work to prevent unintended consequences such as an

increase in use of immediate-release opioids that are not included in the REMS or undertreatment of pain.

AMA comments to FDA

- Revised guidance on reducing risk of HIV transmission through blood products (PDF)
- Position statement on blood deferral policy for MSM (PDF)
- AMA comments on trans fats (PDF)
- AMA comments on REMS development for drugs and biological products (PDF)
- AMA comments on REMS for opioids (PDF)
- AMA comments on development of REMS for opioids (PDF)
- AMA comments on direct-to-consumer TV advertising for prescription drugs (PDF)