November 21, 2014

Division of Dockets Management (HFA-305)
Food and Drug Administration
5600 Fishers Lane, Room 1061
Rockville, MD 20852

Re: CME Coalition Response to the US Food and Drug Administration's Standardizing and Evaluating Risk Evaluation and Mitigation Strategies (REMS) Report

Dear Sir or Madam:

The CME Coalition applauds the FDA's recognition, as noted in its September 2014 report, that continuing medical education (CME) plays an essential role in improving knowledge of drug-related risks. The Coalition supports the FDA's intention to evaluate the feasibility of drug-specific REMS CME training. CME is an established component of physicians' ongoing process of professional growth and development. Education activities help fulfill state requirements for maintenance of licensure and specialty maintenance of certification. Activities accredited by the Accreditation Council for Continuing Medical Education (ACCME) are subject to requirements to demonstrate evidence of fair balance, relevance and effectiveness. As such, activities offer not only a strong incentive for providers to consume information related to drug safety, but can be used to evaluate change in knowledge of the safety issues in question.

Preliminary research suggests that REMS-related CME can reach substantial numbers of providers who do not otherwise choose to engage with standard REMS communication, such as a Dear Healthcare Provider letter. In a 2013 study by Kraus et al, availability of a CME activity doubled the healthcare providers made aware of FDA REMS requirements for a particular agent compared with a letter alone.[1] Ability to answer post-test questions was highest in the cohort which elected to both read the letter and participate in CME, underscoring a complementary role for CME alongside other communication tactics.

[1] Kraus CN, Baldwin AT, McAllister Jr. RG. Improving the effect of FDA-mandated drug safety alerts with internet-based continuing medical education. Current Drug Safety. 2013. 8:11-16.

As noted in the FDA's September 2014 report, REMS CME activities could be developed both for approved drugs as well as for pending drugs prior to FDA approval, with the REMS CME published or presented upon drug launch. This would minimize any interval of drug availability without REMS information but would allow the CME provider to make last-minute changes based on final changes to the prescribing information.

In other circumstances CME, including class-related REMS programming, achieves the ACCME's requirement of fair balance through discussion on multiple agents. In the case of single-drug REMS CME, the FDA's plan will need to include provisions to achieve fair balance within the context of a single agent, possibly through discussion of both risks and benefits of the agent in question. The Coalition urges the FDA to work with ACCME to define clear criteria for single-drug REMS that will be consistent with current CME standards, particularly in the context of REMS CME that receives commercial support from the manufacturer.

Finally, plans to develop CME should include provision of resources to measure and evaluate the effect of the activities, such as through change in knowledge or potential clinical decision-making before and after completion of the activity. Such metrics can be applied to CME across online, live and enduring formats. For agents already approved for use, data gathered from online prescribing databases may further be able to demonstrate changes in behavior tied to completion of CME and other REMS activities.

CME Coalition members offer expertise in online, live and enduring CME formats and can provide data related to change in knowledge and practice for each. The CME Coalition welcomes the opportunity to consult with the FDA regarding priorities for REMS education, resolution of priorities and barriers, and best practices for adult learning in the CME environment as it relates to REMS.

Sincerely,
Andrew M. Rosenberg, J.D.

About the CME Coalition

The CME Coalition (www.cmecoalition.org) is a Washington-based organization comprised of CME providers, beneficiaries of CME (including both educational institutions and professional societies) and supporters of CME (such as pharmaceutical manufacturers and device makers). Additional partnerships and affiliations have also been extended to health policy thought leaders and other interested parties who share an appreciation for the mission of the organization.