Prepared Remarks on FDA ER-LA Opioid REMS

Good morning. My name is Andrew Rosenberg and I am here representing the CME Coalition, an advocacy group representing nearly 3 dozen CME stakeholders from across the spectrum of education providers, supporters and physicians.

Continuing Medical Education (or CME) is critical to the success of the REMS program. Under REMS programs, the FDA reviews and approves programs developed by drug sponsors, and healthcare professionals must then heed the program rules. In order to ensure that healthcare professionals understand the rules, as well as their roles in making sure the rules are followed, CME courses are essential.

There have been numerous studies done as to the effectiveness of CME. Over the course of 39 systematic reviews published between 1977 and 2014, the overall impact has been settled: CME courses "can more reliably change health professionals' knowledge and competence than their performance and patient health outcomes."[1]

CME courses accredited by the ACCME have stringent criteria and standards that must be met. In 2010, a Prescriber Education Working Group stated, "the stakeholders and the Working Group recommend that the REMS prescriber training be designed to exceed the goal of traditional CME methods (i.e. knowledge acquisition) and instead aim to demonstrate optimized practitioner performance and improved patient outcomes."[2] As such, the ACCME has worked to streamline and align CME's purpose with the ideas of the working group, and the needs of practicing physicians.

Today, the types of CME offered for REMS include:

- general information about the use of opioids to aid in patient selection and counseling;
- specific information about the individual drugs in the class;

[1]http://www.accme.org/sites/default/files/652_20141104_Effectiveness_of_Continuing_Medical_Education_Cervero_and_Gaines.pdf

[2]http://www.accme.org/sites/default/files/null/ACCME%20Presentation%20at%20the%20FDA%20slide%20set%20July%202010.pdf

- and information on how to recognize the potential for and evidence of addiction, dependence, and tolerance.[3]

This is not the first time CME has been a part of REMS. As such, lessons have been learned from past REMS, including the following:

- educational venues must be engaging,
- we have to address education needs that underlie the practice gaps of each intended audience,
- and that *hypotheses* must drive the scientific development of audience samples for measurement.[4]

CME as part of REMS is helpful to practitioners because the FDA controls the needs assessment and content requirements… and because it encourages evidence-based debate on risk versus benefit.[5]

ACCME-accredited CME is especially helpful because the scope of evaluation of effectiveness is actually *measured* in one of three ways:

- change in competence;
- change in performance;
- or change in patient outcomes.

This helps to evaluate how well physicians understand the REMS and opioid effects on their patients.

Moving Forward

We believe the FDA should consider standardizing the REMS process, while allowing more flexibility in content. The strength of CME is that it can produce myriad educational activities that are targeted to physicians based on their professional practice gaps, individualized needs, and stages of learning and change. Added flexibility will allow prescriber education to better address individual prescribers' educational and practice needs.

The effectiveness of REMS can also be measured in terms of how successfully it promotes access to education and draws the attention of the medical profession to a problem.

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[3]http://www.accme.org/sites/default/files/661_20120123_REMS_Developing_REMS_In_Alignment_with_The_SCS_ACEHP_Revised.pdf

[4]http://www.accme.org/sites/default/files/661_20120123_REMS_Developing_REMS_In_Alignment_with_The_SCS_ACEHP_Revised.pdf

[5]http://www.accme.org/sites/default/files/661_20120123_REMS_Developing_REMS_In_Alignment_with_The_SCS_ACEHP_Revised.pdf

Several government agencies have also been helping to educate physicians on the dangers and special care that patients who have been prescribed opioids need. Many organizations have previously provided REMS education, but have not dotted every “I” and crossed every “T” when it comes to following the blueprint. CME has worked to comply with the blueprint, while supporting these other programs as part of a larger risk education project.

We believe that REMS should also be expanded to include short acting opioids. While extended release and long acting opioids can be abused, short acting opioids are even more likely to be abused and therefore, much more difficult to manage. We agree with the FDA’s stated position that REMS be expanded to SA-IR, and create a single blueprint for all opioids.

We are encouraged that the FDA sees CME as a valuable tool in combatting the opioids epidemic. Our members have created hundreds of hours of pain education programs and have delivered them to hundreds of thousands of physicians. Through their research and experience, we believe that, rather than requiring the whole three to six hours of content outlined in the blueprint, that counting credit hours towards a goal of three hours of REMS education should be considered.

Finally, we recommend expanding the target audience to include other practitioners NP's, PA's, pharmacists, and nurses.

We believe that this REMS program, in combination with the FDA and Accredited CME Providers, serves as a model of cooperation in helping to address public health issues.

Thank you for your time.