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 educating prescribers about the risks inherent in opioid medications and 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

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

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

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.[4]

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 the effects of opioids on their patients.

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

[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

Moving forward, we believe the FDA should continue to rely on accredited CME as a vital tool in prescriber education in the opioid space. 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.

In addition to REMS, several government agencies have also been helping to educate physicians on the dangers and special care that patients who have been prescribed opioids need.

We are encouraged that the FDA sees CME as a valuable tool in combatting the opioids epidemic. Our members have developed hundreds of hours of innovative and creative pain education programs and have delivered them to hundreds of thousands of physicians.

**Finally, as an incentive for prescribers to participate in opioid REMS, we recommend that the FDA encourage CMS to include opioid REMS as an improvement activity in the Quality Payment Program MIPS.**

Thank you for your time.