

**Joint Meeting of the
Anesthetic and Life Support Drugs Advisory
Committee and the Drug Advisory Committee for
the REMS for Certain Opioid Drugs**

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Disclosure

Pinney Associates develops, implements and evaluates REMS for pharmaceutical developers and manufacturers and consults for many of the companies in the Industry Working Group (IWG).

Pinney Associates worked with the IWG in the development of the REMS and specifically worked with the Metrics and Patient Education Sub-teams.

Assessing the REMS for Certain Opioids

- Prescription drug abuse is a problem
- Any FDA efforts via REMS will have a limited impact on the scope of the problem
 - It is a particular challenge to assess this REMS given that the abuse occurs mainly in non-patients
- To increase access and safety and reduce abuse, FDA should take the lead in developing a task force of federal agencies, industry and other stakeholders to collaboratively develop a comprehensive approach to directly address the inappropriate use of opioids