

Division of Dockets Management (HFA-305)

Food and Drug Administration

5630 Fisher Lane, Room 1061

Rockville, MD 20852

Re: Docket No. FDA-2009-0143

Risk Evaluation and Mitigation Strategies (REMS) for Opioids from the Food and Drug Administration (FDA) is in response to a 2005 Congressional mandate.

The stated goal of the REMS is to *“ensure that the benefits of these drugs continue to outweigh certain risks.”*

The **Michigan Association of Osteopathic Family Physicians** (MAOFP) supports the stated aim expressed by the Food and Drug Administration to ensure the safe and effective use of opioid medications while minimizing potential abuse and diversion of these agents. In consideration of these goals the MAOFP has framed recommendations in the context of two key questions:

1. *What are public policy decisions that will further the desired goal?*
2. *What are public policy decisions that will confound the desired goal?*

1. What are public policy decisions that will further the desired goal?
 - a. Implementing a national (or coordinated state) Prescription Monitoring Program (**PMP**); in Michigan we have extensive experience with the Michigan Automated Prescription System (MAPS) with real-time controlled substances prescription data available to physicians and pharmacists. Prescribers must be able to access PMP data from a confidential site, so that this information can be used as a proactive, rather than reactive, tool.
 - b. *The REMS should cover the **entire class** of opioid medications. An attempt to regulate a limited segment of the opioid class of medications (**schedule II**; i.e. **oxycodone, methadone, fentanyl etc.**) will drive prescribers, users, and misusers of these medications to another, less stringently regulated, but often abused class of medications (**schedule III**; i.e. **hydrocodone, codeine etc.**).*
 - c. Develop REMS education programs with *extensive expert input*. The REMS should provide a comprehensive core curriculum that builds on proven approaches. The curriculum should be offered through a variety of means and media – **including electronic, print or in person options** – to ensure broad accessibility. Individuals completing this curriculum should be entitled to Continuing Education credits from their respective professional organizations or licensing agencies (i.e, medical, nursing, pharmacy). **Content should include core principles of prescribing and practice such as those proposed by the** Federation of State Medical Board Model Policy, the American Academy of Pain Medicine / The American Academy of Pain Management / American Pain Society Guideline for Chronic Opioid Therapy and other authoritative sources and must recognize that some patients with extraordinary conditions may require analgesics exceeding usual and customary practices. The content should be incorporated in medical school and post-graduate education training curricula.
2. What are public policy decisions that will confound the desired goal?
 - a. REMS must protect and not interfere with patient access to these important medicines. The stated goal of REMS is similar to the well known policy principle of balance which is to *curb abuse, misuse, and diversion while maintaining appropriate access.*
 - b. Do NOT include Patient Registries in the REMS. No evidence exists to suggest that a patient registry will diminish abuse or misuses of these medications. Enhancements to the existing and growing state Prescription Monitoring Programs (PMPs) infrastructure would be a better option to consider for achieving the REMS goals.