

REMS: Intended Purpose and Unintended Consequences

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Strategies for Certain Opioid Drugs

Prescription drug abuse

- Not a new problem
 - Laws to address it go back over 100 years
 - Laws only address supply side, not demand
- Is a REMS the right approach to this problem?

REMS are here to stay, but...

- Who were REMS designed to protect?
 - Patients to whom the drug was prescribed
- Should we expect a REMS to have an effect on non-patients?
- Will REMS encourage or discourage innovation in drug dosage forms? (less burdensome REMS for abuse resistant formulations would stimulate innovation)

REMS are here to stay, but...


- What will the impact be on patients?
 - Will it be harder for patients to obtain their medication?
 - Will prescribing decisions be based on REMS or patient need?
- What will the impact be on healthcare providers?
 - Will the impact be different for different providers?
 - Will some current providers opt out?
 - Will there be changes in prescribing patterns?
- What will the impact be on the healthcare system?
 - Will there be increased cost for medical care or medications?
 - Will some drugs be removed from formularies?

REMS are here to stay, but...

- Will REMS have an effect on prescription drug abuse and/or illicit drug abuse?
 - Will abuse shift to other drugs?
 - Combo drugs(NSAIDS, acetaminophen), illicit drugs
 - Will this shift patients outside of medical care?
 - What needs to be measured and how might this be measured?
- Who is responsible for non-patient abuse?
- How are patients different from non-patients?
 - Different expectations of drug effect
 - Different expectations of safety



If you have only one tool....



Beware of unintended
consequences of good
intentions.

Thank you