

OPENING REMARKS

JANET WOODCOCK
Director, CDER, FDA



Prescription Drug Epidemic: FDA Executing Action Plan on Opioids

- Exposure (alternative Rx, education)
- Non-medical opioid use (ADF's, disposal)
- Overdose and deaths (naloxone)
- Treatment options (MAT)



Why is Prescriber Education so Important?

- This epidemic is fueled by opioids that are legally prescribed
- In early 1980's: even some cancer patients refused to take opioid pain relief out of fear
- 2010: more than 200M Rx dispensed

WHAT HAPPENED?



Prescribing Patterns Changed

- Huge increase in opioid prescribing over 3 decades
- Shift in medical dogma about abuse potential when used to treat pain
- Increased awareness of under-treatment of pain and need for therapy
- Promotion of opioid drugs
- Massive shift in prescriber behavior



Consequences of Shift in Prescribing

- Huge increase in population exposure
- Surge in opioid-related substance abuse disorders, deaths from overdose: still ongoing
- Abetted by rise of "pill mills" and related practices
- Many with opioid substance abuse disorder state source of drug is obtaining or stealing from friends or relatives
- Despite general belief, vast majority of exposure is to IR formulations

Medical Dogma Was Not Correct

- Rate of substance abuse correlates with population exposure and brief exposure can lead to prolonged exposure
- Exposure to opioids post-surgery results in extended use, i.e., at 90-180 days (not necessarily substance abuse) in about 6% of people (Brummet et al, JAMA Surgery, 4/17)
- Similarly for opioid prescriptions for musculoskeletal or head pain indications: 6% had persistent opioid use 1 year post-initial prescription; this increased to 30% if initial RX was for more than a month (Shah et al, MMWR, March 17, 2017)



Consequences of 220M Rx

- Some proportion of people exposed go on to chronic use
- A lower proportion develop opioid substance abuse disorder
- A large proportion of patients prescribed take few doses and stop because of side effects (dysphoria, nausea, constipation) and put in home medicine cabinet to be a target for adolescent use or substance abusers

Clinicians Need Good Tools for Pain Management to Control this Epidemic

- The imperative to treat pain will not go away
- In approaching a patient with pain, need to understand clearly and consider carefully, benefits and liabilities of each modality
- Some effective modalities are limited because of reimbursement issues (physical therapy, cognitive behavioral therapy); clinicians may not be aware of other drug modalities—and they have their own liabilities
- Often opioid Rx seen as a good way to provide relief

Prescriber Education on Opioids for Pain Management



- Opioids will continue to be the mainstay for pain relief in many situations, so prescriber awareness of issues is critical
- Renewed understanding that ANY opioid prescription confers risks, either to the patient or to others if not properly disposed; and what these risks are
- Renewed understanding that duration of dosing and amount prescribed are related to risks
- Up-to-date understanding of the modern science of chronic pain and its management



HOW CAN WE ENSURE PRESCRIBER
UNDERSTANDING OF PAIN
MANAGEMENT, BALANCING BOTH THE
CLEAR RISKS OF OPIOIDS AND THE
NEED FOR TREATMENT?

