PAIN MANAGEMENT
POLICY FOCUS: ABUSE-DETERRENT OPIOIDS

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Two Major Public Health Problems

• Prescription opioid abuse:
  • 12.5 million non-medical users per year
  • $70-120 billion cost per year
  • 16,000 overdose deaths per year

• Chronic pain:
  • >100 million with chronic pain, ~39 million with “nearly daily” chronic pain, ~25 million with daily chronic pain, ~10 million disabled
  • $560-635 billion cost per year
  • Suicide risk doubled
    • 39,500 suicide deaths in 2011
    • ~26,000 were people with chronic pain
More Commonalities than Differences

- Prescription drug abuse and chronic pain are more alike than different:
  - Both are highly prevalent
  - Both are very costly, in economic and human terms
  - Both highly stigmatized, and patients are blamed
  - Both involve tremendous suffering
  - Both are poorly understood by the medical profession
  - Both are under-resourced vis-à-vis treatment
  - Both are very complex problems, with many moving parts
  - Both are best treated with a multimodal, interprofessional, biopsychosocial approach
Not A Zero-Sum Game

Often, it feels like any attempt to rein in prescription drug abuse must, of necessity, rein in prescribing, even for people with pain.

Similarly, it often seems as though any effort to improve pain management must involve increased prescribing, which could, in turn, lead to increased prescription drug abuse.

I believe this misstates the case, and that it is possible to address both problems with adversely affecting either.
A Thought

“For every complex problem, there is a solution that is neat, simple, and wrong”—H.L. Mencken

I believe that implementing overly simplistic policy solutions for these two very complex problems leads to the zero-sum game that we so often perceive.

Perhaps the solutions we should be seeking are as complex as the problems we are trying to solve.
Good Pain Management Helps Prevent Prescription Drug Abuse

• Appropriate treatment for chronic pain is multimodal and involves multiple providers
• This kind of treatment focuses primarily on improving function, recognizing that this can happen even with minimal (or no) improvement in pain intensity
• Use of multiple types of treatment should reduce reliance on opioid analgesics as the primary (and sometimes only) means of treating pain
• Multiple barriers exist to providing this type of care for chronic pain
Federal and State Pain Management Policy Issues

• Abuse-Deterrent Opioids
• Mandatory CME/CE
• Availability of substance abuse treatment
• Reimbursement for services other than prescribing and procedures
• Prescription Monitoring Programs
• Prior Authorization/Step Therapy/Specialty Tier
• Good Samaritan/Naloxone Distribution and Administration
• Prescribing Guidelines
• Pain Clinic Regulation
How Do People Die of Overdoses Involving Opioids?

- Accidental, during self-medication or recreational use
- Therapeutic misadventure (one or more of the following)
  - Dose too high
  - Comorbid medical conditions
  - Combination with other prescribed medications
  - Combination with OTC medications
  - Combination with alcohol
  - Combination with illicit drugs
    - Prescription medications obtained illicitly
    - Schedule I controlled substances
- Homicide (rare)
- Suicide (not so rare)
Who Dies of Overdoses Involving Prescription Opioids?

- People without a prescription for those opioids (~55-60% of deaths)
  - Some who alter the route of administration
  - Some who take them orally, with or without other drugs
- People with a prescription for those opioids
  - Some who alter the route of administration
  - Some who take them orally, but with other drugs or otherwise not as directed
  - Some who take them exactly as intended
- How many of the 16,000 deaths a year fall into each category? No one knows…
Important Patterns in Prescription Opioid Abuse

• We see a couple of important shifts as people become more experienced abusers of prescription opioids

• Early in the course:
  • Family and friends are most common source of medication (up to 70% or more)
  • Swallowing is most common route of ingestion (more than 50%)

• Later in the course:
  • Drug dealers and theft are more common sources for medication
  • Inhalation (snorting, smoking) and injection are more common routes of ingestion
FDA Actions: Abuse Deterrent Opioids (ADO)

- FDA has issued guidance for brand-name manufacturers regarding requirements for “abuse deterrent” labeling
- Several extended release ADOs currently approved; more to follow soon
- Work is underway on short-acting ADOs as well
- Evidence so far suggests they are effective in reducing abuse that involves altering the form of the drug to permit inhalation or injection
Six Types of Abuse Deterrent Technology

- Physical/Chemical Barriers: Prevent alteration, or resist extraction using solvents
- Agonist/Antagonist Combinations: If altered, antagonist is released, blocking effect of medication
- Aversion: Combination with a product that produces unpleasant effect if medication is altered
- Delivery System: Drug release or delivery methods that offer resistance to abuse
- Prodrug: Product must be metabolized in the GI tract to produce an active medication
- Combination of the above

*Products currently approved for marketing*
ADO Considerations

Things to remember:

- “Abuse deterrent” is a misnomer. Current ADOs may discourage or prevent crushing, cutting, melting, dissolving, extracting, or other forms of tampering, but they may not prevent chewing; none prevent swallowing.

- These are not THE solution to the problem, but they ARE an incremental step forward.

- Because these are branded products, they will cost more than non-ADO generics.

- It is a (small?) minority of people who alter their ER opioids; most likely don’t even have a prescription.
ADOs: Policy Considerations

- Our position has been this:
  - The decision whether or not to use an ADO should be made by the prescriber in consultation with the patient
  - The decision should be informed by a thorough risk assessment
  - Risk assessment includes the patient and people around the patient
  - If an ADO is prescribed, the pharmacy should provide an ADO—no auto-substitution to a non-ADO
  - If a substitution either to or from and ADO is recommended by the pharmacist, it should be only with the approval of the prescriber
  - Those patients who do not require an ADO should not be forced to pay for one; we propose that any policy requiring use of an ADO also require insurance coverage equivalent to that for a similar non-ADO
A Final Word

• Medical professionals, especially those specializing in pain management, want to be part of the solution for prescription drug abuse
• In part, we need to better use some tools we already have
• In part, we need some additional tools to effectively treat chronic pain in ways that don’t exacerbate prescription drug abuse
• We are eager to work with policymakers to craft the complex solutions we need, for the good of all of their constituents and all of our patients
Thank you for your attention