Prescription Opioid Abuse:
Working together to address a public health concern
Content of presentation

- The problem of prescription opioid misuse, abuse, and diversion
- Who is at risk for opioid misuse and abuse?
- What is being done to reduce the risk of opioid abuse?
- A pharmaceutical industry approach: Abuse-deterrent opioids
The Problem of Prescription Opioid Misuse, Abuse, and Diversion
The important role of prescription opioids

~100 million adult Americans are affected by a chronic pain condition¹

Patients deserve access to effective medications to treat pain, including prescription opioids when appropriate¹

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There is potential for misuse, abuse, and diversion of prescription opioids

**Misuse**
Use of a medicine other than as directed or as indicated to treat an illness

**Abuse**
Any use of an illicit drug or use of a prescription drug for a nonmedical purpose

**Diversion**
Removing a medicine from legitimate circulation: can involve sharing, purchasing, and theft among family and friends

**For example:**
- Taking more than your prescribed dose
- Ingesting medicine to get high
- Sharing prescription opioids among friends or family

Increased use of opioids in treating pain has led to a significant rise in prescriptions.

In 2011, the number of pharmacy prescriptions for opioids nearly tripled.

+175% 1991–2011

In 1991, 76 million pharmacy prescriptions were filled for opioids. By 2011, this number had risen to 219 million.

Prescription opioid misuse and abuse are associated with serious health consequences

Deaths from unintentional and intentional overdose of prescription opioids\textsuperscript{1,2}

\textbf{The number of opioid overdose deaths quadrupled}

\textbf{+300\%}

1999–2013

In 2013, \textbf{44 people died} from opioid overdoses every single day

Opioid overdose deaths are only the tip of the iceberg

In 2010, for every 1 opioid overdose death there were...

- 10 abuse treatment admissions*
- 26 emergency department visits†
- 108 who abused/were dependent‡
- 733 nonmedical users‡

Oral ingestion is the major route of abuse, but injection and inhalation are the most dangerous.

Routes of abuse

- Oral (chewed and whole): 92%
- Inhalation (includes snorting): 5%
- Injection: 3%

Higher rates of major health effects* or death are associated with inhalation (10.2%) and injection (16.5%) compared with oral ingestion (8.6%)\(^1\)

Injecting may result in rise in blood-borne infections (HIV, hepatitis C)

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Extended Release (ER) opioids are tampered with for purposes of misuse and abuse

Nonoral routes of abuse are common with ER opioids*

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Nonoral routes of abuse are common with ER opioids

<table>
<thead>
<tr>
<th>Drug</th>
<th>Oral</th>
<th>Snorting</th>
<th>Smoking</th>
<th>Injecting</th>
</tr>
</thead>
<tbody>
<tr>
<td>ER oxycodone</td>
<td>55</td>
<td>53</td>
<td>6</td>
<td>36</td>
</tr>
<tr>
<td>ER oxymorphone</td>
<td>38</td>
<td>62</td>
<td>&lt;1</td>
<td>9</td>
</tr>
<tr>
<td>ER morphine</td>
<td>47</td>
<td>25</td>
<td>&lt;1</td>
<td>46</td>
</tr>
</tbody>
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This data was collected from a sample of individuals who were at risk for opioid abuse and assessed for substance abuse treatment.
Who Is at Risk for Opioid Misuse and Abuse?
Misuse or abuse of prescription opioids can happen to anyone

~1 out of 5 patients misuse or abuse their opioid medications

Anyone, regardless of age, sex, race, ethnicity, income, or educational level, is at risk for prescription opioid misuse or abuse

Patients with chronic pain are susceptible: an estimated 50–80% of people who die from prescription opioid overdoses have a history of chronic pain

~70% of nonmedical users of prescription opioids obtain them from friends or relatives*

*Nonmedical use is defined as “using without a prescription of the individual’s own or simply for the experience or feeling the drugs caused.”
What Is Being Done to Reduce the Risk of Opioid Abuse?
Groups are taking specific actions against prescription opioid abuse

<table>
<thead>
<tr>
<th>Health care professionals</th>
<th>State government</th>
<th>Federal government</th>
<th>Pharmaceutical industry</th>
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</thead>
<tbody>
<tr>
<td>• Avoid overprescribing</td>
<td>• Prescription Drug Monitoring Programs</td>
<td>• White House Prescription Drug Abuse Prevention Plan</td>
<td>• Development of abuse-deterrent opioids</td>
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<tr>
<td>• Risk assessment for patient opioid abuse</td>
<td>• Naloxone availability</td>
<td>• FDA guidance on the development of abuse-deterrent opioids</td>
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<tr>
<td>• Patient medication/drug monitoring</td>
<td>• Targeting “pill mills”</td>
<td>• CDC draft guidelines for Opioids prescribing</td>
<td>• Nationwide education programs</td>
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<tr>
<td>• Drug abuse treatment programs</td>
<td>• Opioid prescribing rules</td>
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FDA, US Food and Drug Administration.
Groups are taking specific actions against prescription opioid abuse (cont’d)

<table>
<thead>
<tr>
<th>Law enforcement</th>
<th>Patients and advocacy groups</th>
<th>Educational institutions</th>
<th>Managed care</th>
</tr>
</thead>
</table>
| • Prevention of illegal drug distribution  
  • Appropriate disposal of opioids | • Abuse awareness  
  • Appropriate use, storage, and disposal of opioids  
  • Advocacy for patient access to medications | • Youth and teacher education, with a focus on prevention  
  • Monitoring for opioid misuse or abuse | • Patient access to abuse-deterrent opioids |
One approach health care providers can utilize to standardize their prescribing practice*

1. **Assess risk**
   - Assess how likely the patient is to abuse opioid medication.

2. **Select agent**
   - Choose the right medication for the patient. If opioids are appropriate, consider an abuse-deterrent opioid.

3. **Dialogue with patient**
   - Before starting medication, let the patient know about benefits and risks of medication through a patient written agreement.

4. **Monitor treatment**
   - Continue to see the patient to assess whether the medication works, that the side effects are minimal, and whether the patient is using the medication as prescribed.

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*Once other treatments have been tried and the decision has been made to initiate opioid therapy, a standardized set of steps should be applied to all patients. As of yet, there is no empirical evidence of the effectiveness of universal precautions in reducing the abuse of prescription opioids or the outcomes related to the misuse, abuse, or diversion of prescription opioids.
A Pharmaceutical Industry Approach: Abuse-Deterrent Opioids
Abuse-deterrent opioids are designed to provide the same pain relief, while providing an obstacle against tampering.

“One potentially important step towards the goal of creating safer opioid analgesics has been the development of opioids that are formulated to deter abuse. FDA considers the development of these products a high public health priority.”

Some examples of Types of Abuse deterrent technology:

- Physical/chemical barrier*
- Agonist/antagonist combination*

Abuse-deterrent opioids do not address all routes of abuse, but are an important approach.

Abuse-deterrent technology: physical/chemical approach

- Opioids with physical and/or chemical barriers have built-in properties that make the pills **difficult to crush, chew, or dissolve**
- This aims to **deter** abuse through **intranasal** and **intravenous** routes of administration

Several opioids with physical/chemical abuse-deterrent technology are currently on the market

Abuse-deterrent technology: example of an agonist/antagonist approach

- The agonist/antagonist combination contains an isolated antagonist (eg, naltrexone) at the core
- When taken as directed, the antagonist is not released
- Upon **tampering** (chewing, crushing), the antagonist is released and causes a reduction in euphoric effects (eg, high) of the opioid (agonist)

At least one opioid with an agonist/antagonist abuse-deterrent design is on the market
Summary

• Prescription opioid abuse is a significant public health concern with serious health and economic consequences
• Reducing opioid abuse may involve multiple approaches

Use of medications, including abuse-deterrent opioids
Prescriber education and treatment guidelines
Drug treatment programs

Reducing opioid abuse

Law enforcement efforts
Patient advocacy
State/federal efforts