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Dierks Exhibit

**25**

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PLAINTIFF TRIAL  
EXHIBIT**P-22533\_00001**

EXHIBIT

**P-CA-00816**

P-CA-000816.001

1/5



Join Pain Matters and the pain community as we reimagine the exam room experience to foster a more open dialogue between healthcare professionals and people affected by pain.

**Learn More**



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## PAIN MATTERS DOCUMENTARY



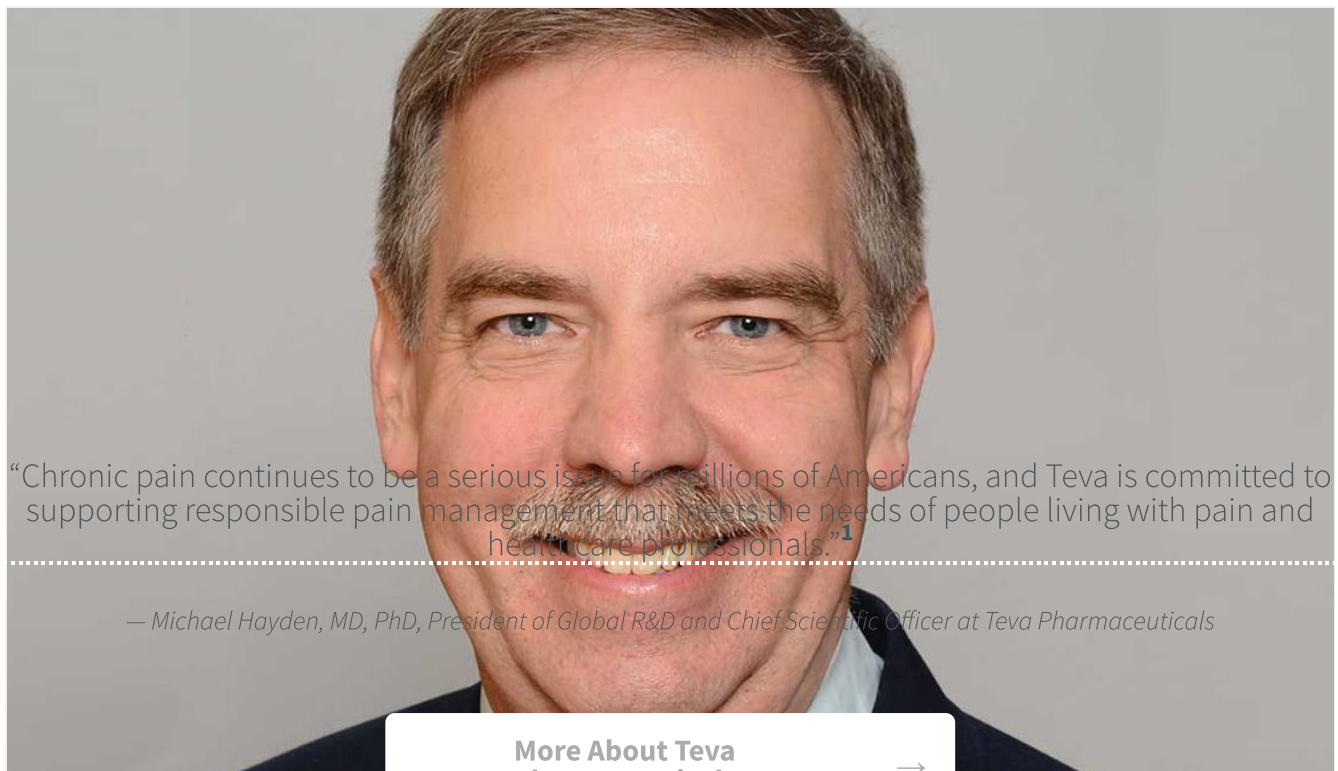
## PAIN PERSPECTIVES

### Hear from the Community



New Survey Results Address Rx Abuse, presented by Bob Twillman, PhD

Check back for regular updates from the pain community.



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# About PainMatters.com

Pain Matters was developed by Teva Pharmaceuticals to offer practical information and resources for healthcare professionals and people affected by chronic pain as they navigate the evolving and complex pain care landscape. [Pain Perspectives](#) provides regular insights from people and families affected by pain, healthcare professionals, and community advocates on a variety of pain topics. The [Pain Matters documentary](#) produced by the Discovery Channel, brings to light the impact of chronic pain on those who live with it and those who treat it. The website includes tailored content for healthcare professionals treating pain and people who are affected by pain.

## Information for Healthcare Professionals in pain care:

- [A multidisciplinary approach to pain management](#)
- [Information on opioid abuse and misuse](#)
- [Government programs and policies](#)
- Emerging [abuse deterrence technologies](#)
- [Practical tools to support your patients and your practice](#)
- [Links to advocacy and professional organizations](#)

## Support for people and families affected by chronic pain:

- Information to help you take an active role in [finding your pain management plan](#)
- Education around [prescription opioid medicines](#)
- Instructions for [appropriate use, storage, and disposal](#) of prescription opioids
- Downloadable tools such as ["Questions to ask your doctor"](#)
- Support to help you [connect to the larger pain community](#)

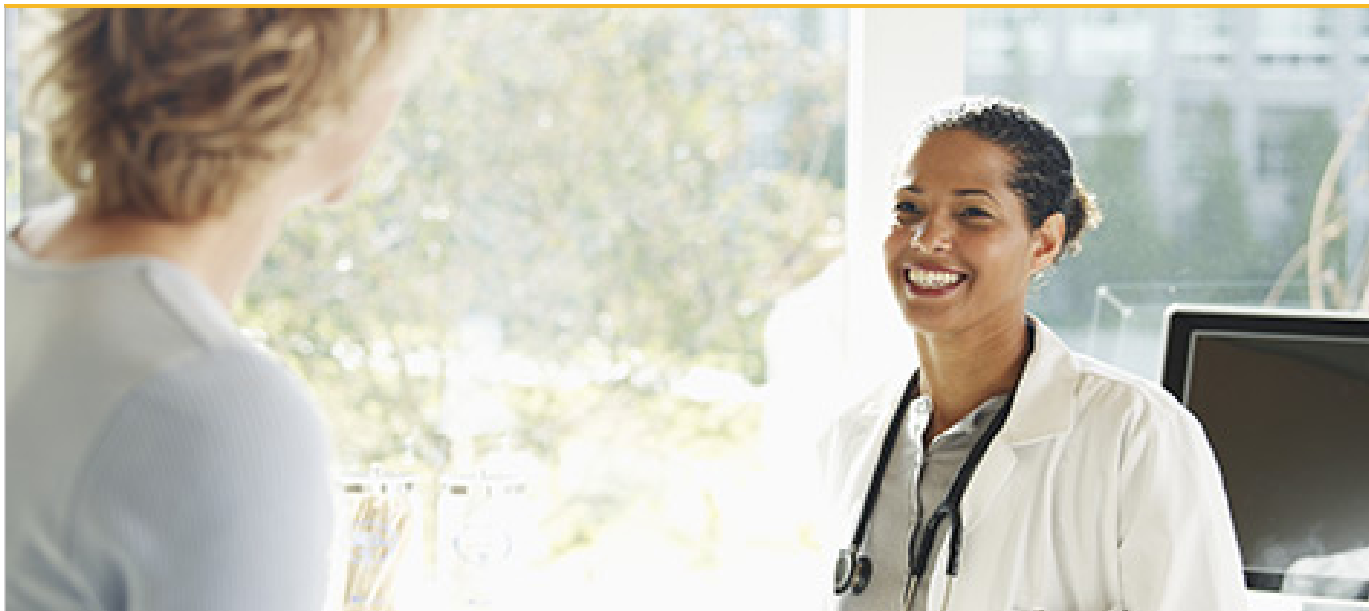
# Watch an introductory video about PainMatters.com



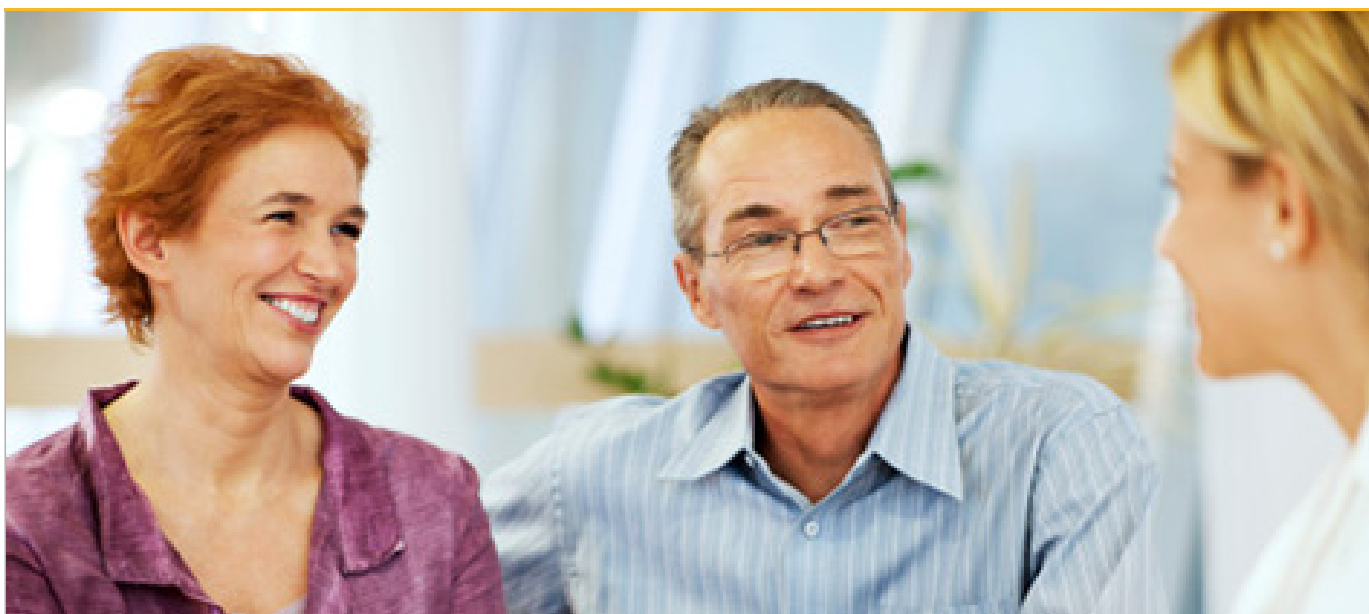
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Healthcare Professionals



People Affected by Pain

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# Be the Voice that Inspires Change

## DESIGN FOR DIALOGUE



According to recent research, both people affected by pain and healthcare professionals treating pain feel that exam room conversations can be uncomfortable.<sup>27</sup> The pressure to open up about the impact of pain on everyday life in an unfamiliar environment and discuss the risks of abuse and misuse associated with opioid

medications may contribute to the feelings of discomfort. Research shows that simple changes to the physical healthcare environment can affect people's mood and behavior.<sup>28</sup>

Design for Dialogue is an initiative intended to allow the pain community to rethink the exam room experience and design a space to help address the uncomfortable nature of these complex issues. What would the ideal doctor's office exam room look like to make you feel most comfortable?

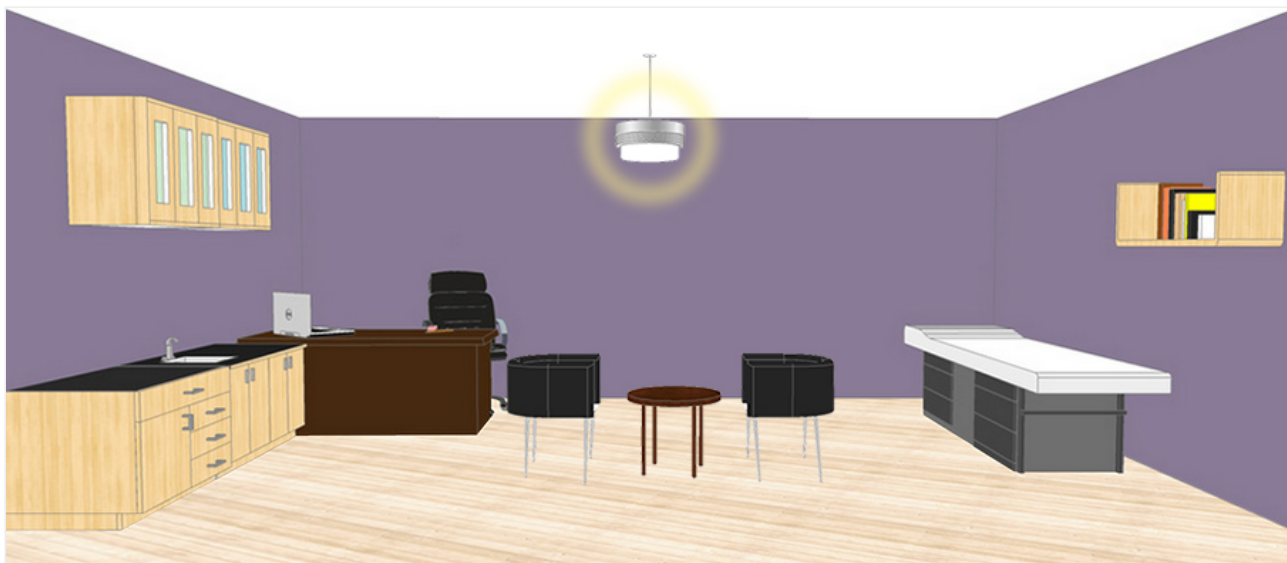
## Customize Your Ideal Exam Room



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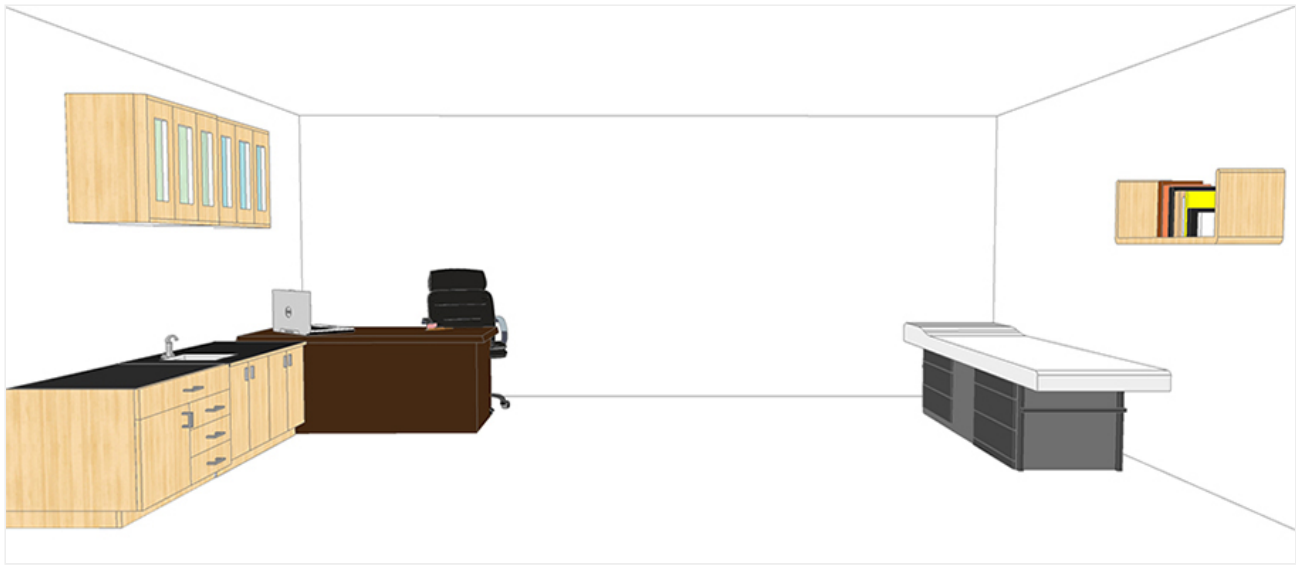
### Get Started

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1. Customize your ideal exam room by selecting:

- Wall color
- Lighting
- Furniture
- Flooring
- And resources you see most valuable



2. Share your insights into how to have a more open conversation around pain and responsible pain management under the “Resources” tab.

**Don’t forget to Save and Submit your expert perspective!**

Your experience may be showcased in 2016 to highlight the community's perspective.

**Let's Start with Wall Color** →

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Wall Color

---

Lighting

---

Furniture

---

Flooring

---

Resources

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# Pain Perspectives Community Insights

Hear insights and perspectives into today's complex pain management landscape from members of the pain community. These individuals guide you through a variety of topics through a rotating series of presentations, which are available in multiple formats, such as articles, Q&As, and videos.

July 2015

## New Survey Results Address Rx Abuse

Bob Twillman, PhD addresses the results of a new survey exploring complex issues impacting the pain care landscape.

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July 2015

## Understanding Clinical Abuse Potential (CAP) Studies

Michael J. Brennan, MD answers commonly asked questions and provides insight into the purpose and rationale for CAP studies.

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June 2015

## One Woman's Inspiring Journey with Chronic Pain

Cynthia Toussaint, founder of For Grace, shares her inspiring journey moving beyond the suffering of chronic pain and battling for grace.

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March 2015

## Welcome to Pain Perspectives

Melanie Rosenblatt, MD, provides an introduction to Pain Perspectives...

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## Pain Matters Film Clips

Short video stories from people and families affected by chronic pain.

[Watch Clips](#)

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## *Pain Matters* Documentary

Discover the impact of chronic pain through the lives of people with pain and their loved ones.

[Watch Film](#)

## Teva's Pain Care Commitment

Learn how Teva is supporting responsible pain management

[Learn More](#)

Michael J. Brennan, MD, Melanie Rosenblatt, MD, and Cynthia Toussaint have been compensated for their work on Pain Matters.

### Related Content



#### **Guidelines for Mitigating Opioid Abuse**

Opioid use and abuse guidance from state and federal governments



#### **Tools & Resources**

Find screening tools and educational resources



#### **Opioid Abuse Deterrence Technology**

Advances in technology address the challenges of opioid abuse

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P-CA-000816.022



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# Pain Matters Documentary

Produced by the Discovery Channel

Pain has reached epidemic proportions in America. Almost a third of the population—100 million people—suffer from chronic pain.<sup>1</sup> The problem is real and can impact many aspects of daily life. To take on chronic pain, you must be willing, as both a healthcare professional and a patient, to keep trying and continue searching for a treatment plan that works. This documentary offers an uplifting overview of the journeys of people dealing with a variety of chronic pain conditions and how they have managed their pain. — *Paul Christo, MD, MBA*



**Request Your Copy of the *Pain Matters* Documentary**

P-CA-000816.024

[web.archive.org/web/20150914033510/http://painmatters.com/community-engagement/pain-matters-documentary.aspx](http://web.archive.org/web/20150914033510/http://painmatters.com/community-engagement/pain-matters-documentary.aspx)

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P-22533 \_ 00024

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Financial support, clinical input and other expertise for Pain Matters were provided by Teva Pharmaceuticals. It was produced by the Discovery Channel in collaboration with seven advocacy organizations, including: American Academy of Pain Management, American Academy of Pain Medicine, American Chronic Pain Association, American Pain Society, American Society for Pain Management Nursing, U.S. Pain Foundation and For Grace.

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**Next Steps**

[Learn About Teva's Commitment](#) >

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Opioid use and abuse guidance from state and federal governments

**Tools & Resources**

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# Teva Pharmaceuticals and Pain Management

At Teva Pharmaceuticals, we understand that chronic pain affects more than 100 million Americans.<sup>1</sup> It can greatly affect people touching many aspects of their lives, including their physical health and ability to participate in daily tasks.<sup>1</sup>



## Our Commitment to Pain Care

Teva is committed to supporting responsible pain management that meets the needs of people living with pain and healthcare professionals treating pain. With a diverse portfolio and pipeline, we are working to help advance treatments in pain management. Prescription opioid medications are an important part of a treatment plan for many people living with chronic pain, but we know that they carry a serious risk of abuse and misuse.<sup>2</sup> Teva is equally committed to addressing the serious problems of chronic pain and prescription drug abuse.

As part of our ongoing commitment to support healthcare professionals and patients dealing with chronic pain, we are developing an innovative **abuse deterrence technology** platform to address the challenges of opioid abuse and misuse.

To learn more about Teva and our commitment, visit us online at [TevaUSA.com](https://www.TevaUSA.com)



## Community Collaboration

As a company, Teva takes this commitment beyond its products, leading education and abuse-mitigation efforts. We're also working to develop educational resources and partner with a variety of stakeholders. In this complex pain care environment, Teva is focused on keeping patient needs at the center of all we do.

[View Calendar](#) →

## The Alliance to Prevent the Abuse of Medicines

In 2013, Teva became one of several leading industry stakeholders including the [American Medical Association](#), [CVS Caremark](#), [Cardinal Health](#), the [Healthcare Distribution Management Association](#), [Prime Therapeutics](#), [Millennium Health](#), and [Kaleo](#) dedicated to developing policy solutions aimed to address prescription drug abuse. This non-profit partnership includes perspectives from all angles of the prescription drug supply chain—from manufacturers to distributors and pharmacies to physicians.

[Learn More](#) →

## Next Steps

[Go to Healthcare Professionals](#) >

[People Affected by Pain](#) >

### Related Content



#### Understanding Chronic Pain

Watch the *Pain Matters* documentary to learn about the impact of chronic pain



#### Tools & Resources

Use these tools and downloads to learn more about responsible opioid use



#### Opioid Abuse Deterrence Technology Guidance

Recent FDA guidance on evolving opioid abuse deterrence technology

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# Pain Community Events Calendar

At Teva, we understand the impact chronic pain has on millions of Americans.<sup>1</sup> We are committed to supporting healthcare professionals, and others who are faced with navigating the complex, evolving pain care landscape. Be sure to check back regularly as regional and national professional meetings, conferences, and events will be updated as details become available throughout 2015 and 2016.

## SEPTEMBER 2015

SEPTEMBER 8-12, 2015

### PAINWeek

*Las Vegas, NV*

## SEPTEMBER 2015

SEPTEMBER 16-19, 2015

### American Society of Pain Management Nursing National Conference

*Atlanta, GA*

## SEPTEMBER 2015

P-CA-000816.031

SEPTEMBER 17-20, 2015

## American Academy of Pain Management Annual Meeting

*Washington, D.C.*

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### OCTOBER 2015

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OCTOBER 24-28, 2015

## Anesthesiology 2015

*San Diego, CA*

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### SEPTEMBER 2016

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SEPTEMBER 26 - OCTOBER 1, 2016

## International Association for the Study of Pain 16th World Congress on Pain

*Yokohama, Japan*

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### Next Steps

[Education & Resources for People Affected by Pain](#) >

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#### Related Content



#### Understanding Pain

Watch the *Pain Matters* documentary to learn about the impact of chronic pain

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## Community Insights

Pain Perspectives—hear from the pain community



## Tools & Resources

Find screening tools and educational resources

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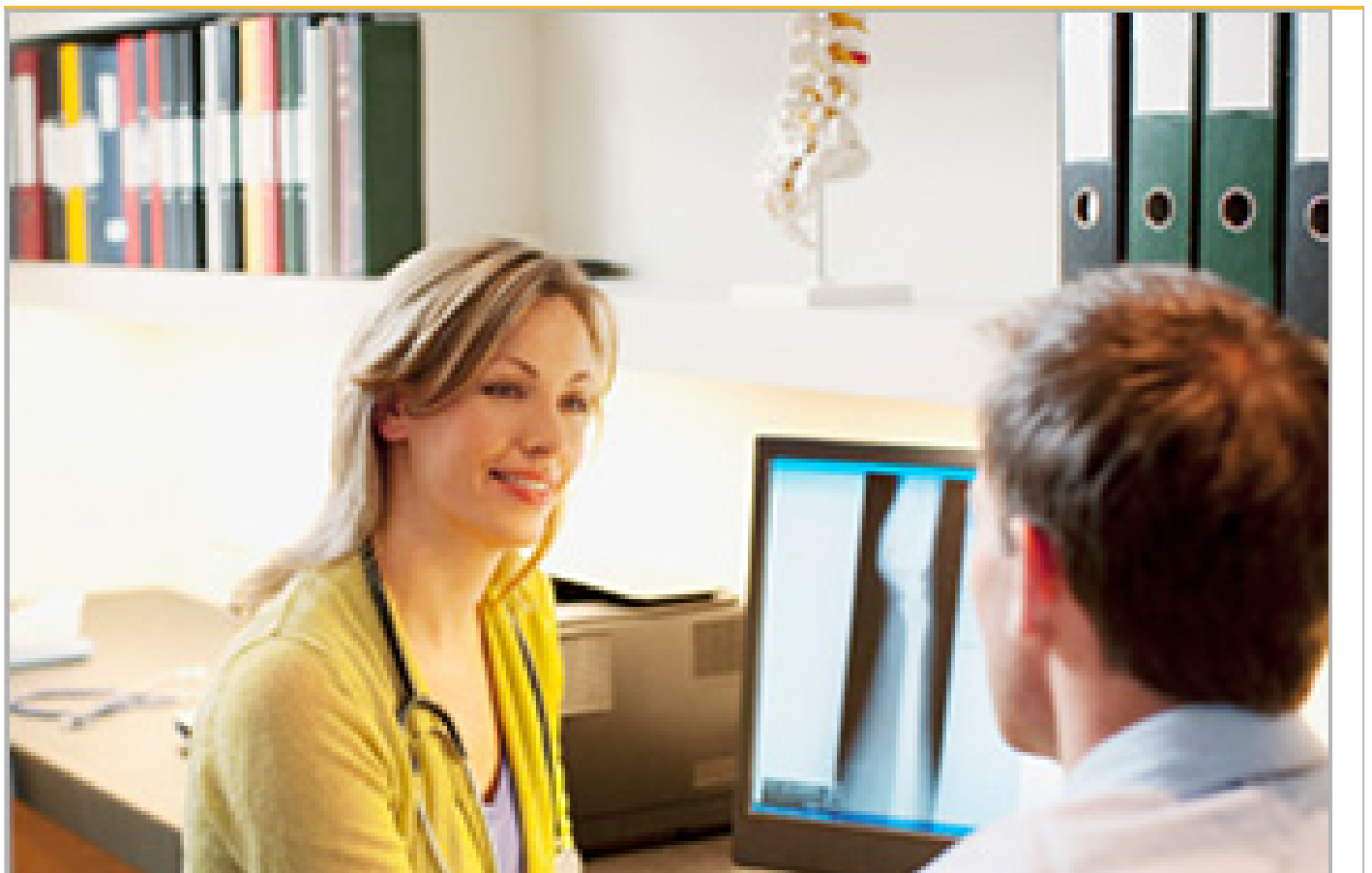
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# Evolving Pain Care in a Complex Landscape

Every patient has his or her own unique experiences with pain; therefore, a multidisciplinary approach is an important part of a patient-centered treatment plan.<sup>2</sup> Prescription drug abuse is the nation's fastest growing drug problem.<sup>3</sup> Federal and state laws and guidelines as well as evolving abuse deterrence technologies can help healthcare professionals mitigate opioid abuse and misuse within their practice.<sup>4,5</sup>





P-CA-000816.035

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# Upcoming Events

## **Pain Care for Primary Care**

*Orlando, FL*

July 23-25, 2015

## **PAINWeek**

*Las Vegas, NV*

September 8-12, 2015

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### **Next Steps**

**[Go to Multidisciplinary Pain Management](#)** >

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# A Multidisciplinary Approach to Managing Chronic Pain

While there are a variety of options available to treat chronic pain, it usually cannot be cured, only managed.<sup>6</sup> There isn't one right way to treat pain.<sup>6</sup>

## Approaches to Pain Management<sup>6,7</sup>



PHYSICAL THERAPY



SPINAL MANIPULATION



COGNITIVE BEHAVIOR THERAPY



ACUPUNCTURE

PAIN MEDICATION  
(RX AND OTC)

# Managing Chronic Pain

The pain experience is individual. Chronic pain is defined by the International Association for the Study of Pain as “a persistent pain that is not amenable, as a rule, to treatments based upon specific remedies or to the routine methods of pain control.”<sup>8</sup> It’s a serious medical condition that may greatly affect people leaving them unable to work, maintain relationships, or participate in daily tasks.<sup>1</sup>

Chronic pain can affect anyone. The Institute of Medicine estimated that 100 million American adults are impacted by chronic pain, which includes people who reported having “severe pain, moderate pain, joint pain, arthritis, or functional limitation.”<sup>1</sup>

## The Role of Opioids in Chronic Pain Management

Prescription pain medications, such as opioids, may be an appropriate treatment option for people whose chronic pain is not adequately managed by other methods.<sup>2</sup> Opioids are an important option for the treatment of certain types of chronic pain.<sup>9</sup>

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### Next Steps

[Go to Understanding Opioid Abuse](#) >

#### Related Content



##### **Tools & Resources**

Use these tools and downloads to learn more about responsible opioid use



##### **Understanding Opioid Abuse**

Statistics and insights into opioid abuse and misuse



##### **Abuse Deterrence Technology**

Advances in technology address the challenges of opioid abuse

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# Understanding Abuse & Misuse

More than 12 million people reported using prescription pain medications nonmedically in 2010.<sup>10</sup> That number encompasses both abuse and misuse. The abuse and misuse of prescription pain medications were responsible for more than 475,000 emergency department visits in 2009, a number that nearly doubled in just five years.<sup>10</sup> Further, opioid overdoses in particular are increasingly due to the abuse of prescription painkillers.<sup>3</sup>

## Abuse

**Abuse is a nonmedical use of a drug, repeatedly, or even sporadically, for the positive psychoactive effects it produces.**<sup>11</sup> The most common form of opioid abuse is swallowing a number of intact pills or tablets to achieve a feeling of euphoria.<sup>5</sup> While this is the most widespread form of abuse, opioid analgesics can be abused in a number of ways<sup>5</sup>:

- Swallowed whole
- Crushed and swallowed
- Crushed and snorted
- Crushed and smoked
- Crushed, dissolved, and injected



Percent of patients being treated with chronic opioid therapy with high likelihood of abuse/addiction<sup>26</sup>

Alcohol-induced dose dumping, or the associated intake of alcoholic beverages together with oral controlled-release opioid formulations, is another form of abuse that may result in an uncontrolled and immediate drug release.<sup>12</sup>

## Misuse

**Misuse is using the prescription drug for a reason other than for which it was prescribed.**<sup>11</sup> The key differentiator being the drug is not being used for an intentional high, so it is labeled misuse rather than abuse. Misuse can also take many forms, for example<sup>11</sup>:

- Using a drug for a different condition than that for which the drug is prescribed
- Taking more drug than prescribed or at different dosing intervals
- Using a drug not prescribed for them for other therapeutic purposes

---

## Next Steps

[Go to Stakeholder Efforts in Abuse Deterrence](#) >

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# A Multifaceted Approach to Abuse Deterrence

## Key Stakeholders Are Making Strides to Mitigate Risk

As part of the pain care community, we understand that we all have an active role to play to help advance responsible pain management and abuse deterrence.<sup>13</sup> In a recent statement on prescription opioid abuse, the FDA underscored the need to work together to invest in strategies and responsible approaches that deter or mitigate abuse while preserving access to pain medications for the patients that need them most.<sup>13</sup>



HEALTHCARE PROFESSIONALS



POLICY MAKERS



PHARMACEUTICAL INDUSTRY



ADVOCACY ORGANIZATIONS



## Healthcare Professional Training and Education

The FDA has identified three key ways prescribers can help curtail the US opioid epidemic<sup>13</sup>:

- Ensuring that they have adequate training in opioid therapy
- Knowing the content of the most current opioid drug labels
- Educating patients about the appropriate use of opioids, their potential risks, and proper disposal techniques



## Understanding Appropriate Use of Medications

It is important for people who are prescribed pain medications to understand how to appropriately use, store, and dispose of their prescription opioids.<sup>14</sup> Since many people who abuse or misuse prescription opioids are not the person the medication was prescribed to, understanding and following appropriate use, storage, and disposal instructions could help reduce the risk of abuse and diversion. The American Academy of Family Physicians has provided **general guidance and helpful tools** on the appropriate use, storage, and disposal of opioid medications.<sup>15</sup>

**Resources are available** to help educate around the appropriate use, storage, and disposal of prescription opioid medications.



## Policies and Programs Provide Guidance

There are many government **policies and programs** in place to help address the opioid abuse public health issue. Laws and policies of today must simultaneously prevent abuse, addiction, and diversion while allowing and supporting the legal use of prescription drugs by those who need them.<sup>4</sup>

## Advocacy Organizations Offer Ongoing Support

Public education programs engage local healthcare professionals and antidrug coalitions to promote and distribute public education materials supporting the appropriate use and storage of prescription pain medications and understanding of the associated risks of abuse and misuse.<sup>3</sup>

## Pharmaceutical Industry Drives Evolving Technology

The FDA also encourages the ongoing study of **abuse deterrence technologies** for prescription opioid medications. Currently, the concept of abuse deterrence is viewed as the introduction of some limits or impediments to abuse, as opposed to the outright elimination of abuse.<sup>5</sup>

At Teva Pharmaceuticals, we take our responsibility to help mitigate the risks of abuse seriously. In 2013, we partnered with five leading industry organizations across the prescription drug supply chain to form the **Alliance to Prevent the Abuse of Medicines**. We are dedicated to raising awareness of the risks of opioid drug abuse.

## Next Steps

[Go to Abuse Mitigation Programs & Policies >](#)

### Related Content



#### Managing Chronic Pain

Find information on treatment options for managing pain



#### Abuse Mitigation Programs & Policies

Opioid use and abuse guidance from state and federal governments



#### Advancements in Abuse Deterrence

New strategies address abuse potential

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# Abuse Mitigation Programs & Policies

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## The Role of Government in Mitigating Opioid Abuse

Due to the complex issues surrounding opioid abuse and misuse, various national and state programs, policies, and laws have been put in place to help mitigate opioid abuse and misuse.

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### Prescription Drug Monitoring Programs (PDMPs)

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### Controlled Substance Scheduling

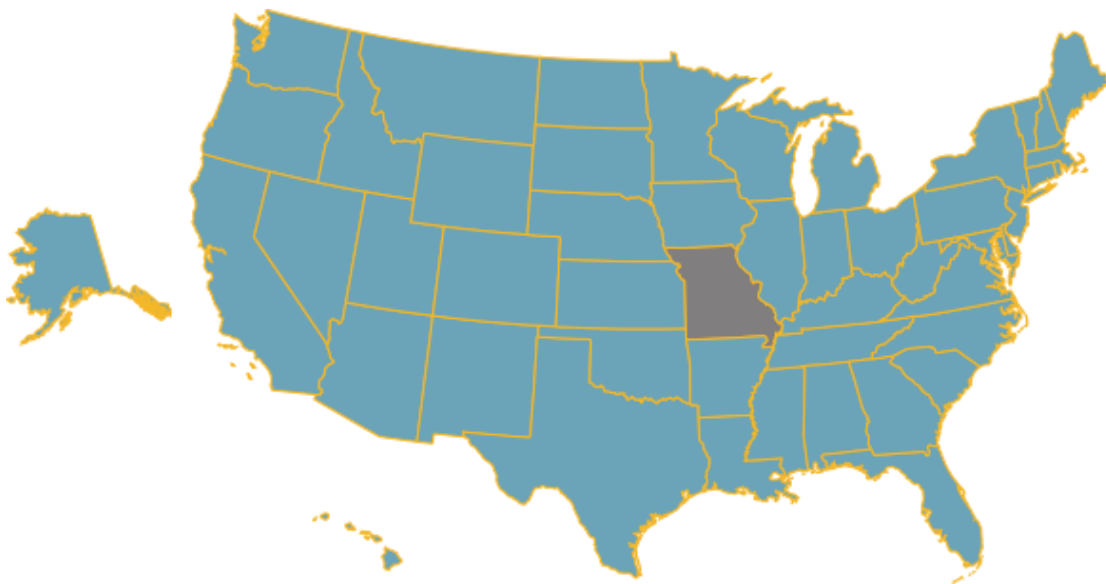
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### Risk Evaluation and Mitigation Strategy (REMS)

## Prescription Drug Monitoring Programs (PDMPs)

PDMPs are in place in 49 states to help detect and reduce the risk of diversion and abuse of prescription drugs at the practice and retail levels. These state programs allow for the collection and analysis of prescription data.<sup>17</sup> Proactive reporting through the use of PDMPs can help<sup>18</sup>:

- Alert prescribers and pharmacists to potential prescription opioid abuse or diversion among their patients
- Educate prescribers to make better decisions about prescribing controlled substances, thus improving patient care
- Provide an opportunity to intervene and refer patients for substance use disorder treatment when appropriate



## Schedules of Controlled Substances<sup>19</sup>

The DEA plays an important role in mitigating abuse and diversion of opioids. This federal agency enforces the controlled substance laws and regulations in the US, including the scheduling of controlled substances, such as opioids.<sup>19</sup> Controlled substances are classified into five categories, or schedules, according to the accepted medical use and the potential for abuse.<sup>19</sup> Schedule I drugs are considered the most dangerous, while Schedule V drugs are seen to have the least risk for abuse.<sup>19</sup> Prescription opioid medications generally fall under Schedules II and III.<sup>19</sup>

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### SCHEDULE & DESCRIPTION

I

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II

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### III

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### IV

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### V

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In addition to classifying potentially dangerous substances by schedule, the DEA's Office of Diversion Control requires physicians who intend to prescribe scheduled (controlled) medications to register in the state where they obtained a valid medical license.<sup>20</sup> The goal of this initiative is to detect and investigate diversion of controlled substances from legitimate sources while ensuring an adequate and uninterrupted supply for legitimate medical, commercial, and scientific needs.<sup>20</sup>

## Risk Evaluation and Mitigation Strategies (REMS)

REMS are requirements set by the **Food and Drug Administration (FDA)** for pharmaceutical manufacturers to help ensure that the benefits outweigh the risks for certain drugs.<sup>16</sup> There are several components of REMS that can be used by the pharmaceutical industry, including one or more of the following<sup>16</sup>:

### Medication Guides or Patient Package Inserts

- FDA-approved instructions for appropriate use and instructions for patients focused on avoiding serious adverse events

### Communication Plans

- A comprehensive plan for providing healthcare professionals with education, information, and increased awareness of risks associated with a drug

### Elements To Assure Safe Use

- Some products are required to have additional actions that healthcare professionals need to execute prior to prescribing or dispensing the drug to the patient, known as Elements To Assure Safe Use (ETASU)

### Implementation Systems

- When ETASU are required as part of a REMS program, the FDA may also require pharmaceutical companies to create a plan to ensure prescribers are complying with ETASU

## Timetables for Reporting REMS Assessments

- REMS assessments are intended to determine if the REMS requirements are proving effective. Assessment results may be used to modify the REMS, or even eliminate it, if the assessment shows changes are needed or that the REMS have met its goals

---

## Next Steps

[Go to Advancements in Abuse Deterrence >](#)

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#### Tools & Resources

Find screening tools and educational resources



#### Abuse Deterrence Technology

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# Advancements in Abuse Deterrence

## Evolving Strategies Address Abuse Potential

According to the CDC, [opioid abuse](#) is the nation's fastest growing drug problem and it ranks among the top three for prescription drug abuse.<sup>3</sup> Scientifically driven solutions are needed to help combat this serious public health epidemic, including:

- New [strategies to mitigate risk](#)
- Abuse deterrence technology, which is a modality to help reduce opioid abuse
- Continued scientific research and development of abuse deterrent technologies<sup>5</sup>

In April 2015, the Food and Drug Administration (FDA) issued a [guidance document](#) to assist the pharmaceutical industry to develop new formulations of opioid drug products with potentially [abuse-deterrent properties](#).<sup>5</sup> The FDA encourages the development of abuse-deterrence formulations and believes that these products have promise to help reduce, though not necessarily prevent, opioid abuse.<sup>5</sup> The FDA guidance document explains<sup>5</sup>:

- Current thinking about studies designed to demonstrate abuse-deterrence properties in a given formulation
- How studies will be evaluated
- Labeling claims that may be approved based on study results

# Studies Evaluate New Potentially Abuse Deterrent Technologies

In order to assess the impact of a potentially abuse-deterrent product, the FDA recommends that premarket and postmarket studies should be performed.<sup>5</sup> Data from each of the four categories are recommended.<sup>5</sup>

## Category 1

Laboratory-based in vitro manipulation and extraction studies

## Category 2

Pharmacokinetic studies

## Category 3

Clinical abuse potential studies

## Category 4

Postmarket studies

## Category 1: Laboratory Manipulation and Extraction Studies

The goal of laboratory-based studies should be to evaluate how easily potentially abuse-deterrent properties of a formulation can be defeated or compromised.<sup>5</sup> Such studies would examine how an abuser may alter the formulation to change the rate or amount of drug released.<sup>5</sup> Extractability and solubility studies should be designed to determine whether any of the formulation components might be dissolved and extracted, allowing a user to bypass the drug's abuse-deterrent properties.<sup>5</sup>

## Category 2: Pharmacokinetic Studies

The goal of the clinical pharmacokinetic studies should be to understand the in vivo properties of the formulation by comparing the pharmacokinetic profiles of the manipulated formulation with the intact formulation and with manipulated and intact formulations of the comparator drugs through one or more routes of administration.<sup>5</sup>

## Category 3: Clinical Abuse Potential Studies

Clinical Abuse Potential studies, also known as human abuse potential studies, human abuse liability studies, or “drug-liking” studies, evaluate the abuse liability or abuse potential for prescription drugs.<sup>5</sup> These studies provide information on the relative abuse potential of a drug in the same class.<sup>5</sup> Companies with abuse-deterrent formulations of opioid products are generally expected to conduct these studies to obtain an understanding of the impact of the technology on the product's abuse potential.<sup>5</sup>

### Methodology

These studies are usually conducted among experienced, recreational drug users who have a recent or current history of using a drug in the pharmaceutical class of the test drug. These studies are typically double-blind, double-dummy, placebo-controlled, and positive-comparator controlled, utilizing a crossover design.<sup>5</sup> For the study to be interpretable, the subjects should be able to reliably report “drug-liking” of the test drug and rate the effects of the test drug compared with placebo and with the positive control, such as an immediate-release formulation.<sup>5</sup>

Several instruments have been used to measure the potential for abuse including overall drug-liking, abuse, and likelihood of using the drug again.<sup>5</sup> Key instruments include<sup>5</sup>:

- Visual Analogue Scale (VAS)—a 100-point scale that measures drug-liking, overall high, good effects or euphoria, bad effects or adverse events, and likelihood of repeated use



- Profile of Mood States

## Category 4: Postmarket Studies

The goal of postmarket studies is to determine whether the marketing of a product with abuse-deterrent properties results in meaningful reductions in abuse, misuse, and related adverse clinical outcomes, including addiction, overdose, and death in the post-approval setting.<sup>5</sup> Currently, data on the impact of an abuse-deterrent product on drug abuse in the U.S. population are limited, and thus the optimal data sources, study variables, design features, analytical techniques, and outcomes of interest of postmarket epidemiologic studies are not fully established.<sup>5</sup>

## Labeling for Abuse Deterrent Opioid Formulations

Labeling for an abuse-deterrent product should include a description of the abuse-deterrent properties as well as the specific routes of abuse that the product has been developed to deter to inform health care professionals, the patient community, and the public about a product's abuse potential.<sup>5</sup> The FDA also encourages pharmaceutical companies to include the results of premarket studies in Categories 1, 2, and 3, and formal Category 4 postmarket studies.<sup>5</sup>

When premarket data show that a product's abuse-deterrent properties can be expected to result in a meaningful reduction in that product's abuse, these data are included in product labeling.<sup>5</sup> When postmarket data become available, that data may also be added to the product labeling.<sup>5</sup> If the

postmarket data do not demonstrate a reduction in abuse, or if the data demonstrate a shift in routes of abuse that represent a greater risk, the FDA may determine that labeling revisions are needed.<sup>5</sup>

For more information see the [FDA's Guidance for Industry: Abuse-Deterrence Opioids—Evaluation and Labeling](#)

---

## Next Steps

[Go to Abuse Deterrence Technology >](#)

### Related Content



#### Guidelines for Mitigating Abuse

Opioid use and abuse guidance from state and federal governments



#### Community Insights

Pain Perspectives--hear from members of the pain community



#### Managing Chronic Pain

Find information on treatment options for managing pain

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# Understanding Abuse Deterrence Technology

## Understanding Abuse Deterrence Technology and How It Works in the Changing Chronic Pain Management Landscape

Abuse deterrence technology must continue to adapt to the changing chronic pain management landscape, though this technology does not completely eliminate the risk of abuse.<sup>5</sup> Abuse deterrence technologies are just one of the measures physicians can employ to help mitigate the risk of opioid abuse and misuse. This video provides an overview of opioid abuse, including the **FDA guidance** on abuse deterrence technology.<sup>5</sup>



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## Abuse Deterrence Technology Formulations Target Known Routes of Abuse

In April 2015, the [FDA issued a guidance document](#) to assist the pharmaceutical industry to develop new formulations of opioid drug products with potentially abuse-deterrent properties.<sup>5</sup> Most abuse-deterrence technologies developed to date are designed to make:

- Product manipulation more difficult
- Abuse of the manipulated product less attractive or rewarding

**Click on a deterrence category below to learn more**

### PHYSICAL & CHEMICAL BARRIERS

## OPIOID AGONIST/ANTAGONIST

---

## AVERSION

---

## NEW MOLECULAR ENTITY OR PRODRUG

---

## DRUG DELIVERY SYSTEM

---

## COMBINATION

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## NOVEL APPROACHES

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### Next Steps

[Go to Tools & Resources](#) >

### Related Content



#### **Guidelines for Mitigating Abuse**

Opioid use and abuse guidance from state and federal governments



#### **Tools & Resources**

Find screening tools and educational resources



#### **Advancements in Abuse Deterrence**

New strategies address abuse potential

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# Tools & Resources for Managing Chronic Pain

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## Resources for Your Practice

As a prescribing healthcare professional, there are many strategies you can adopt in your practice to help decrease the likelihood of abuse. The following links provide tools and resources to help ensure responsible opioid use.

### Evolving Roles Same Goals Presentation

Based on a presentation at PAINWeek in September 2014, in Las Vegas, Nevada, and at the American Academy of Pain Management (AAPM) meeting in Phoenix, Arizona, September 18-21, 2014, this slide deck provides insight into key areas of the changing pain management landscape, including:

- An overview of the pain landscape and common routes of abuse
- The roles of key stakeholders in addressing this serious health epidemic
- Guidance provided to help mitigate opioid abuse and misuse moving forward
- Education on the evolution of abuse deterrence technology, its role in pain management, and how it helps address the challenges of opioid abuse

[View Slides](#)[Register to Download These Slides](#)[SHARE](#)

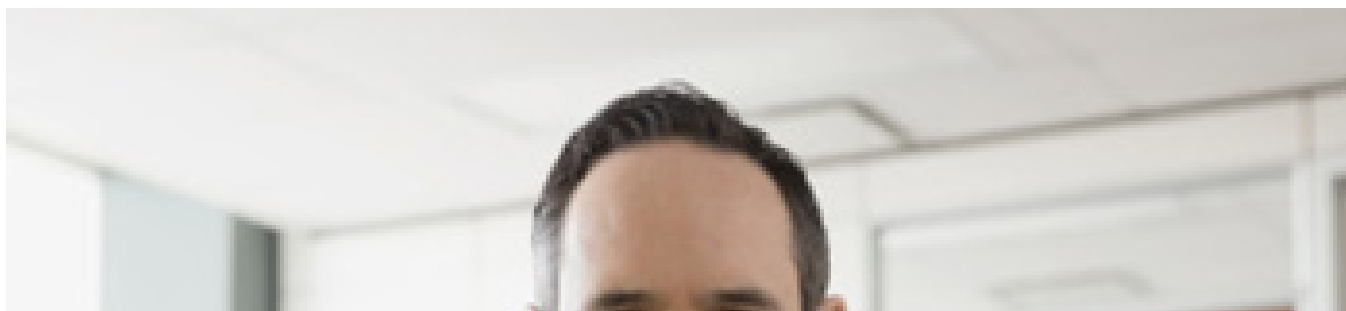
### Brief Pain Inventory

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## Exam Room Discussion Guide

Navigating the changing landscape of pain management is becoming increasingly difficult. There is a need for physicians to screen for signs of abuse and misuse and to educate patients on how to appropriately use, store, and dispose of prescription pain medications.

This brochure provided by the [Substance Abuse and Mental Health Service Administration \(SAMHSA\)](#) can help guide a discussion with your patients.

[View Guide](#)[SHARE](#)

## Diagnosing & Treating Pain

The American Pain Society has provided a comprehensive tool, “Pain: Current Understanding of Assessment, Management, and Treatments” to assist healthcare professionals in

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## Patient Screener

This screener provides an objective guide to identifying patients who may be appropriate candidates for prescription opioid medication and mitigate risk by identifying those who

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## Treatment Agreement

It's important for prescribers to build trust and foster an open, honest partnership with their patients through an understanding of the treatment goals in prescribing and taking an opioid medication. Prescriber-patient treatment agreements are available in several forms and can be customized to your practice and the laws in your state including:

- [US Department of Veterans Affairs and the Department of Defense](#)
- [American Academy of Family Physicians](#)

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## Drug Disposal Guidelines

The US Department of Justice and the Drug Enforcement Administration have provided a wealth of guidance and information for healthcare professionals and patients on the disposal of opioid medications.

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## Professional Pain Care Organizations

There are many organizations dedicated to providing ongoing education, programs, and resources for healthcare professionals and people living with chronic pain. These organizations have a commitment to furthering research and policies that shape the future of pain management.

- [The American Academy of Pain Medicine](#)
- [The American Academy of Pain Management](#)
- [The American Pain Society](#)
- [Center for Lawful Access and Abuse Deterrence](#)
- [Alliance for Patient Access](#)
- [The American Society for Pain Management Nursing](#)

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## Professional Events Calendar

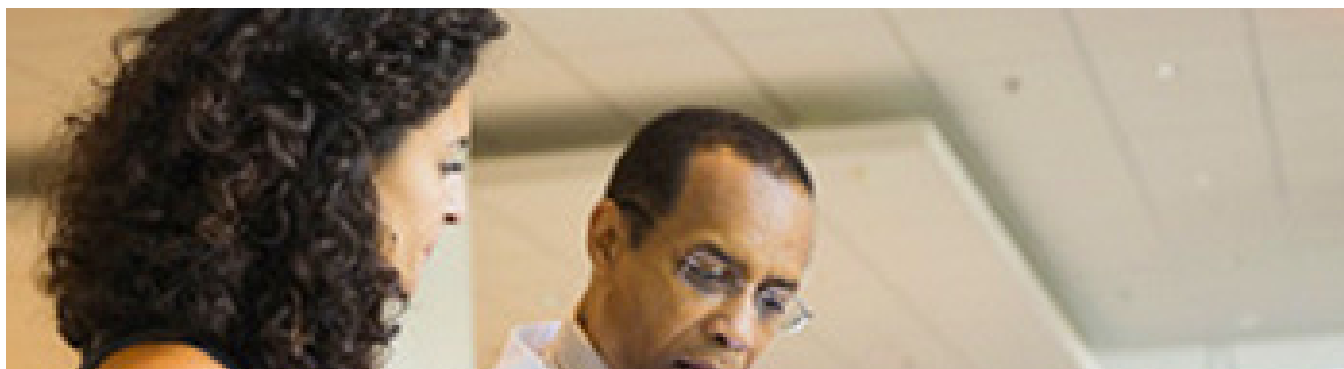
Keep track of professional meetings and events throughout 2015

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## FDA Guidance on Abuse Deterrent Opioids

In April 2015, the Food and Drug Administration (FDA) released an updated guidance document to help guide the evaluation and labeling of opioid drug products with potential abuse deterrent properties.

[Read the Full FDA Guidance](#)[SHARE](#)

### Next Steps

[Go to People Affected by Pain >](#)[ABOUT PAIN MATTERS](#)[HEALTHCARE PROFESSIONALS](#)

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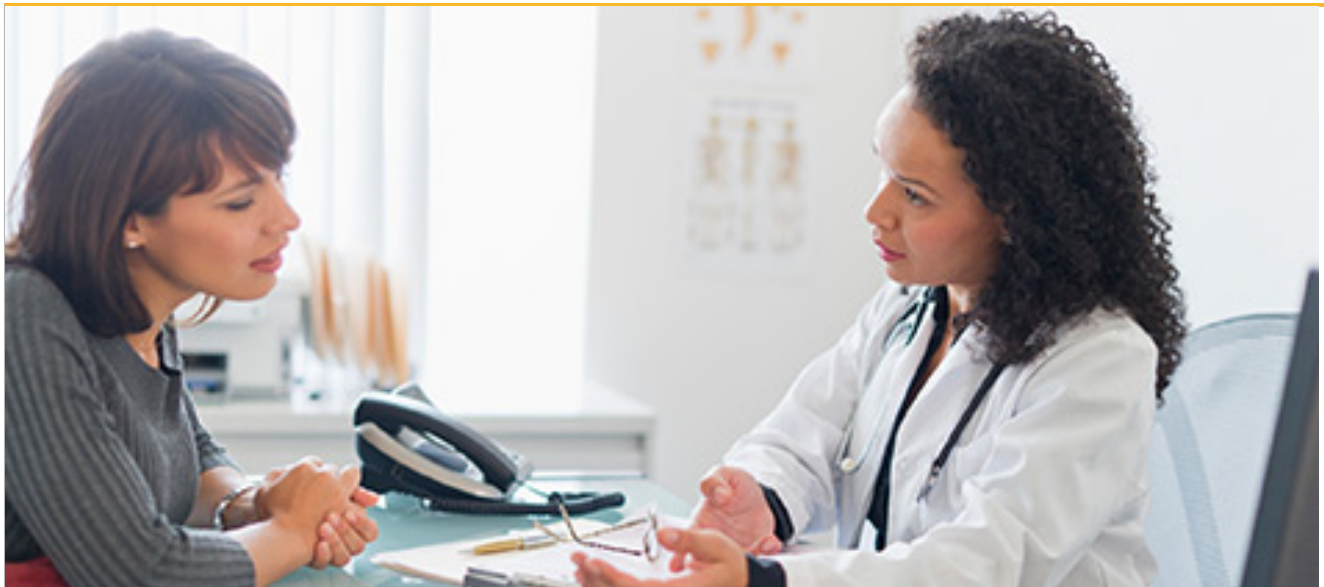
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# Finding a Pain Care Plan That Is Right For You

Chronic pain is a serious medical condition that affects approximately 100 million American adults.<sup>1</sup> Pain can impact anyone at any time, and everyone's experience is unique. It's important to understand your options and work with your doctor to determine what pain care plan is right for you.



## About Pain



## Use, Storage & Disposal



## Managing Your Pain



## Resources & Support

### Next Steps

[Go to About Pain](#) >

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# Understanding Pain



## Chronic and Acute Pain

Pain is a serious medical condition that can impact anyone at any time. Pain that lasts only for a short period of time is called acute pain; it's a normal feeling that typically alerts us to a possible injury.<sup>6</sup> Chronic pain is very different. Chronic pain is often defined as any pain that lasts for 12 weeks or longer.<sup>6</sup> According to the Institute of Medicine, chronic pain is estimated to affect approximately 100 million American adults.<sup>1</sup>

Chronic pain may be caused by an initial injury or there may be an ongoing cause, like a medical illness.<sup>6</sup> But for some people, there may also be no clear cause.<sup>6</sup> Other health problems, such as fatigue, sleep disturbance, decreased appetite, and mood changes, often accompany chronic pain.<sup>6</sup> Chronic pain may affect people's ability to participate in daily tasks.<sup>1</sup>

### Next Steps

[Go to Managing Your Pain >](#)

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## Related Content

**Understanding Chronic Pain**

Watch the *Pain Matters* documentary to learn about the impact of chronic pain

**Managing Your Pain**

Work with your doctor to find the pain care plan that is right for you

**Support for Living With Pain**

Links to advocacy and support groups for people with pain

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# Finding the Right Pain Care Plan for You



## Working with Your Doctor

How chronic pain is experienced is unique to every person.<sup>6</sup> There is no test to measure how chronic pain feels or exactly where it is located.<sup>6</sup> So, your doctor will rely on you to tell him or her how the pain feels, how often you experience the pain, and where exactly it hurts.<sup>6</sup> Defining pain as sharp or dull, constant, on-and-off, burning, or aching may give the best clues to the cause of the pain.<sup>6</sup> These descriptions are part of what is called the pain history. Your healthcare team will usually start your appointment by discussing your pain so they understand your pain history.<sup>6</sup>

## A Pain Treatment Team

Since chronic pain may occur in a variety of locations in the body and for many different reasons, it is important for you to work with your doctor to identify the causes and symptoms of your pain to find the treatment plan that works for you.<sup>6</sup> The best treatment plans are tailored to each individual person with input from healthcare team members.<sup>6</sup> It may be helpful to work with several healthcare professionals who have different training backgrounds and an understanding of chronic pain.<sup>6</sup> The person in pain and his or her loved ones must also be actively involved in the treatment plan.<sup>6</sup>

## Types of Pain Management

The overall goal of chronic pain management is to reduce the pain to help people return to daily living.<sup>6</sup> While there are a variety of options available to treat chronic pain, it usually cannot be cured, only managed.<sup>6</sup> A variety of options exist for you and your pain care team to create the treatment plan that is right for you.<sup>7</sup> These options include<sup>6,7</sup>:

- Psychotherapy
- Meditation
- Massage therapy
- Behavior modification
- Acupuncture
- Electrical stimulation
- Nerve blocks
- Surgery
- Medicines (aspirin, acetaminophen, nonsteroidal anti-inflammatory drugs, topical anesthetics, opioid medicines)

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### Next Steps

[Go to Prescription Opioid Medicine >](#)

#### Related Content



#### Talking to Your Doctor

Helpful tips on talking to your doctor about your pain and questions to ask

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## Understanding Chronic Pain

Watch the *Pain Matters* documentary to learn about the impact of chronic pain

## Use, Storage & Disposal

Appropriate use, storage and disposal guidelines for your prescriptions

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# Prescription Opioid Medicines

## What You Need to Know

Your doctor may decide to prescribe a prescription pain medicine known as an opioid.<sup>9</sup> These prescription medicines may be an appropriate treatment option for people living with chronic pain that is not adequately managed by other methods.<sup>2</sup> It's important to understand that all prescription opioid medicines have the potential to be abused and misused.<sup>10</sup> If you are prescribed a prescription opioid medicine, it is important to understand the risks and who else may be affected.

## Why does prescription drug abuse matter to me?

The person prescribed the medicine isn't necessarily the only person who is at risk for abuse. More than three out of four people who misuse prescription pain medications do so by using medication prescribed to someone else.<sup>21</sup> Some factors that may contribute to higher risk potential could include living in a household with adolescents or teenagers, living in a home with a high traffic volume of visitors or household staff, having a history of substance abuse or misuse, or living with someone who does.

## What should I know about abuse and misuse?

It's important to know the difference between prescription drug abuse and misuse to understand who may be at risk.

## Abuse

**Abuse is a nonmedical use of a drug, repeatedly, or even sporadically, for the positive psychoactive effects it produces.**<sup>11</sup> The most common form of opioid abuse is swallowing a number of whole pills or tablets for the feeling or “high” it can cause.<sup>5</sup> While swallowing pills is the most common form of abuse, prescription opioids can also be abused by being crushed or dissolved.<sup>5</sup>

## Misuse

**Misuse is using the prescription drug for a reason other than for which it was prescribed.**<sup>11</sup> The key difference in abuse and misuse is that the medicine is not being used for an intentional high, so it is labeled misuse rather than abuse. Misuse can take many forms most people may not realize is misuse, for example<sup>11</sup>:

- Using a drug for a different condition than that for which the drug is prescribed
- Taking more drug than prescribed or at different dosing intervals

## Diversion

**Diversion is a type of misuse that happens when people take prescription opioids that were not prescribed for them.**<sup>22</sup> Unaware of the dangers of sharing medications, people often unknowingly support diversion by sharing their unused pain medication with their family members.<sup>23</sup>

## What can I do to reduce the risk of abuse?

Everyone who is prescribed an opioid medicine can play a role in reducing the risk of those medicines being abused. Understanding how to appropriately use, store, and dispose of prescription opioid medicines can help decrease the chances that they will be abused or misused.

## What else is being done to reduce the risk of abuse of prescription medicines?

Because prescription drug abuse is the nation’s fastest growing drug problem, it's important for everyone involved to play a role if we are going to reduce the impact of prescription drug abuse on society.<sup>3</sup> This means that doctors, pharmacists, government policy makers, advocacy organizations, pharmaceutical companies, and people who are prescribed opioid medications must work together.<sup>13</sup>

In order to help reduce the risk of prescription opioid medicines being abused, the pharmaceutical industry is changing the way they make, or manufacture, these medicines. Abuse deterrence technologies may make it more difficult to crush or dissolve opioid medicines and may help reduce how much someone likes the drug when they use it with the intention of getting high.<sup>5</sup>

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## Next Steps

[Go to Appropriate Use, Storage & Disposal](#) >

### Related Content



#### Prescription Drug Abuse

Learn about who is at risk for prescription drug abuse and misuse



#### Managing Your Pain

Work with your doctor to find the pain care plan that is right for you



#### Support for Living With Pain

Links to advocacy and support groups for people with pain

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# Appropriate Use, Storage & Disposal

## Using Prescription Opioid Medicines Appropriately

Following guidelines on appropriate use, storage, and disposal of your prescription pain medications is important. Prescription drug abuse is a serious public health issue.<sup>3</sup> Remember, the person who was prescribed a prescription opioid medication isn't always the only one who is at risk for abuse.



### Use<sup>14</sup>

- Take medications only as prescribed
- Be aware of risks
- Understand inappropriate use
- Never give prescription medicines to anyone else



### Storage<sup>14,15</sup>

- Hide or lock up opioid medications to avoid access by family, friends, or houseguests
- Keep prescription medications in their original packaging so it is clear for whom the medications were prescribed and to save the directions for appropriate use





## Disposal<sup>15</sup>

- Opioids may be disposed of through [community-sponsored take-back programs](#)
- If there are none available in your area, follow the Office of Drug Control National Policy recommendations for [environmentally friendly disposal](#)<sup>5</sup>
- Learn more about appropriate [use, storage and disposal](#) of prescription opioid medications. Many communities also host drug take-back days to make proper prescription drug disposal easy

---

### Next Steps

[Go to Resources & Support](#) >

#### Related Content



##### Understanding Chronic Pain

Watch the *Pain Matters* documentary to learn about the impact of chronic pain



##### Resources for Living with Pain

Links to advocacy and support groups for people with pain



##### Prescription Drug Abuse

The risk of prescription drug abuse and misuse

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# Community Resources for People Affected by Chronic Pain

## Practical Resources

Finding a pain care plan that is right for you starts by working with your doctor. Find tools and resources to help you get the information you need to reduce the risk of prescription medicine abuse and misuse.

### Questions to Ask Your Doctor



Each person experiences chronic pain differently.<sup>6</sup> While you may live with the pain every

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## Assessing Pain



The feeling of pain can impact life by interfering with activities. Use the results of this assessment to help you have a clear conversation with your doctor

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[Take The Assessment](#)[SHARE](#)

## Appropriate Use and Storage of Opioid Medications

Prescription medications must be appropriately stored. They should be in a locked container that does not allow others to gain access to them.<sup>15</sup>

- **Taking opioids responsibly** from the US Department of Veterans Affairs and the Department of Defense
- **Eight Opioid Safety Principles for Patients and Caregivers** from the American Academy of Pain Medicine

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## Appropriate Disposal of Opioids

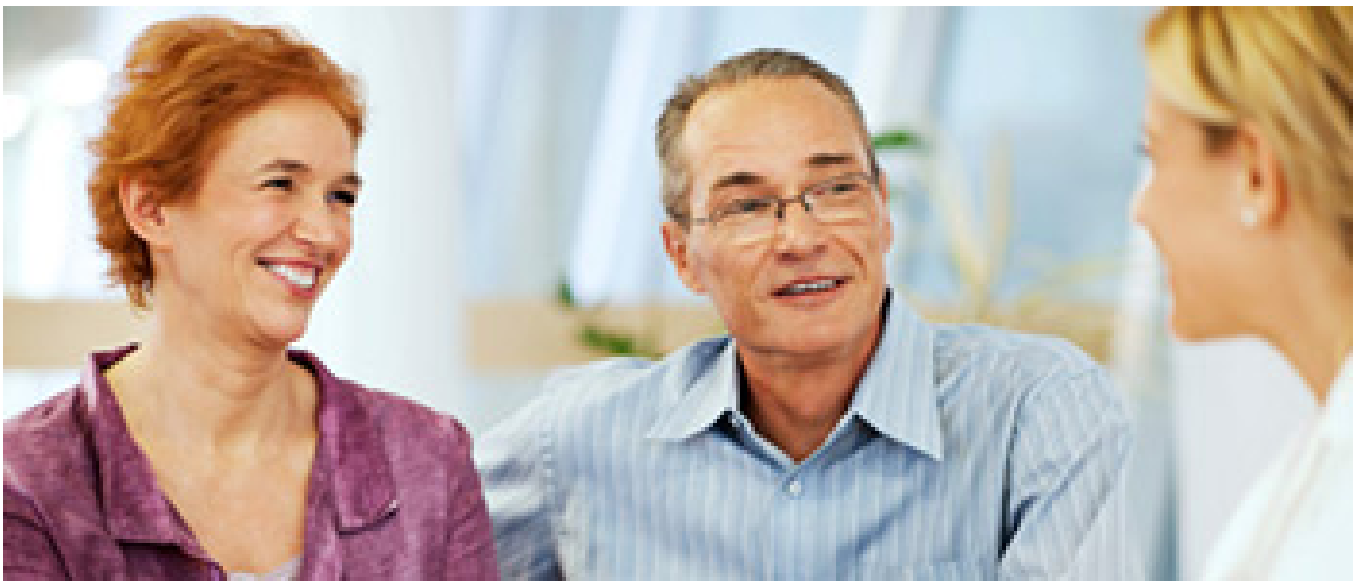
The FDA has provided a variety of downloadable resources on the proper disposal of prescription opioid medications.

Appropriate disposal of opioids resources are also available [\*\*en Español\*\*](#)

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## Pain Support & Advocacy Organizations



Several national organizations are dedicated to supporting people living with chronic pain and their families by providing ongoing education, community programs, and support research that helps shape the future of this complex condition.

- [American Chronic Pain Association](#)
- [US Pain Foundation](#)
- [Pain Action Alliance](#)

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#### Understanding Chronic Pain

Watch the *Pain Matters* documentary to learn about the impact of chronic pain



#### Tools & Resources

Use these tools and downloads to learn more about responsible opioid use



#### Appropriate Use, Storage & Disposal

Appropriate use, storage and disposal guidelines for your prescriptions

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# Glossary

**AAPManagement:** American Academy of Pain Management

**AAPMed:** American Academy of Pain Medicine

**AANP:** American Association of Nurse Practitioners

**AAPA:** American Academy of Physician Assistants

**Abuse Deterrence Technology:** The introduction of limits or barriers in a drug formulation that are designed to make abuse or product manipulation less attractive or more difficult.

**ACPA:** American Chronic Pain Association

**Alcohol-Induced Dose Dumping:** Alcohol-induced dose dumping, or the associated intake of alcoholic beverages together with oral controlled-release opioid formulations, may result in an uncontrolled and immediate drug release.<sup>12</sup>

**Appropriate Disposal:** Prescription drugs may be disposed of through community-sponsored take-back programs. If not available, environmentally friendly disposal should be undertaken per Office of Drug Control National Policy recommendations.<sup>15</sup>

**Appropriate Storage:** Keep medicines hidden or locked to avoid access by family or friends. Never share opioids with others.<sup>15</sup>

**Appropriate Use:** Take medications only as prescribed, and make sure you understand the risks. Gain awareness of inappropriate use and take precautions to avoid missteps.<sup>14,15</sup>



**APS:** American Pain Society

**ASPMN:** American Society for Pain Management Nursing

**Aversion:** It is defined by the Food & Drug Administration as “substances can be combined to produce an unpleasant effect if the dosage form is manipulated prior to ingestion or if a higher dosage than directed is used.”<sup>5</sup>

**Chronic Pain:** It is defined by the International Association for the Study of Pain as “a persistent pain that is not amenable, as a rule, to treatments based upon specific remedies or to the routine methods of pain control.”<sup>8</sup>

**DEA:** Drug Enforcement Administration

**Diversion:** Drug diversion occurs when legitimately made prescription substances are used without prescriptions.<sup>22</sup>

**Dose Dumping:** Dose dumping is the rapid release of the entire dose of a drug in a shorter time frame than intended.<sup>24</sup>

**ER Opioids:** Extended-release opioids

**Extractability & Solubility Studies:** Extractability and solubility studies assess the ease of opioid extraction from the intact and manipulated product, compared with extraction from comparator product(s) in similar states using commonly available solvents.<sup>5</sup>

**FDA:** Food & Drug Administration

**HCP:** Healthcare Professional

**In Vitro Study:** Refers to a study which examines and utilizes a whole, living organism in its natural form.

**In Vivo Study:** Refers to a study which utilizes partial organisms outside of the living body (like in a test tube).

**IR Opioids:** Immediate-release Opioids

**Misuse:** Using the prescription drug for a reason other than for which it was prescribed<sup>11</sup>

**ONS:** Oncology Nursing Society

**Opioid Antagonist:** An opioid antagonist can be added to interfere with, reduce, or defeat the euphoria (or high) associated with abuse. For example, a drug may be formulated such that the antagonist is not clinically active when swallowed but becomes active if the product is not used in its original form, such as being crushed, injected, or snorted.<sup>5</sup>

**Opioid Risk Evaluation & Mitigation Strategies:** The FDA requires a Risk Evaluation and Mitigation Strategy (REMS) program. The program is designed to make available training for healthcare professionals who prescribe opioid analgesics on proper prescribing practices. This program provides educational materials to prescribers and patients on the appropriate use of these pain medications.<sup>16</sup>

**PCPC:** Pain Care for Primary Care

**Physical & Chemical Barriers:** Physical and chemical barriers can change the physical form of an oral drug, making it less responsive to abuse. Physical barriers can prevent chewing, crushing, cutting, grating, or grinding; and chemical barriers resist extraction of the opioid using common solvents like water, alcohol, or other organic solvents.<sup>5</sup>

**Prescription Drug Abuse:** Prescription drug abuse is broadly defined as the intentional use of a medication without a prescription; in a way other than as prescribed; or for the experience or feeling it causes.<sup>25</sup>

**Prescription Drug Monitoring Program:** Prescription Drug Monitoring Programs (PDMPs) are in place in several states to detect and reduce the risk of diversion and abuse of prescription drugs at the retail level. These state programs allow for the collection and analysis of prescription data.<sup>17</sup>

**SAMHSA:** Substance Abuse and Mental Health Services Administration

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