

FDA Opioid Policy Steering Committee Public Hearing Silver Spring, MD

### Policies for Opioid Prescribing Intervention: Implications for Care of Intractable Pain Patients

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Families for Intractable Pain Relief January 30, 2018

Freedom from pain, to the extent achievable, is the most fundamental of all human rights.



# Families for Intractable Pain Relief

* **We are an advocacy and educational group comprised of Intractable Pain patients and their family members.**
* **Our goals:**
  + **Raise awareness of Intractable Pain and the challenges faced by those who suffer from it**
  + **Advocate for access to standard and non-standard pain therapies to treat Intractable Pain, including opioids and non-opioid pain medications, hormones, anti- inflammatory agents, and adjuvant treatments as appropriate.**

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# What is Intractable Pain? How does it differ from Chronic Pain?

* Intractable Pain:
  + A severe, constant pain that is not curable by any known means, causes adverse biologic effects on the body’s cardiovascular, hormone, and neurological systems, and leads to a bed- or house-bound state and early death if not adequately treated.
    - Treatment Goal: Provide life-long pain relief sufficient to normalize physiologic and mental function and enable the patient to independently carry out activities of daily living to the maximum extent possible.
* Chronic Pain:
  + Mild to moderate, irregular, recurrent, and intermittent pain that may not require daily medical treatment.
    - Treatment Goal: Total independent living and normal mental, social, and physical functions.

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# Characteristics of Intractable Pain

### Constant, excruciating, 24/7 pain

* Elevated blood pressure and pulse rate
* Poor sleep and reduced food intake
* Physical and mental incapacitation
* Underlying cause incurable, not removable
* Endocrine and immune system abnormalities
* Elevated serum inflammatory and neuroinflammatory markers

May lead to death from stroke, cardiac arrest, or adrenal failure if untreated or undertreated

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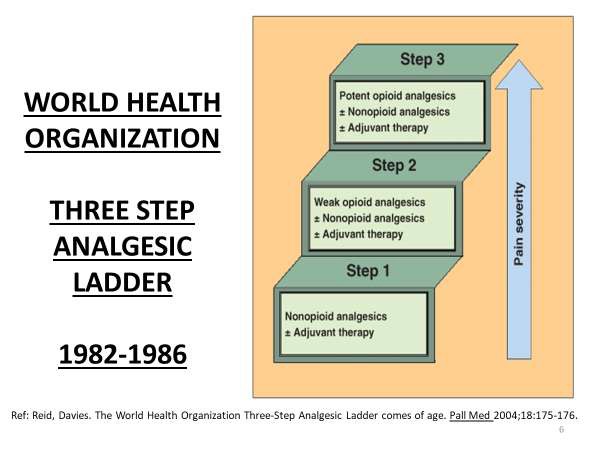
# Treatment of Intractable Pain

* All standard treatments fail
  + Standardized types and dosages of medicines, physical therapy, cognitive-behavioral therapy, and interventions such as steroidal epidural injections
* High opioid analgesic doses often required to manage Intractable Pain
  + Genetic variations cause individual differences in the way commonly used analgesics are metabolized
  + Unique, personalized medicine regimens are required which may include, as a last resort, higher dose opioids and non-standard medications.
* Centralization of pain results if pain is not adequately treated
* World Health Organization (WHO) Analgesic Ladder provides a model for care

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# WHO Analgesic Ladder



Failure of standard care in the era of the CDC Guideline: When treatment at Step 3 including opioids at 90-100 MMED fails to effectively manage pain. Failure = Intractable Pain.

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# Profile of WHO Failure Patients or Intractable Pain Patients

### Pain has centralized

* + Abnormal hormone and inflammatory markers
  + Nonfunctional, family verified
  + Genetic abnormalities
  + Sought care from multiple health facilities
  + Long list of failed therapies
  + Short list of underlying causes

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# Underlying Cause of Intractable Pain is Two-Fold

### Initial injury or disease is severe enough to cause pathologic transformation of microglial cells in spinal cord and/or brain

* + Causes neuroinflammation and constancy of pain
  + Process: “centralization” Result: Central Pain Syndrome

### Only the most serious diseases or conditions are severe enough to cause centralization

* + Adhesive arachnoiditis
  + Reflex sympathetic dystrophy
  + Post-viral neuropathy/encephalopathy
  + Traumatic brain injury
  + Genetic diseases such as Ehlers-Danlos syndrome, porphyria, sickle cell disease

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Why Treat Intractable Pain?

#### Because compassionate relief of severe long-term unrelenting pain is the right thing to do,

* Because medical management of Intractable Pain can enable a patient’s overall condition to be stabilized, while the underlying causes are identified and treatments are attempted,
* Because effective medical management of Intractable Pain can be accomplished without undue risk of such adverse outcomes as overdose, addiction, or death, and
* Because relief of human suffering should be the goal of the practice of medicine.

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1. **Specify Opioid Dose Thresholds for Justification? At What Doses for Various Clinical Indications?**

##### FIPR Position:

* Agree that documentation of medical necessity to prescribe above a single set threshold (e.g. 90 MMED per CDC Guideline) is appropriate.
* Disagree with setting different thresholds for various clinical indications.
  + Every patient is unique. A dose that works well for one patient may be inadequate for another with same diagnosis and too much for a third patient.
  + Appropriate dose should be left to discretion of qualified pain physician in consultation with patient and family.
  + Documentation should be retained in patient’s medical chart, not provided to pharmacist or insurance company.

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1. **How Ensure Compliance? How Measure Outcomes?**

##### FIPR Position:

* Disagree that additional efforts to verify compliance with documentation requirements are needed or likely to be effective.
* Disagree that new documentation requirements will bring about measurable reductions in misuse, abuse, and new addictions.
* Key point: New misusers, abusers, or addicts rarely emerge from the ranks of persons seeking care for chronic or intractable pain.
* Recommend no such efforts be undertaken. Step back from “enforcement” and focus on protecting patient access and educating the public.

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## Develop and Implement Nationwide PDMP?

### FIPR Position:

* Integration of existing state PDMPs into a single system would be a project doomed to failure.
* Development and implementation of a new national PDMP is feasible, but would be very a costly multi- year initiative; cost/benefit analysis unlikely to show potential benefit exceeds cost.
* Recommend no such efforts be undertaken. Even if found to be feasible and cost/effective, PDMP is more likely to be used as a tool for “spying” on physicians and patients in a manner that causes a chilling effect on chronic and intractable pain care.

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## Assess Impact of Nationwide PDMP?

FIPR Position:

Assessment of PDMP impacts is a very important issue!

* Doubtful that sponsors (drug companies) can make such assessments or should have that role.
* Significant failures of Federal agencies to assess unintended consequences of their actions have caused great harm to Chronic Pain Patients and Intractable Pain Patients:
  + CDC failure to assess unintended consequences of the CDC Guideline
  + DEA apparent failure to assess unintended impacts of diversion efforts
* Our expectation: PDMPs will continue to encourage overreach by DEA and state/local law enforcement agencies with a chilling effect on medical care for chronic and intractable pain care.
* Recommend policy be established that requires all PDMPs to be assessed for unintended consequences.

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## Should FDA Require More Education on Safe Storage and Opioid Risks?

##### FIPR Position:

* Disagree that a public health campaign is needed.
  + Opioid education efforts never acknowledge that opioid medications are necessary and effective for some Intractable Pain patients.
  + A public health campaign presenting a balanced view of positive patient outcomes; misuse, abuse, and addiction risks; and importance of proper storage could be very effective.
  + A simple brochure on safe disposal methods may be useful to educate post-surgical or other acute pain patients.

##### Pain physicians have, in our experience, clearly explained risks and required signed acknowledgement.

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## Should FDA Require Additional Safety Measures for Opioid Storage and Handling?

### FIPR Position:

* + Educate patients prescribed opioids for the first time on opioid risks, secure storage, and safe disposal
    - Post-surgical and other acute pain patients

### Store all opioid medications out of sight in locked cabinets

* + Communicate clearly and honestly with children, pre-teens, and teenagers about the danger of ingesting any medication that has not been prescribed specifically for them.
  + If these steps are taken, other measures may not add value.

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## Unit-of-Use Packaging Needed?

FIPR Position:

* Agree unit-of-use packaging may be useful for certain indications for acute pain.
* Unit-of-use packaging should NOT become standard for all opioid medications.
* Unit-of-use packaging is a bad idea for Intractable Pain patients:
  + Need flexibility in dosing from day to day
* Packaging adds storage volume for pharmacies and cost that will be passed on to patients.
* Recommend unit-of-use packaging be tested for selected acute pain treatment needs, but not adopted for Chronic Pain or Intractable Pain.

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## Additional Drug Take-Back Programs Needed?

### FIPR Position:

* DEA’s National Drug Prescription Take-Back Day
  + In operation for 8 years
  + Appears to work well

### Disagree that another take-back program is needed

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# Myths and Misconceptions

### Intractable Pain patients are NOT addicts

* + Intractable Pain patients do NOT fit the definition of Substance Use Disorder
  + Intractable Pain patients on high-dose opioids are NOT likely to overdose or die from their prescribed medications or to become addicted
  + Intractable Pain patients on opioids do NOT get high, do NOT appear drugged or incapacitated, are NOT impaired by their medications

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# More Myths and Misconceptions

### Intractable Pain patients on high-dose opioids:

* + Do NOT engage in drug-seeking behaviors
  + Are NOT drug diverters or drug traffickers
  + Would NEVER sell or give away their medications
  + ARE helped by their high dose pain meds
  + CAN remain on stable high opioid doses for years
  + ARE able, with doses sufficient to control and manage their pain, to regain function, enjoy participation in life, and achieve greatly improved quality of life
  + ARE able to again become functional family members and productive citizens
  + ARE enabled, not disabled, by opioid pain medications!

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# Who Are Intractable Pain Patients?

**What Are They Like?**

##### Doctors, pharmacists, lawyers, nurses, writers, master craftsmen and tradesmen, IT specialists, government workers, musicians, business owners, HR specialists, account executives, athletes

* + - Not dead-end people with nothing going for them
    - Just regular folks whose lives have been hi-jacked by an illness, injury, or accident that left them with Intractable Pain
    - Don’t fool yourself – it could happen to you!

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**Continued Access to Opioid Pain Medications: The Issues at Stake for Intractable Pain Patients**

### The right to life, liberty, and the pursuit of happiness

* + Impossible to “live” your life when excruciating pain keeps you on the couch
  + Impossible to feel at liberty when chained to the bed by unrelenting pain
  + Impossible to pursue happiness when every waking moment is dominated by suicidal pain

### The right to be free from cruel and unusual punishment

* The right to equal treatment

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## Continued Access to Opioid Pain Medications: The Issues at Stake for Intractable Pain Patients

##### We, Families for Intractable Pain Relief, assert and insist that:

* + It is impossible to experience “life, liberty, and the pursuit of happiness” when Intractable Pain is undertreated.
  + Freedom from pain, to the extent achievable, is the most fundamental of all human rights.
  + Withholding or withdrawing readily available and effective pain treatment from a person suffering Intractable Pain is equivalent to the commission of torture.
  + You are accountable!

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**What Can FDA Do?**

* Hold focus groups around the country to talk to Intractable Pain patients and family members. Include FDA senior leadership! Listen to patients and families. Listen to us!
* Help to change the public narrative by acknowledging the existence of Intractable Pain!
* Establish through regulation a means to protect Intractable Pain patients from loss of care, e.g. Intractable Pain patient identification program.
* Establish a training and licensing program to enable community-based doctors to treat Intractable Pain patients, including authority to write whatever doses of opioids are necessary, with no specific threshold to restrict them.
  + Program should be open to internal medicine specialists and primary care physicians
* Stop causing harm through inaction and denial of care!

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