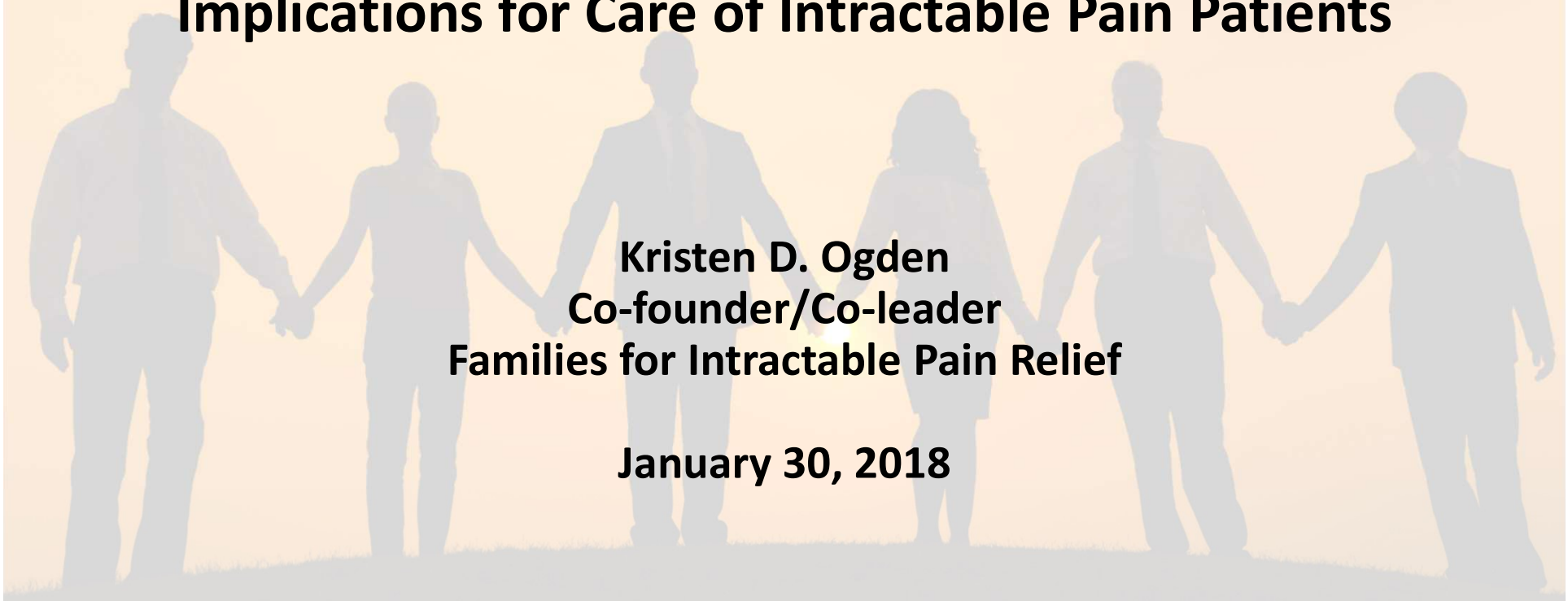
FDA Opioid Policy Steering Committee Public Hearing

Silver Spring, MD

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



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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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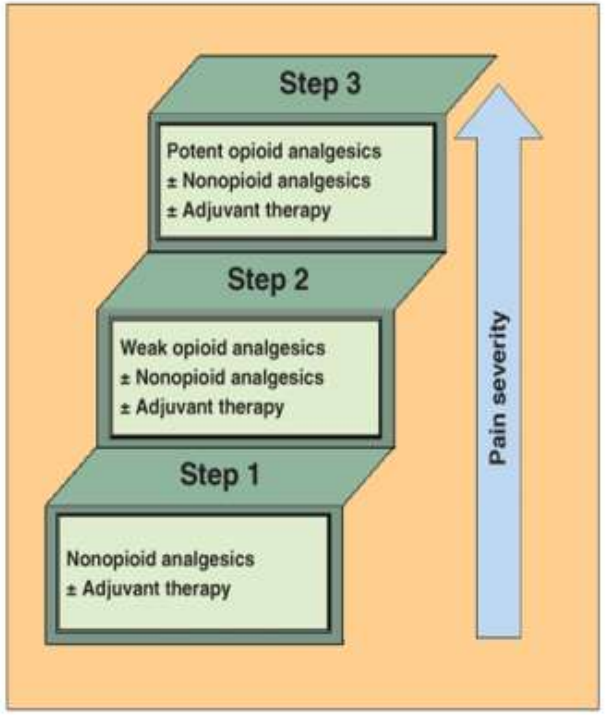
WHO Analgesic Ladder

WORLD HEALTH ORGANIZATION

THREE STEP ANALGESIC LADDER

1982-1986



Ref: Reid, Davies. The World Health Organization Three-Step Analgesic Ladder comes of age. Pall Med 2004;18:175-176.

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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2. 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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3. 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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4. 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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5. 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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6. 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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7. 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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8. 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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