The Appropriate Management of Opioid Therapy

C. Scott Anthony, DO

No Disclosures

Objectives:

- Develop an understanding of established guidelines and current literature concerning the balanced approach to management and risks of opioid therapy
- Gain knowledge in the risk assessment of the chronic pain patient and the appropriate management of these patients in a multi-modal treatment plan
- Better understand the implications of SB 1446 and 848 in the management of chronic pain and how it impacts your practice
- Review appropriate risk mitigation strategies to avoid abuse and diversion

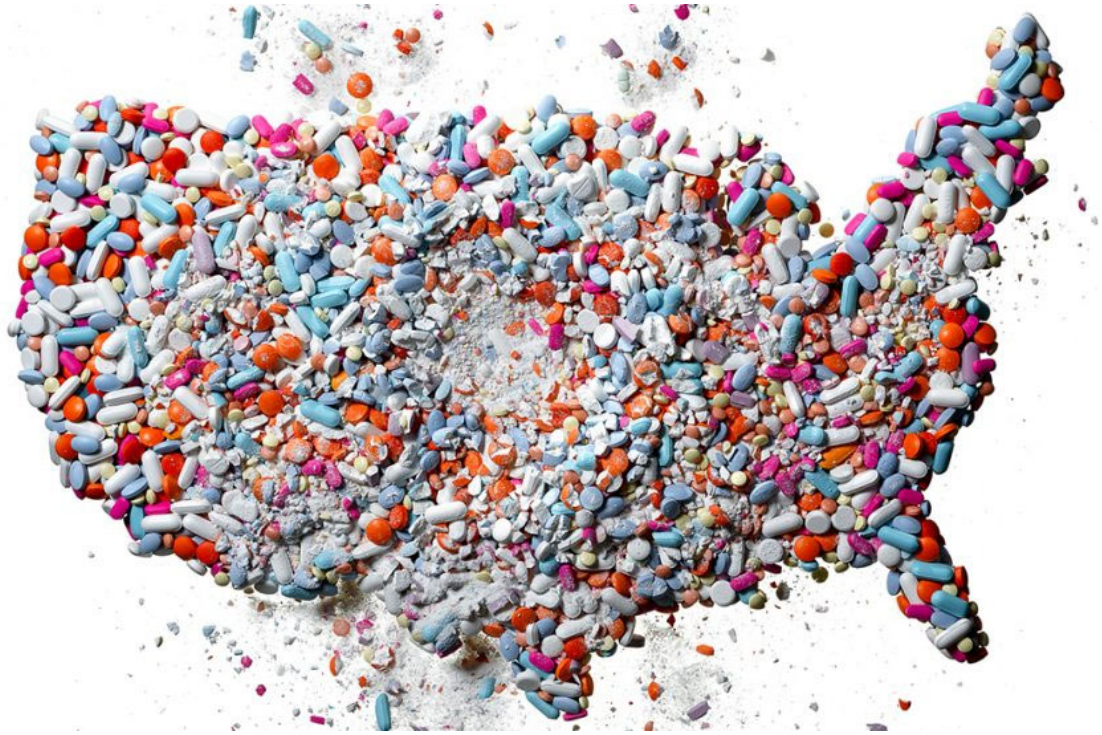
“The ongoing opioid crisis lies at the intersection of two substantial public health challenges - reducing the burden of suffering from pain and containing the rising toll of the harms that can result from the use of opioid medications”

HHS 2019. “Pain Management Best Practices”

The “Painful” Origin:

1995-2010

- Physician education
- “Under treatment” of pain
- Addiction less than 1%
- Big pharma and opioid sales
- 5th vital sign
- Pain scores
- Pill mills



Factors Leading to Inadequate Management:

- Physician lack of knowledge in best clinical practices
- Treating pain as a “symptom” and not as a disease state
- Lack of multi-modal treatment
- Not appreciating the “serious nature” of this therapy
- Poor understanding of risk mitigation
- Physician misunderstanding of risks including dependency and addiction
- Complete relief of pain is most likely not attainable

CDC: Unintended Consequences of 2016 Guidelines

- Recommendations were voluntary and intended to be flexible
- Rigid policies regarding MME
- Extension to patient populations not covered by the guidelines
- Some policies have been notably inconsistent
- Rapid tapers, duration limits and abandonment (FDA warning 2019)
- Applied to OUD treatment

“These actions are not consistent with the guidelines and have contributed to patient harm, under treatment, withdrawal, psychological distress, overdose and suicide”

2022 CDC Opioid Prescribing Guidelines

The Forgotten Patient:

- Previous guidelines did not address these vulnerable patients
- Compliant and functional on opioids
- Often higher dose therapy
- Long-standing opioid therapy
- Often exposed to forced tapering or abandonment with withdrawal
- Increased risks of psychological distress, overdose and suicide

Emphasis of the 2022 CDC Guidelines

- Not a replacement for clinical judgement
- Emphasizes individual care
- Not intended to be applied as an inflexible standard of care
- Focus on initiation, patient selection, duration and follow up
- Not intended to be a law, regulation or policy to dictate care

2022 CDC Guidelines: Emphasis on Patient

- Patient selection
- Understanding various pain states
- Understanding high dose opioids
- Having an “exit plan”
- Guidelines for tapering
- Avoiding abandonment
- Awareness of OUD and misuse

Factors Contributing to Prescription Opioid Reduction:

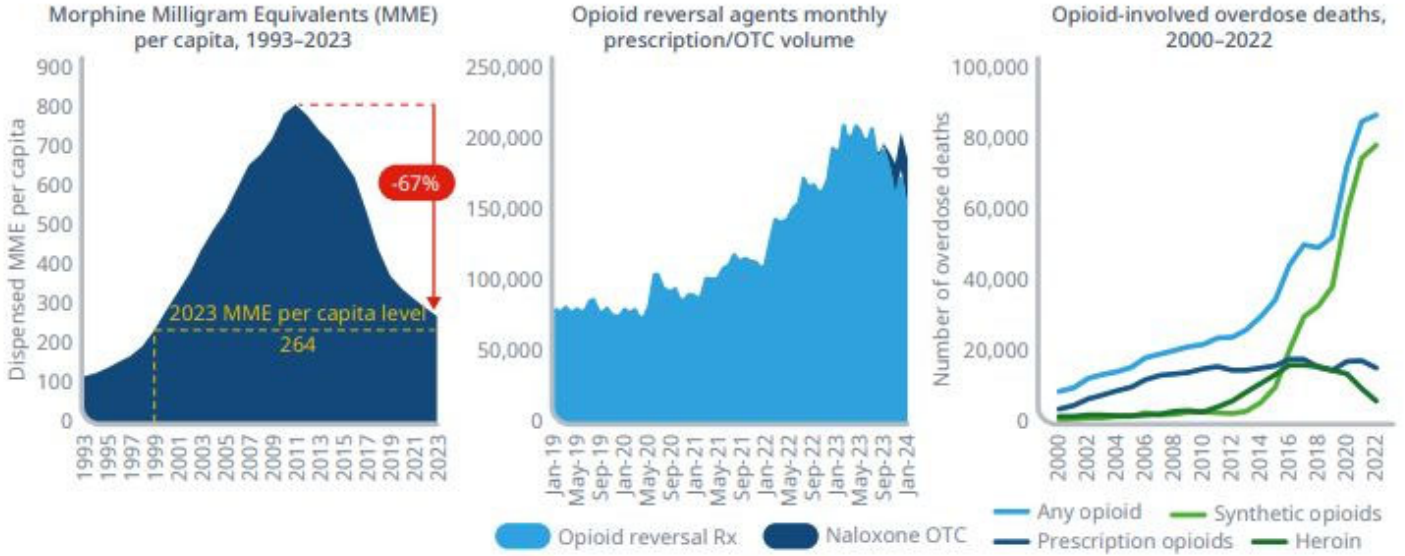
- Awareness and education
- Regulatory oversight
- Much better understanding of high dose opioids
- Increased vigilance and monitoring targeting misuse
- Better awareness of misuse and addiction
- Fear and frustration

Encouraging Trends:

Prescription Opioid Use

Per capita prescription opioid use has declined to levels last seen in 2000, while overdose deaths continue to rise

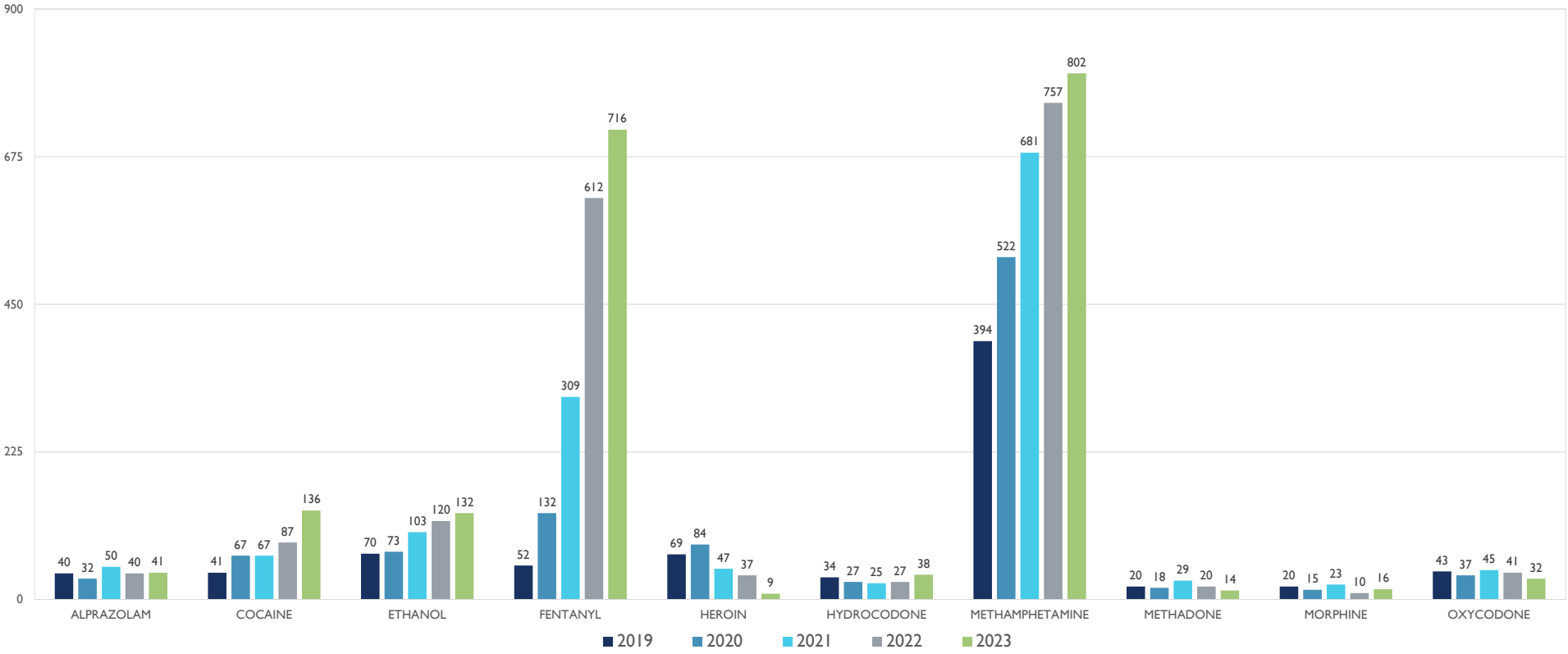
Exhibit 17: Prescription opioid use overall, opioid reversal medication volume, and opioid-involved overdose deaths



Source: IQVIA Xponent, IQVIA National Prescription Audit, Dec 2023; IQVIA Institute, Mar 2024; National Institute on Drug Abuse, Feb 2024.

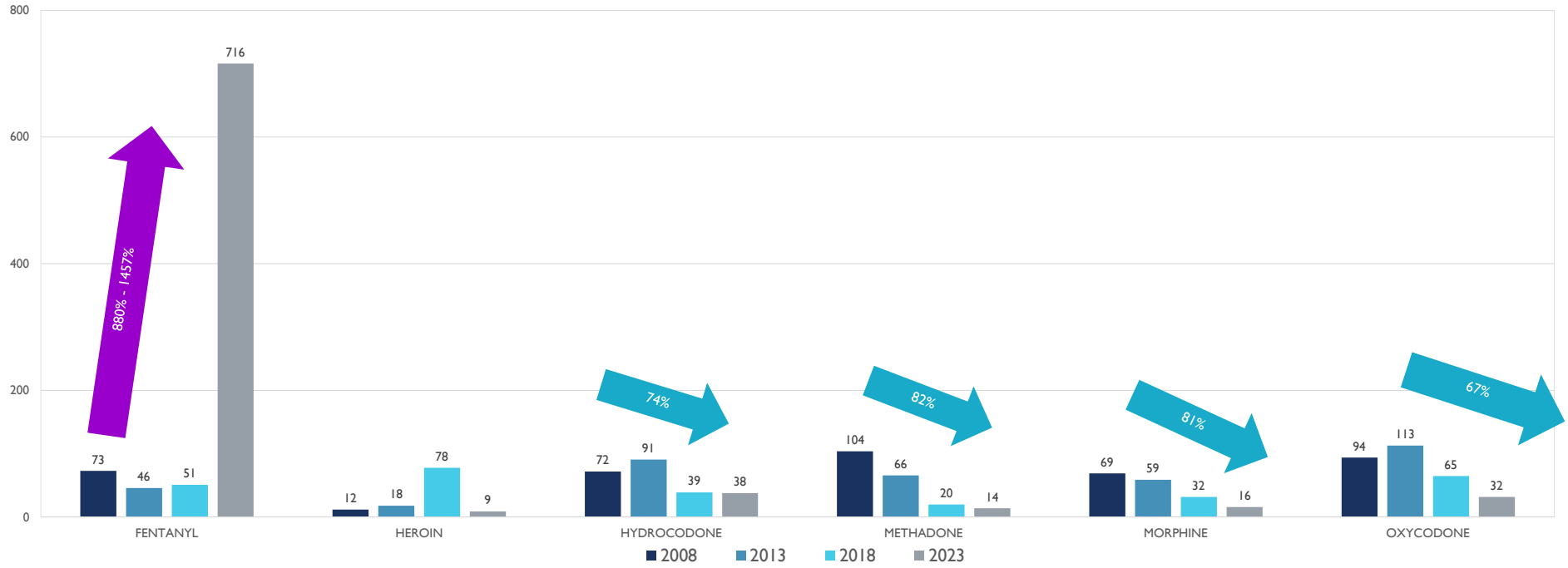
Top 10 Drugs Listed as Cause of Death

OCME Opioid Death Investigations 2024



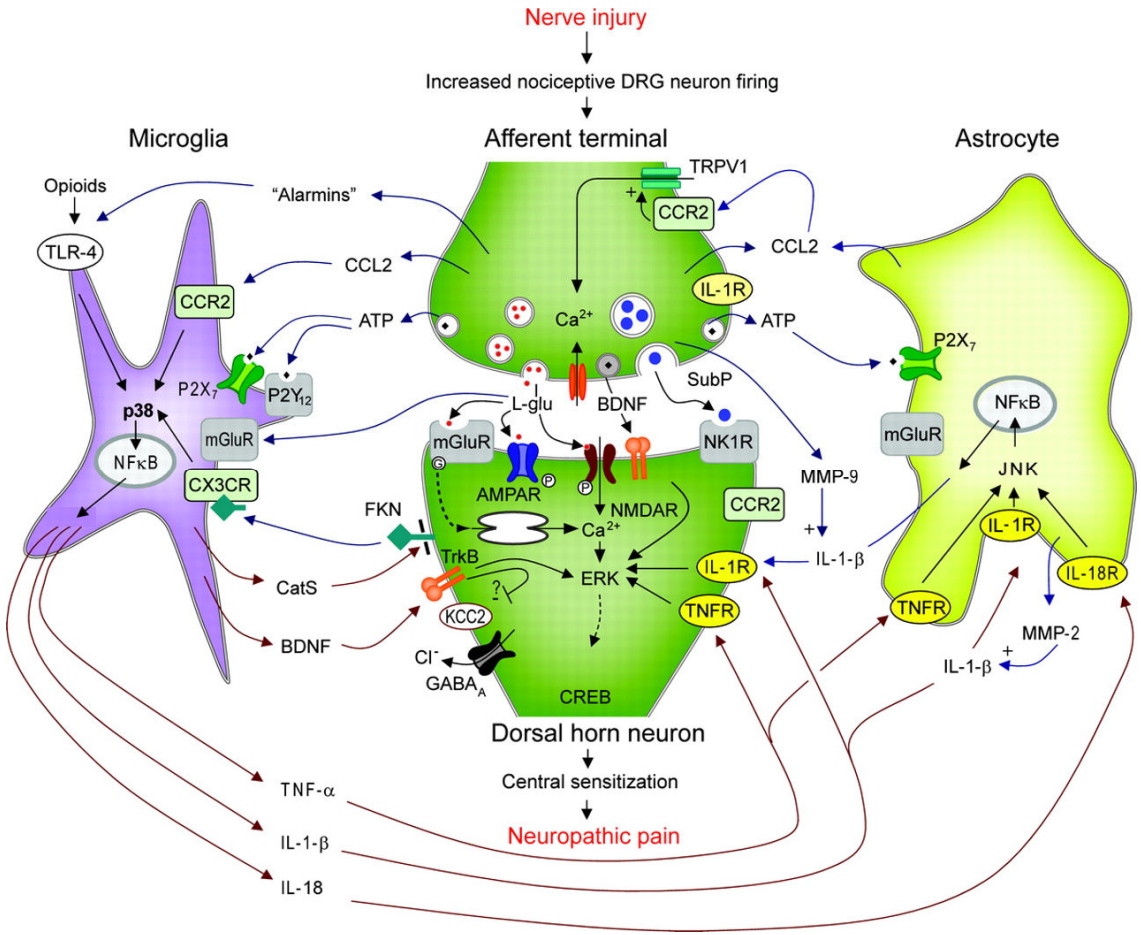
Opioid Deaths 2008-2023

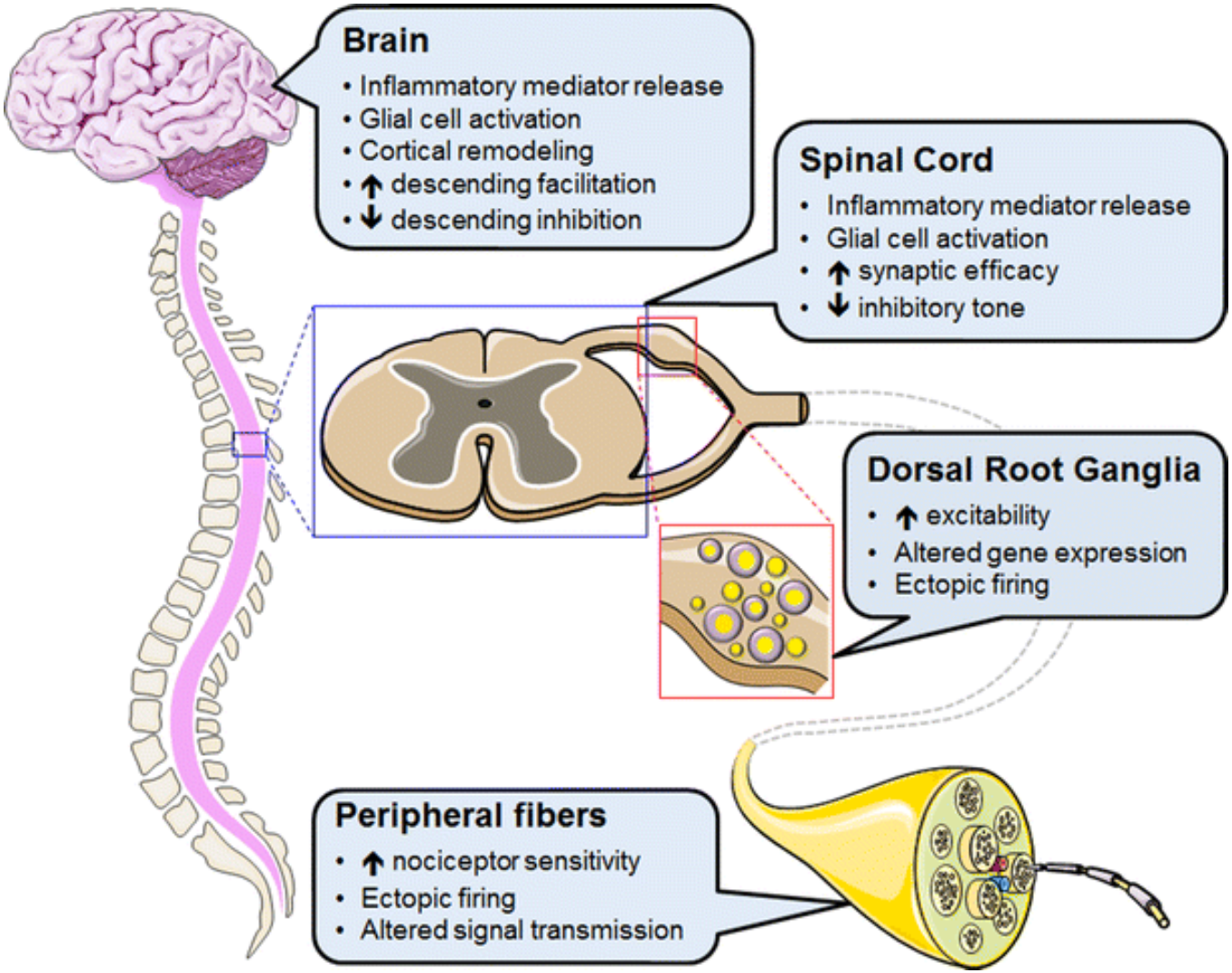
OCME Opioid Death Investigations 2024



Pain:

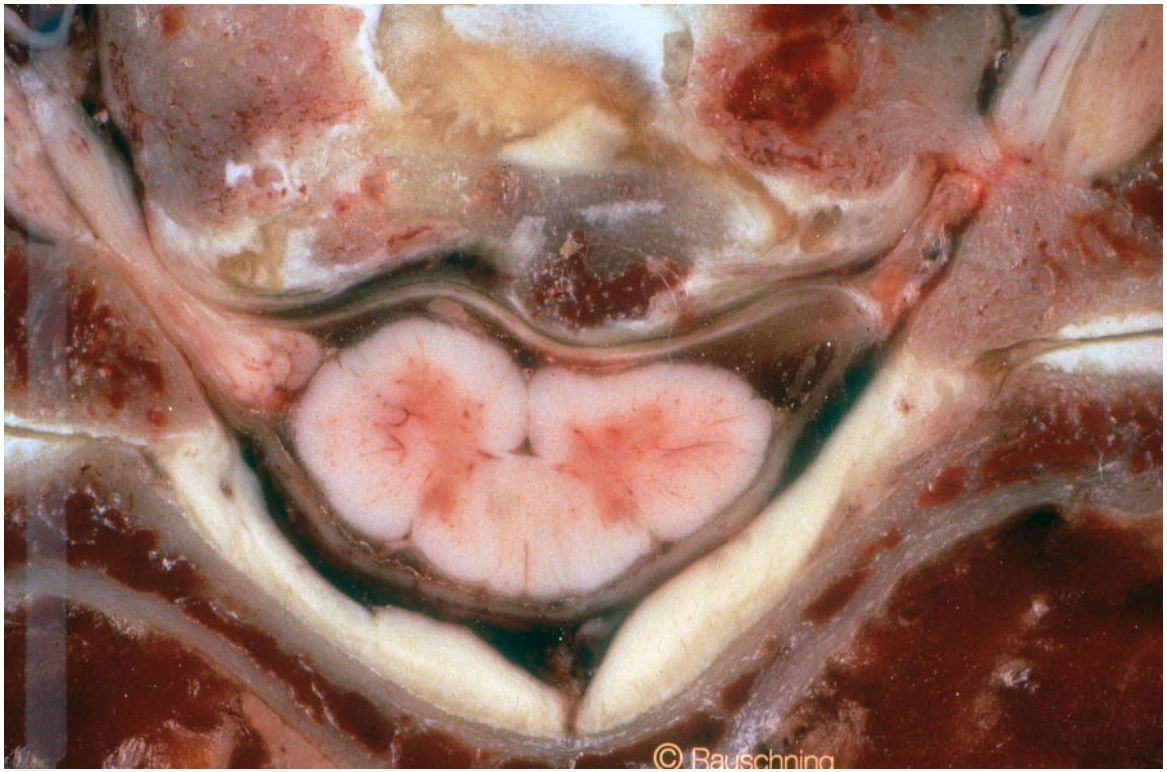
A physiologic response to a noxious stimuli that can become pathologic

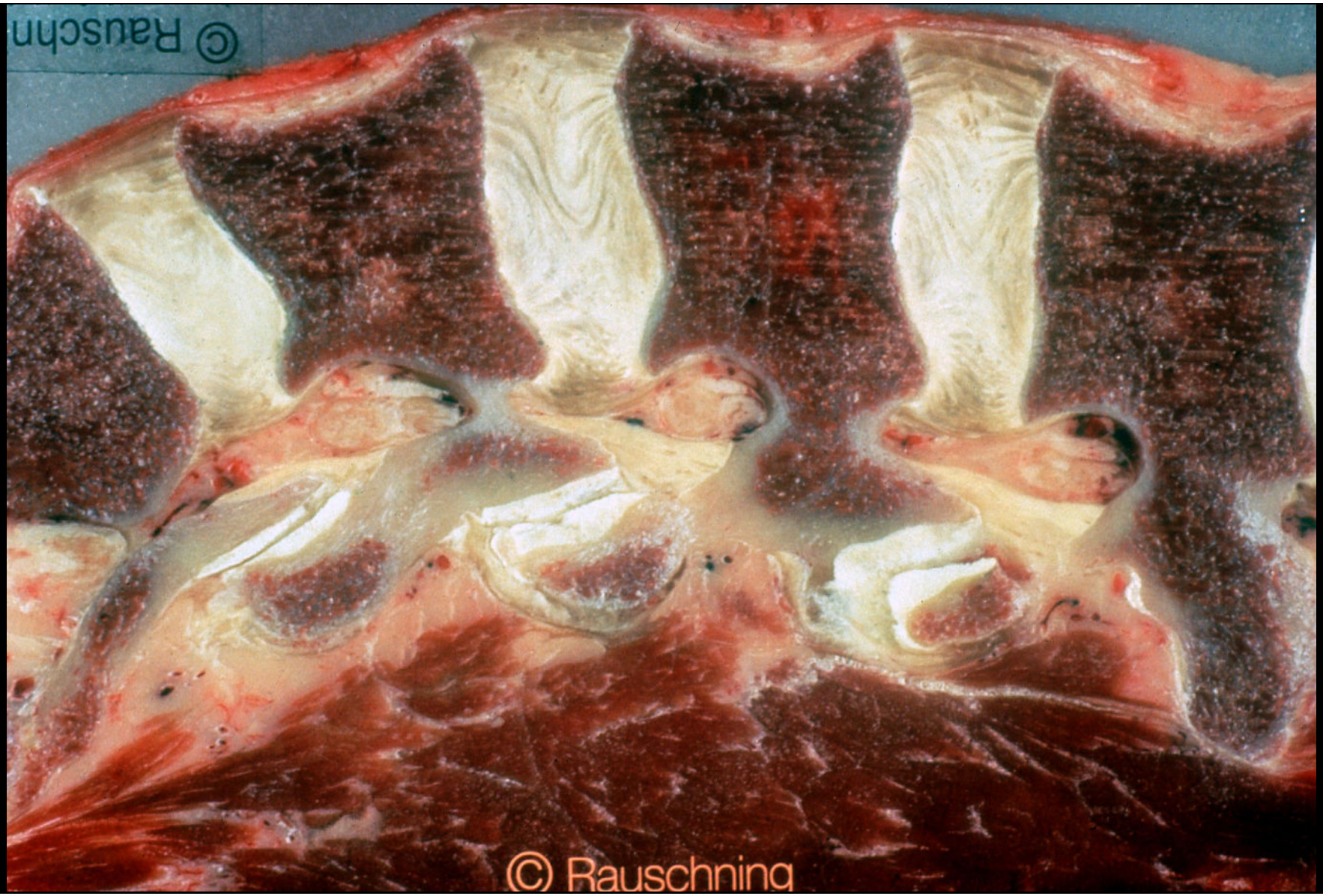



Brain
• Inflammatory mediator release
• Glial cell activation
• Cortical remodeling
• ↑ descending facilitation
• ↓ descending inhibition
Spinal Cord
• Inflammatory mediator release
• Glial cell activation
• ↑ synaptic efficacy
• ↓ inhibitory tone
Dorsal Root Ganglia
• ↑ excitability
• Altered gene expression
• Ectopic firing
Peripheral fibers
• ↑ nociceptor sensitivity
• Ectopic firing
• Altered signal transmission

What is the Diagnosis?

- Not as simple as “chronic neck pain”
- What are we actually treating?
- “Work up” the pain complaint
- Important for determining patient selection for appropriate therapy
- Important for documentation
- Very common error




© Rauschning

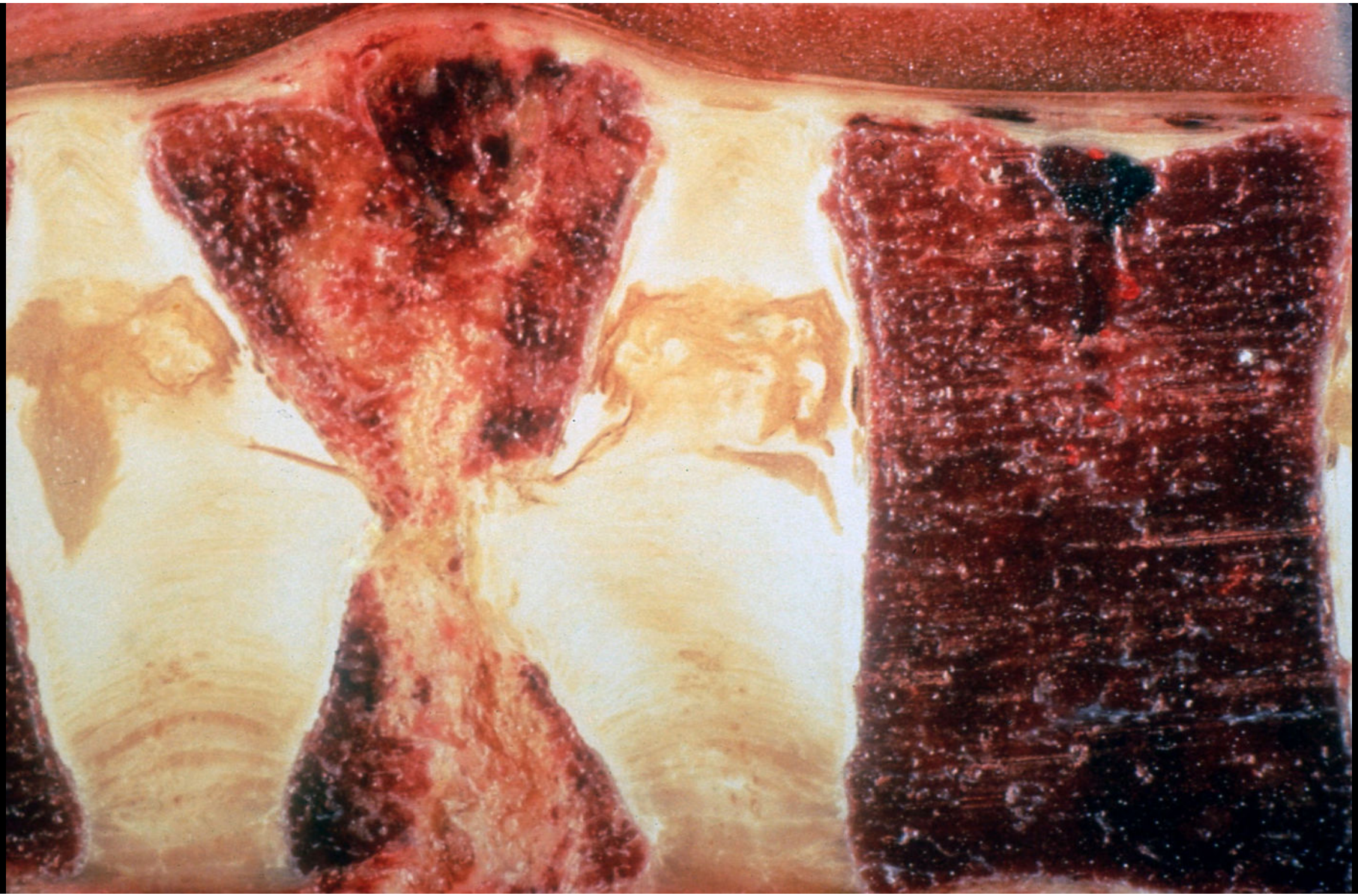
First Line Approach

- Need to document therapies that patient has attempted
- Non-opioid approach
- Emphasis on
  - Behavioral therapies
  - Functional therapies
  - Adjunctive medications
  - Interventional therapies

The Decision to Start, Escalate or Continue Opioid Therapy

Opioids for Acute Pain

- Differences of acute vs. chronic pain
- Typically no central sensitization
- Most commonly inflammatory nociceptive pain
- Acute neuropathic pain often better managed with adjunctive medications
- There are still known risks utilizing opioids for acute pain including addiction
- Caution with patients having known SUD or OUD



Prescribing Opioids for Acute Pain

- A major emphasis in SB 1446/848
- Goal is to limit quantity and use lowest effective dose
- Initial prescription not to exceed 7 days and must state “acute pain”
- Document rationale for script and caution of addiction and risks
- Check the PMP
- 2nd 7 day script after visit or phone call with documentation of rationale unless confined
- PPA required after 3rd prescription or if the patient is a minor, pregnant or using benzodiazepines

Opioids For Chronic Pain:

- Chronic pain is highly complex and challenging
- Person centered care base on trust
- Opioids ***alone*** are often inadequate (mild-moderate)
- Opioids can be essential medications for pain but can carry considerable risk
- Best outcomes are in a multi-modal setting
- Often the ***only*** remaining option for some patients

Important Opioid Caveats:

- Insight based on available evidence:
  - **Opioid use may be the most important factor impeding function recovery**
  - **Opioids may not consistently relieve pain and can decrease quality of life**
  - **Routine use of opioids cannot be recommended**
- ***Appropriate only for selected patients with moderate-severe pain that significantly affects quality of life***

Patient Selection and Risk Stratification:

- History, physical examination and diagnostic testing
- Documentation of previous modalities and therapies
- Psychosocial risk factor screening
- Controlled substance agreement depending on several factors
- Ongoing assessment of patient for abuse
- Expectations: Patient ***and*** physician

Documentation:

- Required by state law (SB 1446/848)
- Carefully document decisions to start, continue or increase opioids
- Document the rationale for the prescription after history and physical exam
- Document discussion of risks to include addiction, overdose and death
- Make a point of documenting normal/abnormal monitoring and rational for changes
- With electronic charts this can be a trap
- Documentation is ***very*** important to those who review charts

Documentation Required SB 848:

- Any new information about the etiology of pain
- The course of treatment including various non-opioid modalities attempted
- Progress of the patient toward treatment goals
- Monitor risk and compliance with the PPA
- Periodically make reasonable efforts, unless clinically contraindicated, to stop the controlled substance, decrease the dose or try other modalities
- Assess the patient for potential abuse or development of physical or psychological dependence

Important Points:

- Start low and go slow
- Avoid ER/LA formulations
- Benzo-opioid combinations and other sedating medications
- Underlying health issues and elderly
- COPD and sleep apnea
- Offer naloxone
- Ongoing assessment of benefit vs. harm

Moderate to High Dose Opioids:

- Higher MME demands documented functional improvement
- Benefits >50 MME not well established
- “Clinical pause” should be taken at 50 MME
- Additional precautions above 50 MME
- Overdose risk is dose dependent
- Higher MME requires more frequent visits and perhaps consultation
- Documentation of rationale for higher doses is imperative

Opioid Induced Hyperalgesia

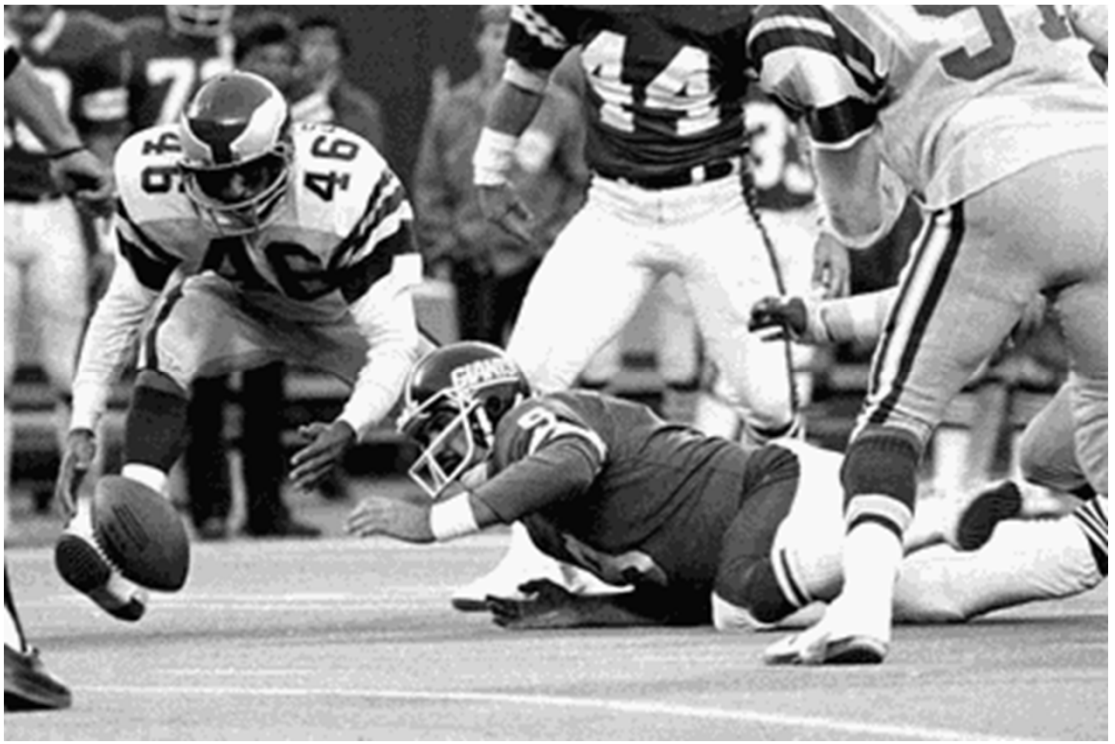
- Caused by high dose opioid therapy and rapid dose escalation
- Perhaps up to 10-20% of opioid therapy patients (including malignant pain)
- Activity at the both the peripheral and central pathways
- Glial cell activation and inflammation at the mu-receptor
- Increased sensitivity to non-noxious and noxious stimuli
- Commonly confused with tolerance
- Treatment is slow dose reduction

Low Dose Naltrexone

- Novel CNS “anti-inflammatory”
- Success with pain due to central augmentation due to glial cell activation
- Fibromyalgia, RA and inflammatory arthritis, multiple sclerosis, CRPS
- Modulates “inflamed” glial cells in the CNS
- Typically 1.5 - 6.0 mg once daily
- Careful with opioid therapy as can precipitate withdrawal

Fumbled Handoff:

- Landing with just enough fuel
- “Well now that you’re seeing…”
- ER visits and discharge
- Post op pain medications
- What about pain contracts?
- Do NOT abandon the patient. Please provide the patient with a “soft landing” if at all possible



“Forced” Reduction:

- No evidence for this approach
- Vulnerable patient population
- Evidence shows harm (FDA warning)
- Increased disability, overdose, illicit drug use and suicide
- Destroys patient-physician trust
- ***Only*** exception is severe opioid side effects

“I Felt Like I Had a Scarlet Letter”

- Three elements of structural stigma identified with tapering/discontinuing opioids
  - Overlooked subjects of the U.S. opioid crisis
  - Felt invalidated by cultural norms linking chronic pain to stereotypes
  - During and after tapers feelings of marginalization were enhanced
- Patients felt orphaned by the system
- Tapering initiatives reinforced devalued status of patients with chronic pain, reduced well-being and confidence in the medical system
- Conclusions found tapering may exacerbate the burden of stigma in those with chronic pain

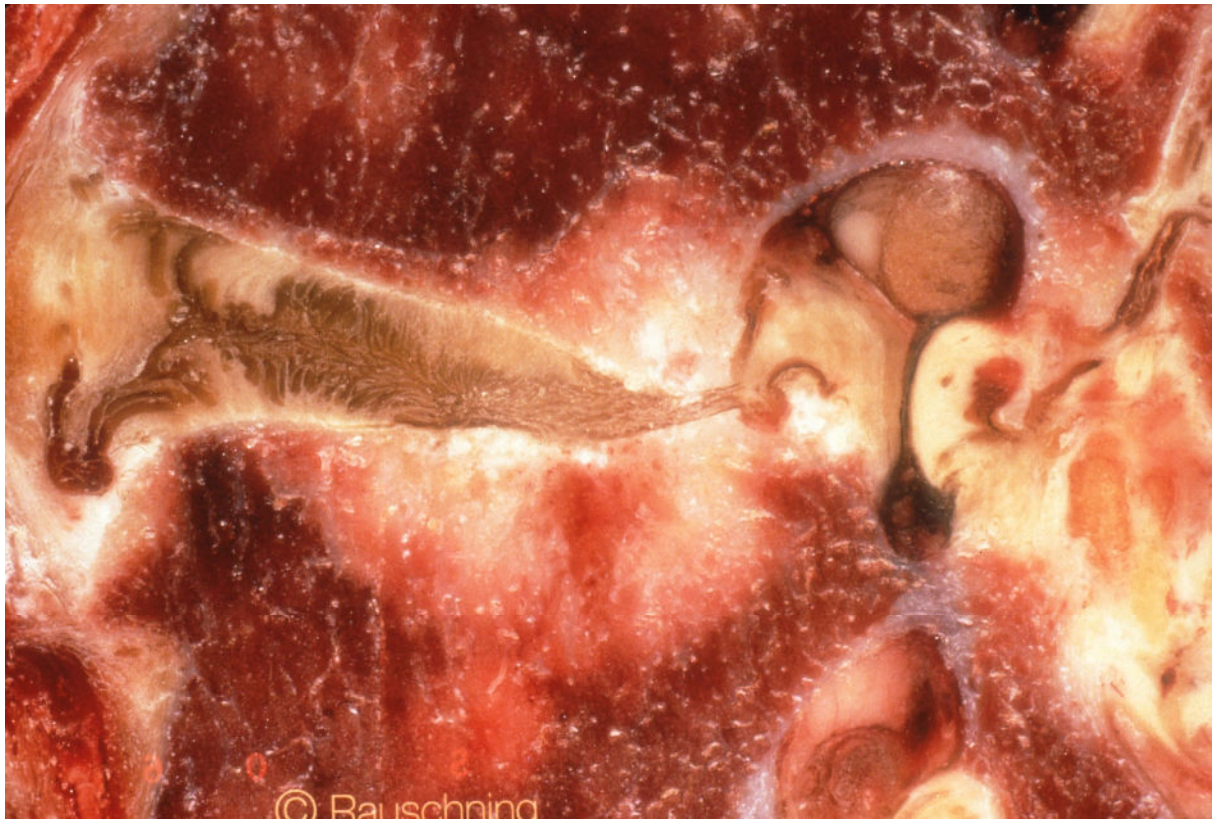
Benintendi A, Kosakowski S, Lagisetty P, Larochelle M, Bohnert ASB, Bazzi AR. "I felt like I had a scarlet letter": Recurring experiences of s

Tapering Considerations:

- Patient education and discussion of risks and benefits
- Patient agreement and interest is paramount
- Patient collaboration on plan to include length of taper and possible pause
- Typically can take weeks to months
- Key is to avoid withdrawal
- Goal may not be cessation but rather lower dose
- Needs frequent follow up

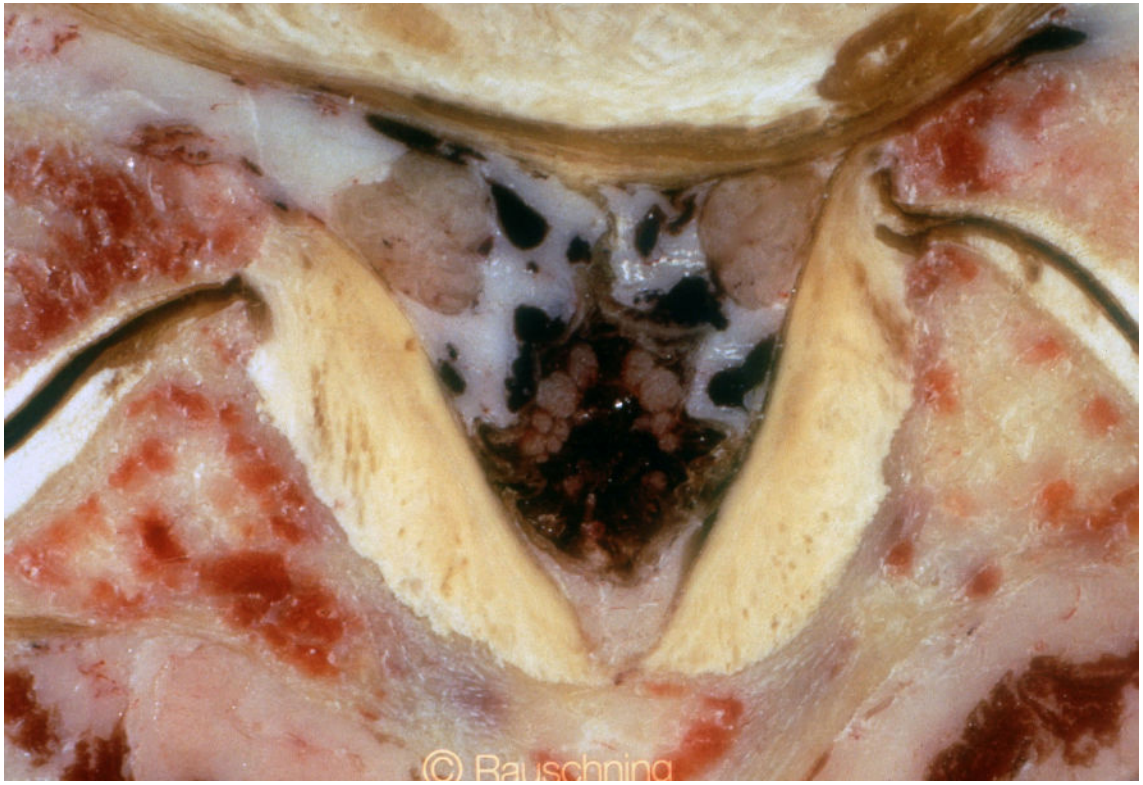
A “Biased” View:

- Functionality
- Compliance
- Safety
- Caution
- Gravitas of the situation
- Respect and trust
- Dignity



An Opposing View:

- “Legalized heroin”
- “No legitimate purpose”
- Risks outweigh any benefits
- All patients on chronic opioids will develop addiction
- Doctors as “pushers”
- Troubling encounters



“The catalyst of the opioid crisis was a denial of the addictive potential of prescription opioids”

HHS 2019. “Pain Management Best Practices”

Risk Mitigation in Opioid Management:

Many Hats and Headaches

Opioid Use Disorder:

Predicting risk is challenging and available tools are not reliable to test for risk of OUD (CDC: 2022)

- A major emphasis across the spectrum
- 3-26% incidence (controversial)
- Inability to reduce or control opioid use
- “Craving”
- Reduced function despite opioids
- Often poor insight and social support

Patients at Risk:

- Psychosocial issues
- History of substance use disorder
- History of ACE’s
- Poor motivation and lack of insight
- No firm cause of pain delineated
- Prior overdose

Common Pathways to OUD:

- Poor pain control (65% per CDC)
- Taking medications to feel good or decrease withdrawal symptoms
- Initial exposure to opioids at a young age
- Ongoing emotional stress
- Higher opioid dose
- Longer term use of opioids
- Lipophilic opioids?

Risk Mitigation:

- Predicting risk is challenging
- PMP, UDS, pill counts, behavior evaluation
- Monitor based on risk
- Address at follow up
- Document findings
- Not a reason to dismiss patient

Patient Provider Agreement (PPA)

- PPA: *Required by law*
  - At time of a 3rd prescription
  - Pregnant or minor
- PPA and Written Policy: *Required by law for "Qualifying Opioid Therapy Patient"*
  - Patient requiring more than 3 months of opioid therapy
  - Patient prescribed benzodiazepines with opioids
  - Patient requiring >100 MME

Urine Drug Screening:

Immunoassay

- Immunoassay (dipstick) in the office
  - Prone to false positives
  - Tests for opiates typically
- All initial patient visits
- Follow up testing based on risk
- Will not detect synthetic opioids
- When to send for confirmatory?

Urine Drug Screening:

Confirmatory with Spectrometry

- Expensive and often over utilized
- Obtain randomly and when patient disputes initial screen
- Suspected diversion or over utilization
- Important to understand metabolites of opioids
- Important screen for benzodiazepines (poor sensitivity and specificity with dipstick)
- Is the drug there or not?

Abnormal Results:

What to Do??

- Positive or negative results demand a response
- Don’t ignore but document counseling, change in treatment or discontinuation
- Second chances? Depends….
- CDC recommends not terminating care and abandoning patient

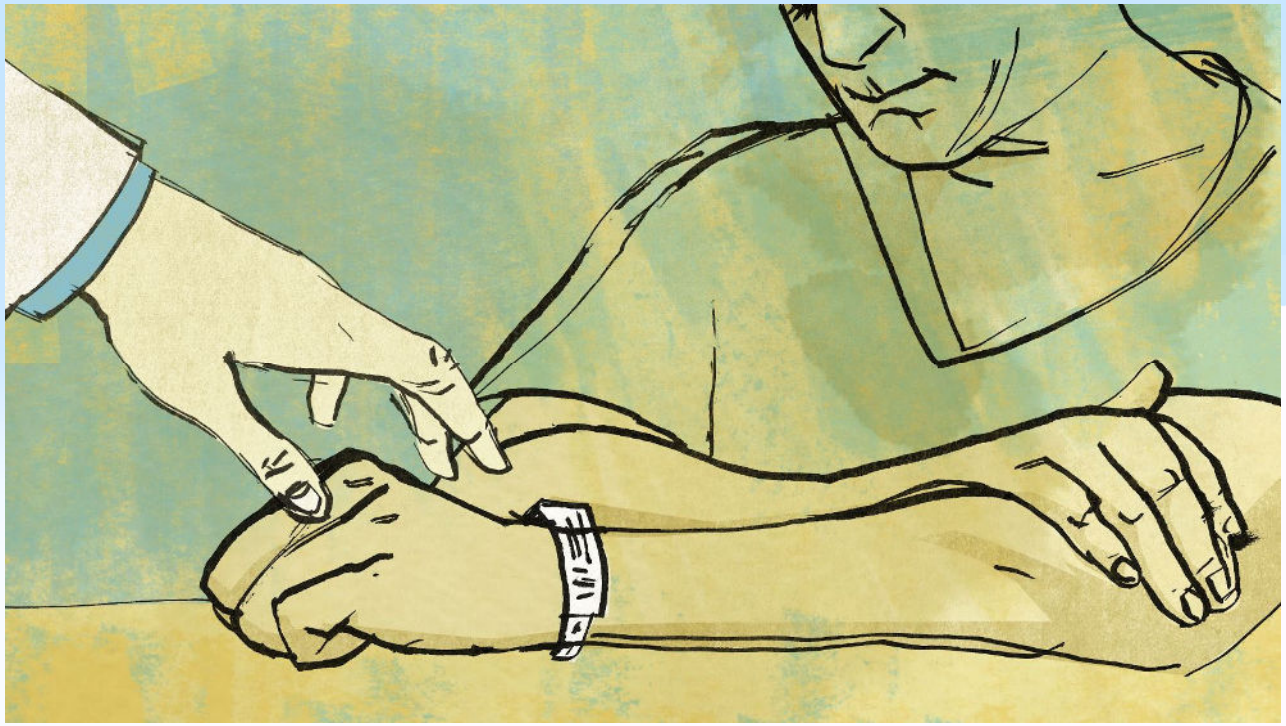
Summary of SB1446 and 848:

- Addiction and abuse
- Dose reduction and cessation if not clinically contraindicated
- Emphasis on lower MME’s
- Alternative therapies attempted
- Decreasing risks of acute pain leading to chronic opioid therapy
- Document your care and treatment decisions
- Both board websites have **“Compliance and Best Practices for Opioid Prescribing”** for review

Grace…

Empathy…

Understanding…



References:

- 2022 CDC Clinical Practice Guidelines. Nov 4, 2022. (*cdc.gov*)
- HHS Pain Management Best Practices Task Force. (*hhs.gov*)
- Oklahoma Senate Bills 1446 and 848
- OCME Presentation to Attorney General Community Task Force on Substance Abuse. 2024

Thank You and Questions

scott@painoftulsa.com