

Pain Management and Opioid Therapy 2022: New Guidelines

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Objectives:

- Develop an understanding of the newer guidelines and position statements and their emphasis on balancing management of pain with risks associated with opioids
- Gain knowledge in the risk assessment of the chronic pain patient and the appropriate management of those patients in a multi-modal treatment plan
- Understand the implications of SB 1446 and 848 in the management of the acute and chronic pain patient and how it impacts your practice

Unintended Consequences Addressed by 2022 Guidelines

- Forced opioid tapering
- FDA warning: “Serious harm”
- Patient abandonment and fumbled handoffs
- Increase in “over” referrals
- Reduction in physicians willing to prescribe
- Stigma associated with opioids
 - Patient and physician
- Suffering, suicide and disability

2022 CDC Guidelines: Focus

- Not a replacement for clinical judgment and emphasizes individualized patient care
- Not intended to be applied as an inflexible standard of care (especially with dose limitations)
- Not intended to be a law, regulation or policy that dictates clinical practice
- Focus is on initiation, patient selection, duration and follow up care
- Addresses the misapplication of the 2016 guidelines

The “Legacy” Patient

- Previous guidelines did not address
- Often high dose opioid therapy
- Long-standing opioid therapy
- Emphasizes clinician-patient decision making
- Important to establish goals
- Guidelines emphasize flexibility
 - Dose and duration are seen as flexible and not rigid standards

Contributing Factors to Opioid Reduction

- Awareness and education
- Regulatory oversight
- Fear
- Increased vigilance
- Targeting of misuse
- Better awareness of misuse and addiction
- Tightening of availability of opioids

Contributing Factors to Inadequate Management and Prescribing

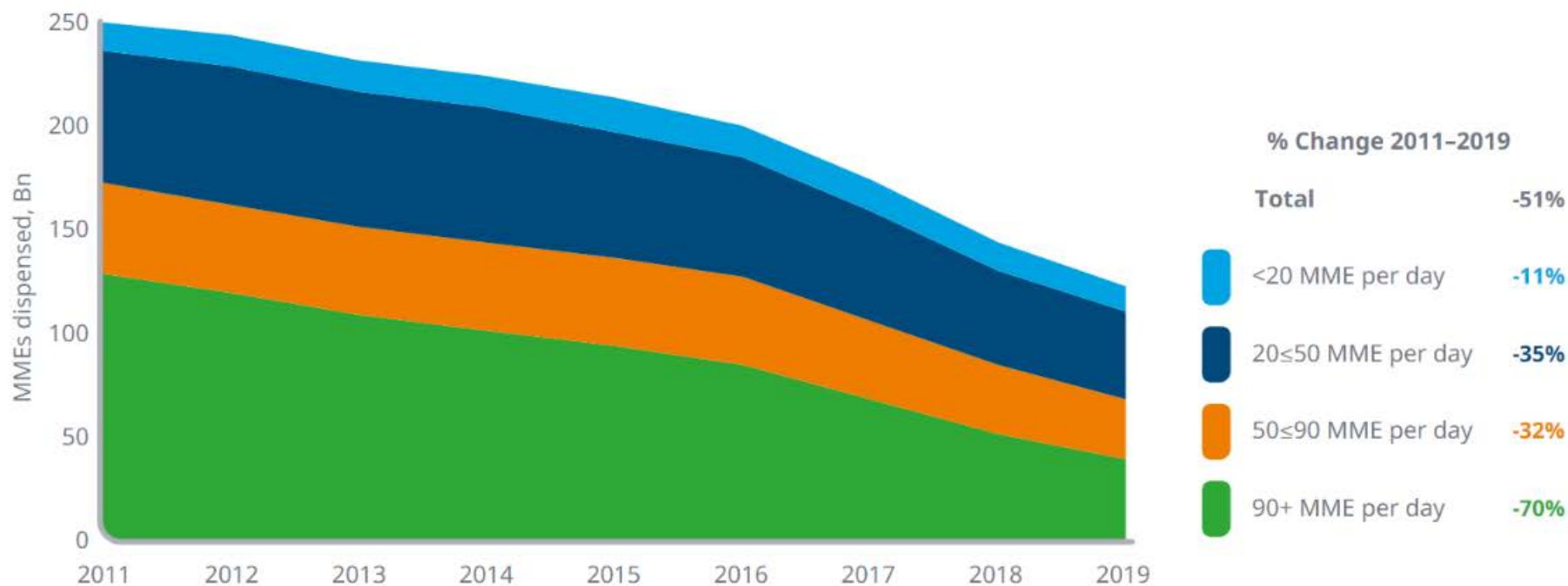
- Physician lack of knowledge in best clinical practice
- Inadequate research
- Poor understanding of risk mitigation
- Lack of multi-modal treatment
- Physician misunderstanding of dependence/addiction
- Complete relief may not be an attainable goal

Signs of Progress

- Reduction of prescription opioid deaths
- Reduction of high MME's (< 100)
- Lessening of total opioids prescribed
- Better education and tools to assess for misuse
- Improvement in identifying and managing OUD

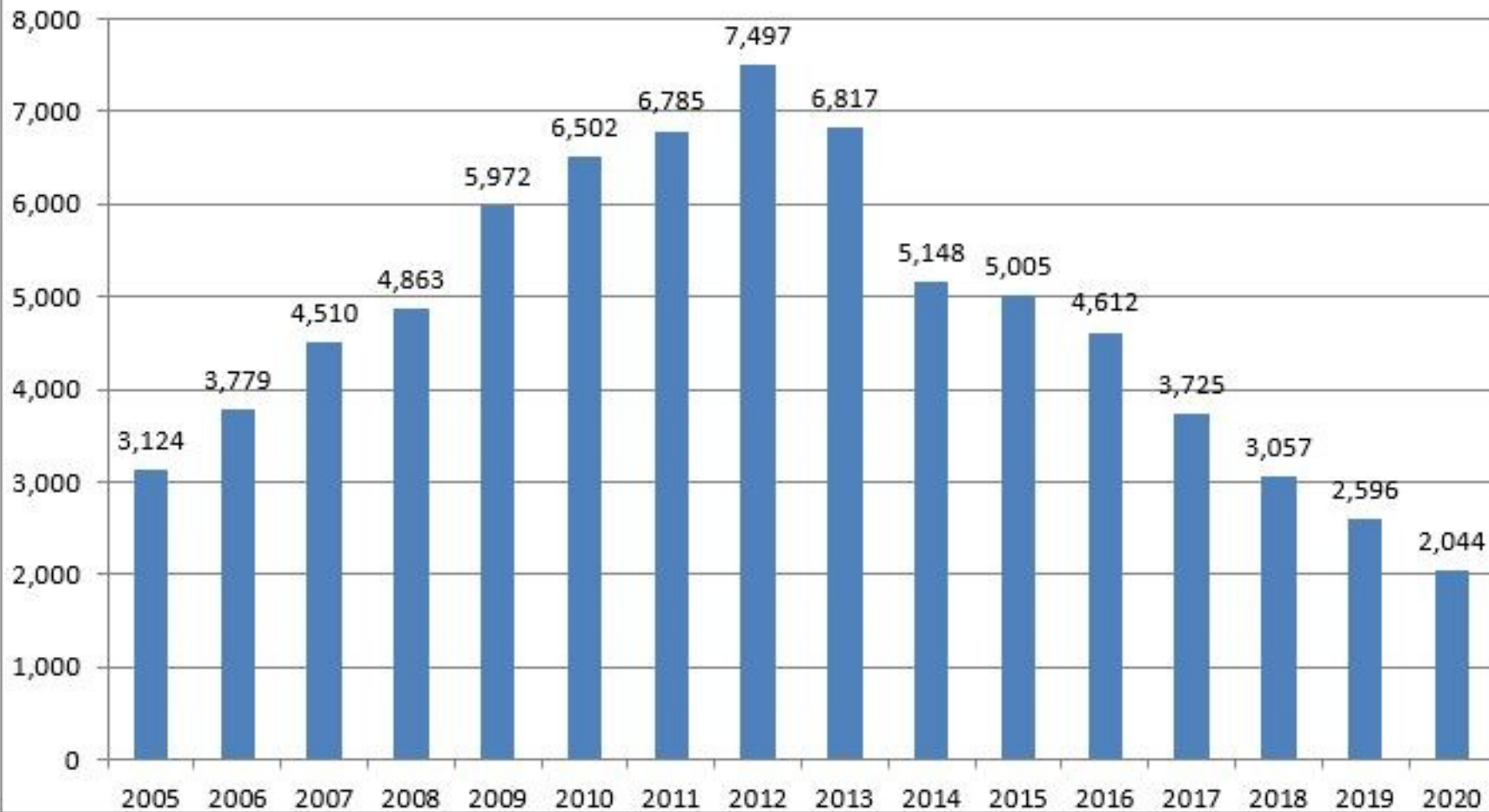
The greatest reduction in prescription opioid use has been in the highest risk segment, which contain more than 90 MMEs per day

Exhibit 3: Prescription Opioid Use Segmented by Morphine Milligram Equivalents (MME) per Day, 2011-2019



Source: IQVIA Xponent, Mar 2020; IQVIA Institute, Nov 2020

Total Prescription Opiates (Excluding Buprenorphine)

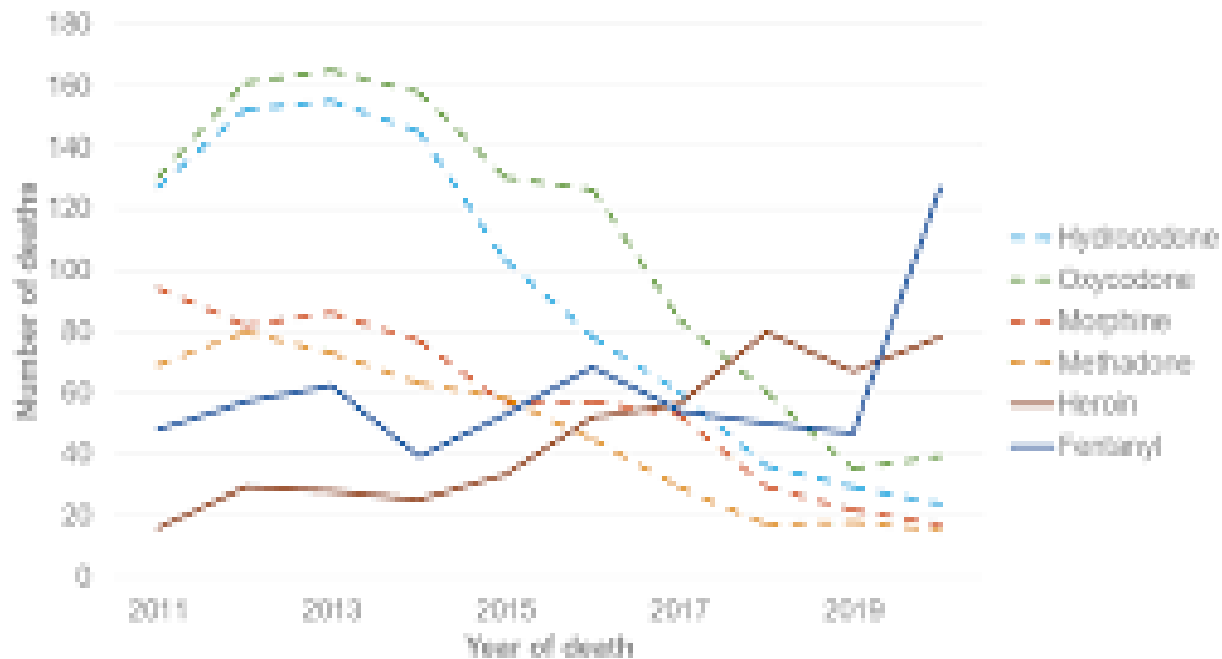


Opioid Deaths

- 108,000 deaths in US involving all opioids in 2021
- Oklahoma:
 - Methamphetamine highest overdose deaths in 2020
 - 77% of opioid deaths involved fentanyl or heroin
 - 24% increase in drug overdose deaths in 2020
 - From 2019-2020 a 170% increase in fentanyl deaths
 - Prescription opioid deaths continue to decline
 - Benzodiazepine/opioid combinations

Unintentional Opioid Deaths in Oklahoma

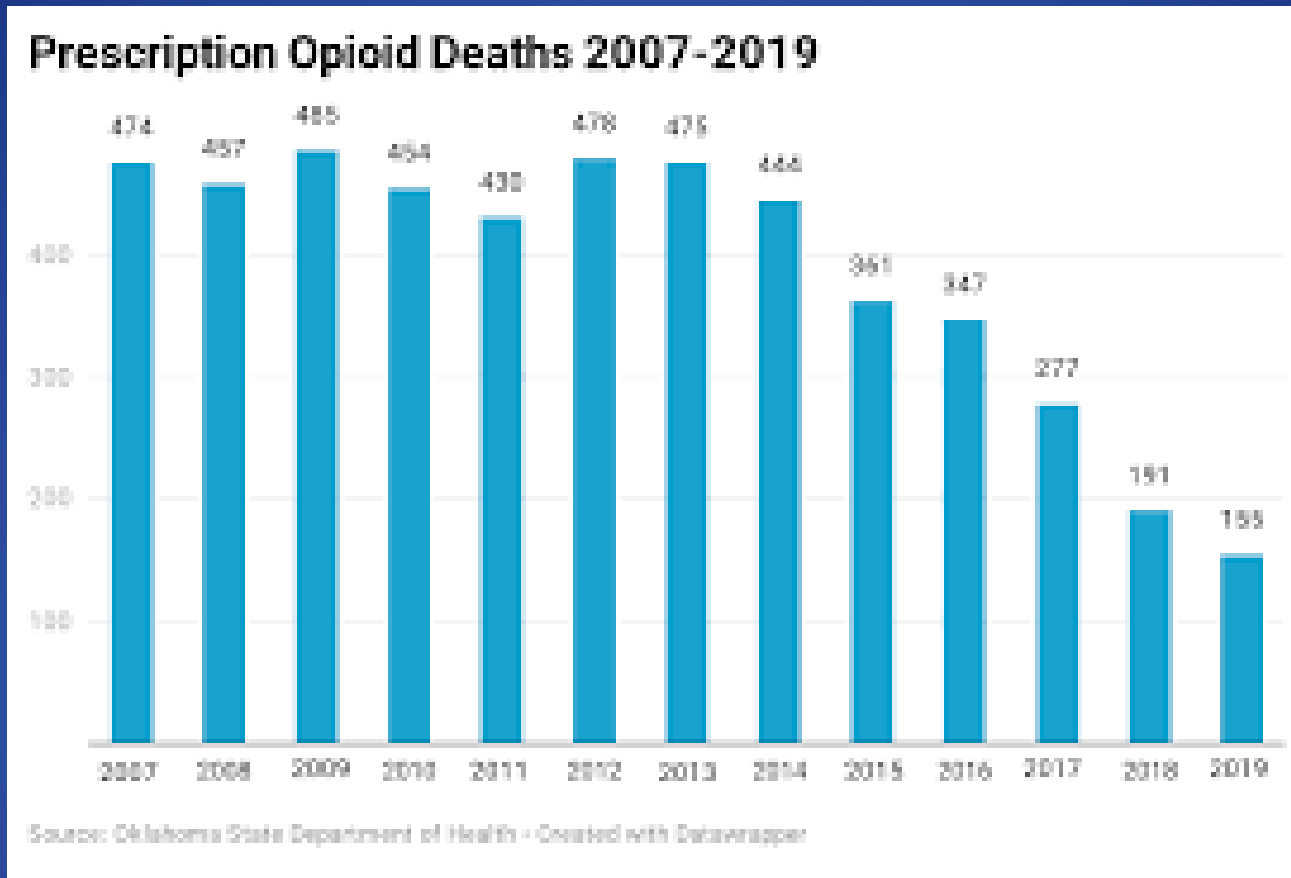
► Unintentional Opioid Overdose Deaths by Drug, Oklahoma, 2011-2020



Source: OSDH, Injury Prevention Service, Fatal Unintentional Poisoning Surveillance System



Oklahoma Prescription Opioid Deaths



SUDORS Data 2020: Oklahoma

- 20.8 deaths per 100,000 persons below national average of 30.6
- Missed opportunities
 - Potential bystander present 39.1%
 - Mental health diagnosis 19.8%
 - Fatal drug use witnessed 8.9%
 - Recent release from institutional setting 8.7%
 - Prior overdose 3.3%
 - Current treatment for SUD/OUUD 1.5%

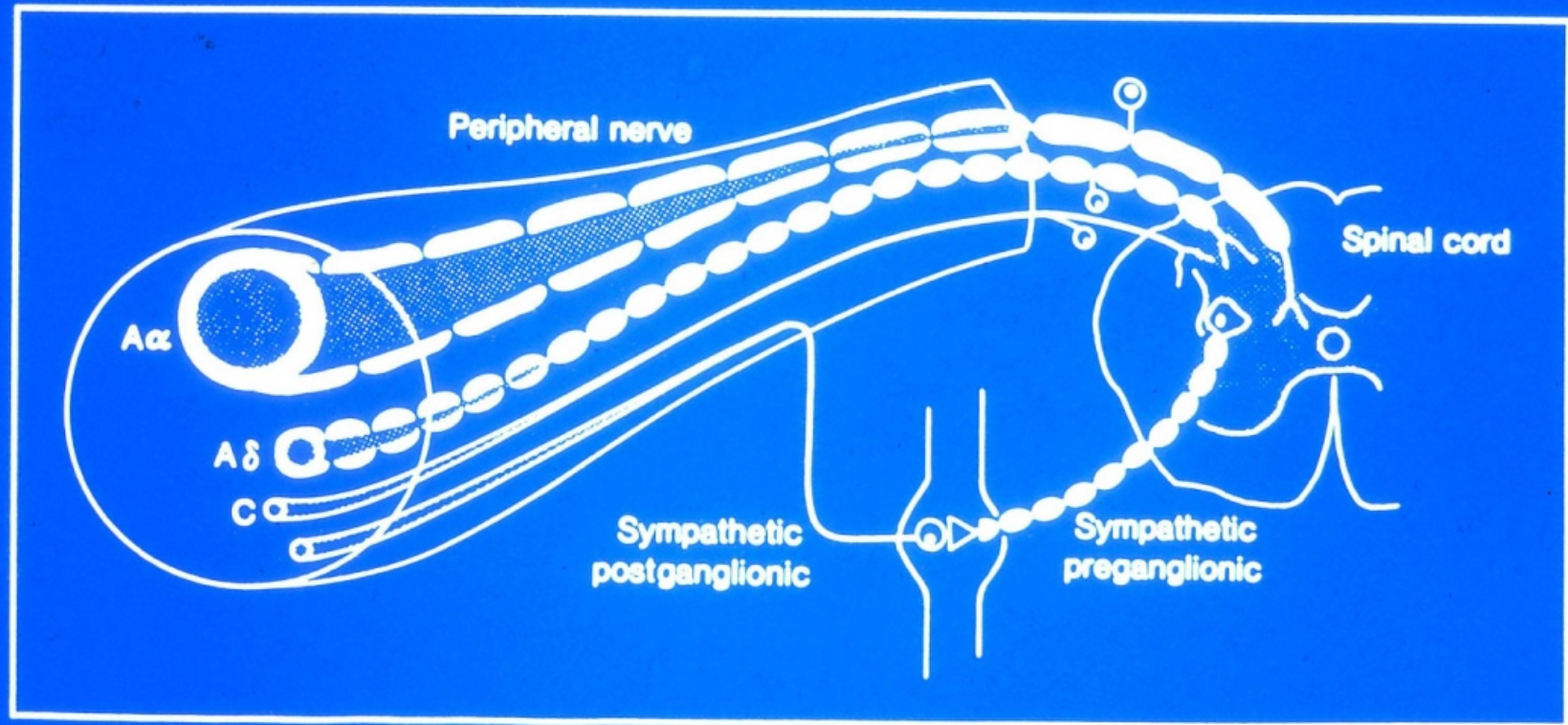
“Opioid Crisis” Confusion:

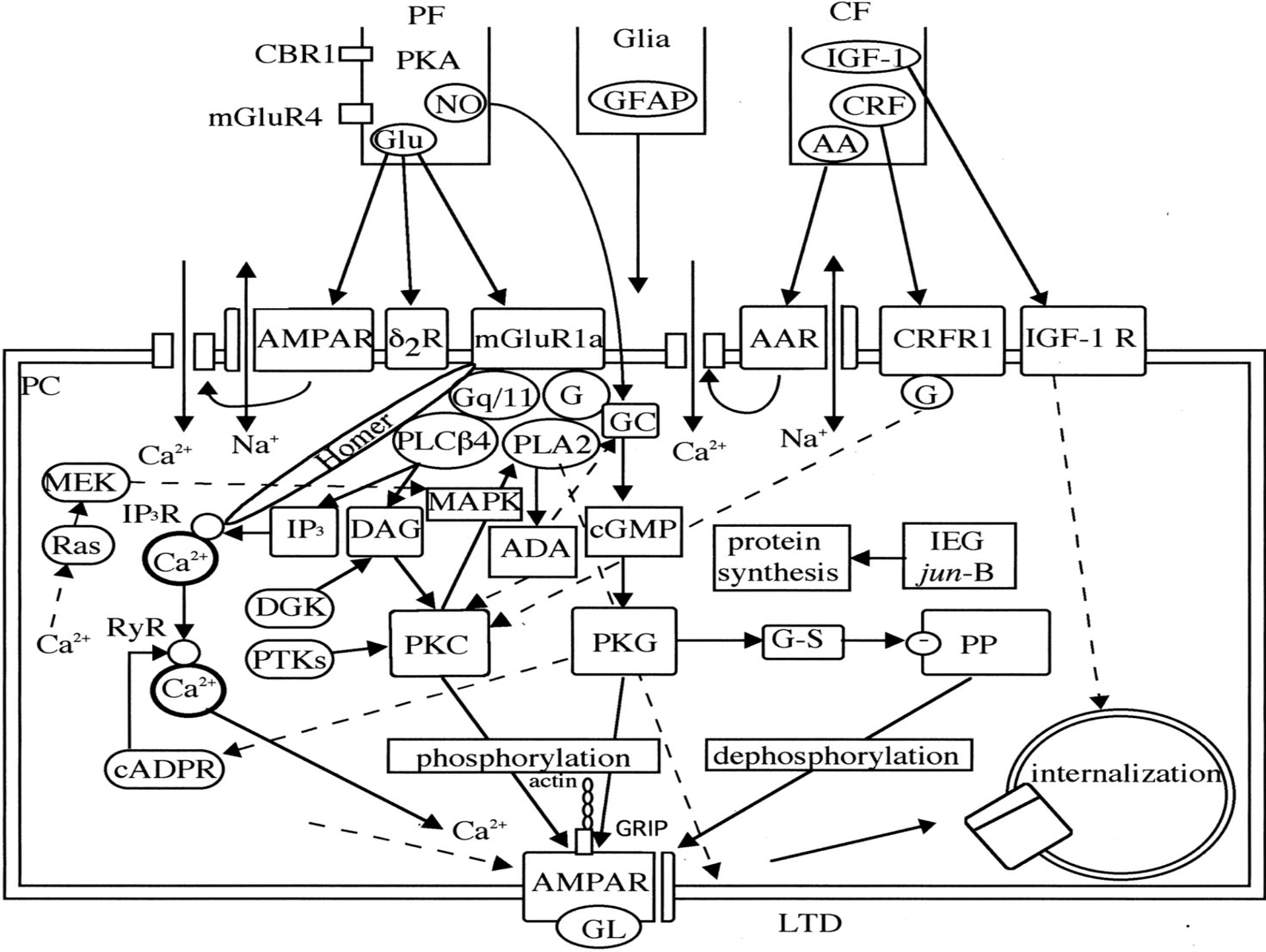
- Prescription vs. illicit opioids
- Important distinction for the chronic pain patient
- Contributes to stigma faced by patients and physicians
- A significant contributor to the reduction of opioids
- Recent AP article July 2022
 - “Opioids are claiming more lives than ever”
 - Ongoing FDA review of prescription opioids

Types of Pain:

- Nociceptive pain
 - Inflammatory
 - Mechanical
 - Thermal
- Neuropathic pain
 - Hyperalgesia
 - Allodynia
- Peripheral and central sensitization

The Basic Pain Pathway



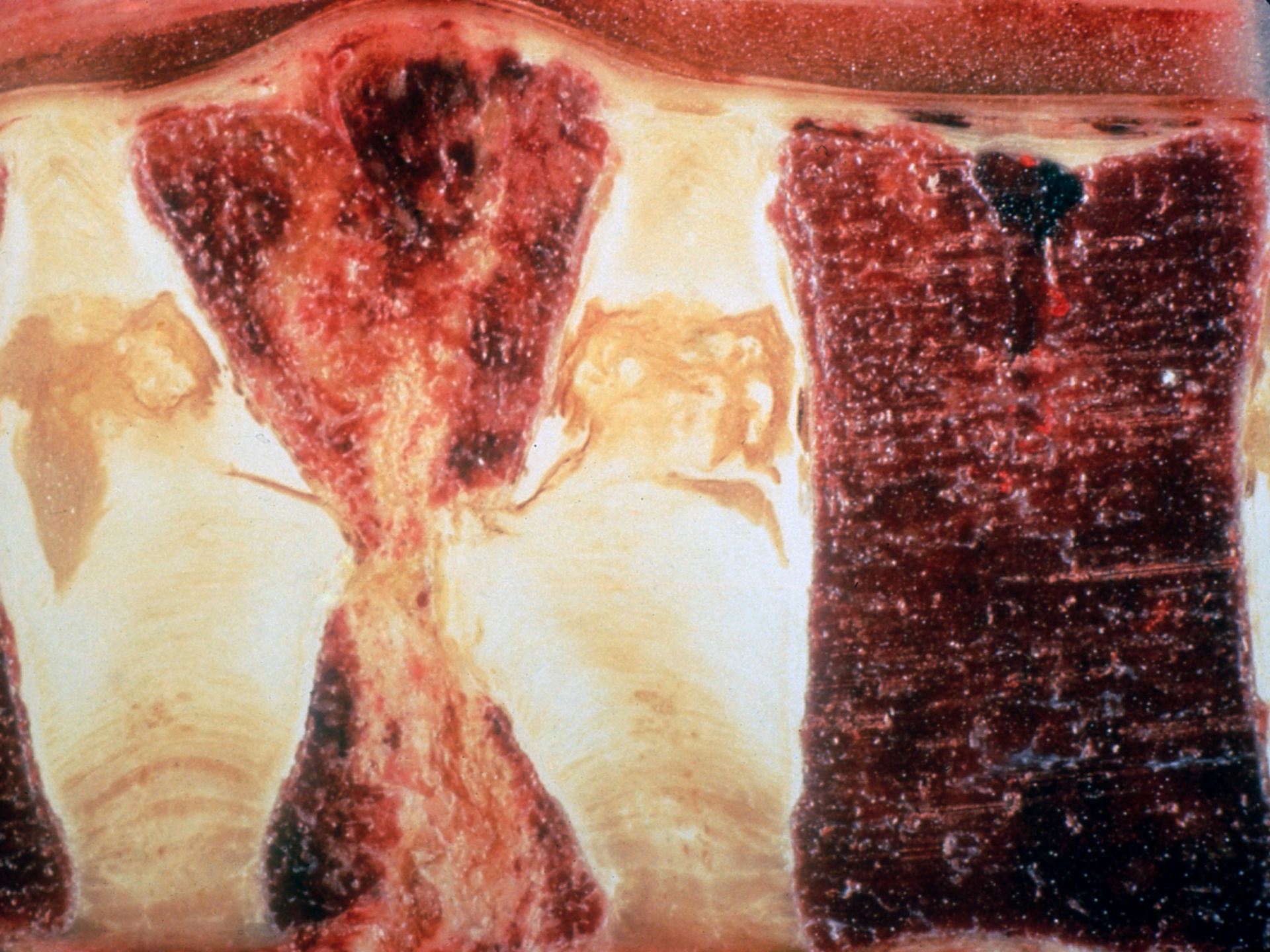


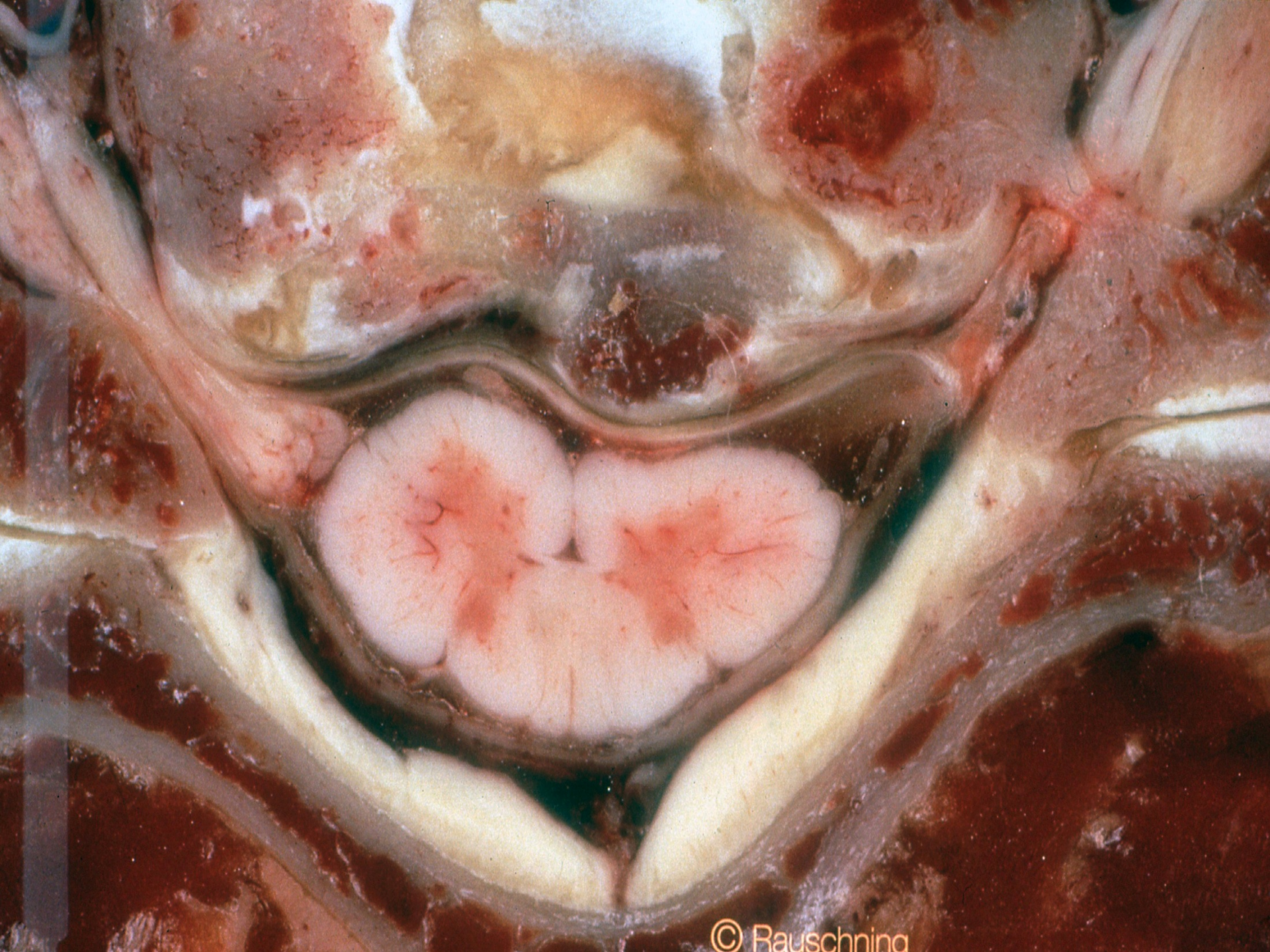


Determine a Diagnosis

- Important for determining patient selection for appropriate pain therapies
- Are other options available to the patient?
- What are we actually treating/managing?
- Not as simple as “musculoskeletal pain”









Opioids For Chronic Pain:

- Chronic pain is highly complex
- Opioids alone are often inadequate (mild-moderate)
 - 25-50% improvement in pain scales
- Opioid therapy can be beneficial in select patients who demonstrate compliance and function
- Often the only remaining option for some patients
- Best outcomes are in a multi-modal setting

Are Opioids Efficacious for Chronic Pain?

- Long term outcome studies are lacking
- Good quality data showing moderate relief in some
- Insight based on available evidence
 - Opioid use may be the most important factor impeding recovery of function
 - Opioids may not consistently and reliably relieve pain and can decrease quality of life
 - The routine use of opioids cannot be recommended
- *Appropriate only for selected patients with moderate-severe pain that significantly affects quality of life*

2022 CDC Emphasis:

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

First Line Approach

- Important issue in SB1446/848
- Non-pharmacological approach
- Non-opioid approach
- Emphasis on
 - Behavioral therapies
 - Functional therapies
 - Adjunctive medications
 - Interventional therapies

Patient Selection and Risk Stratification

- History, physical examination and diagnostic testing
- Psychosocial risk assessment
- Expectations: physician and patient
- Risk assessment is an underdeveloped skill for most clinicians
- SB1446/SB 848 requires vigilant monitoring for abuse and addiction
- SB1446/SB 848 emphasizes documentation of the progress of the patient to the treatment objectives

Chronic Opioid Therapy (COT)

- Consensus agreement that it can be useful in carefully selected patients with moderate to severe pain
- Absolutely demands:
 - Compliance: As with any medical problem
 - Documentation
 - Vigilant monitoring for SUD and OUD
 - Assessment of opioid related side effects
 - Understanding of opioid use in chronic pain

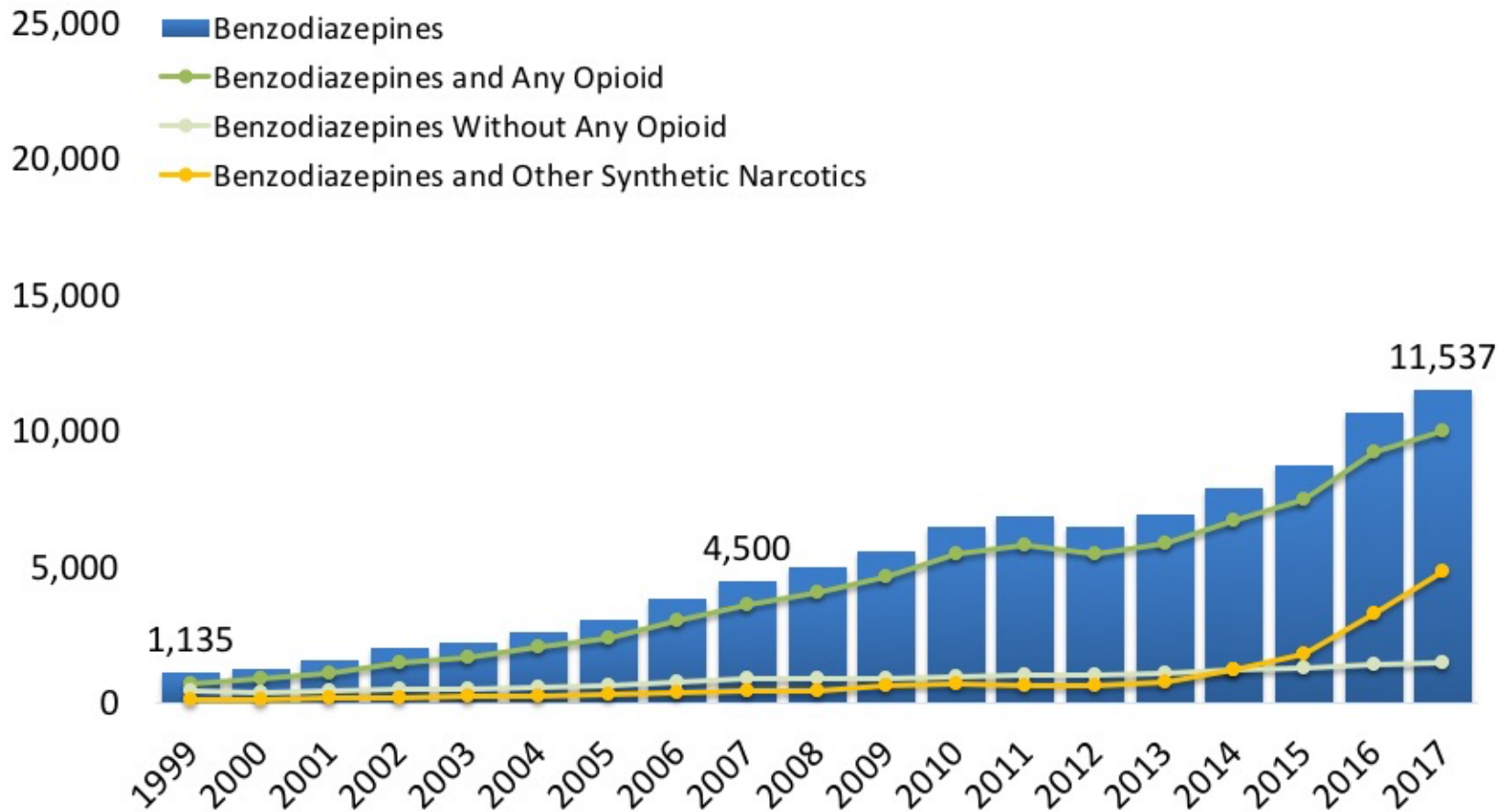
Appropriate Initiation of COT

- Informed consent and discussion of risk vs. benefit
- Therapeutic trial of 4-6 weeks with exit strategy
- Exhaustion of other modalities (within reason)
- Avoidance of ER/LA opioids
 - Start low-go slow
- Ongoing monitoring and assessment of benefit vs. risk, expectations and alternative modalities
- Consider a taper or wean even in functional patients

Opioid Prescribing Caveats:

- IR vs. ER/LA opioid therapies
- Lowest effective dose
- Benzodiazepine use with opioids
 - Significant increase in deaths and ER visits
- COPD and sleep apnea
- Combine with other modalities
- Offering naloxone to patients at risk (50 MME's)
- Ongoing assessment of psychological risks

Figure 8. National Drug Overdose Deaths Involving Benzodiazepines, by Opioid Involvement, Number Among All Ages, 1999-2017



Source: : Centers for Disease Control and Prevention, National Center for Health Statistics. Multiple Cause of Death 1999-2017 on CDC WONDER Online Database, released December, 2018

Moderate to High Dose Opioids

- Benefits are not well established but risks are higher
- Providers should prescribe lowest possible dose
- Additional precautions at > 50 MME's
- Should try to avoid > 90 MED's
- Risks of fatal and non-fatal overdoses increase
- Demands documented increase in function and no or manageable adverse side effects

High Dose Opioid Therapy

- Doses >50 MME more likely to provide diminishing returns relative to the risks
- Defined typically as >90 MME's
- Strong evidence linked with poor outcome
- Higher risk of OUD
- 9x increase in deaths with 100mg or higher MME
- Remember, existence of persisting pain does NOT constitute evidence of undertreatment

“Forced” Dose Reductions

- There is really no evidence for this approach
- A vulnerable population of patients
- Evidence shows harm
- Rupture of patient-physician relationship
- Increased disability, overdose and suicide
- Risk of illicit drug use
- An exception is severe side effects

Tapering Considerations

- Patient education and discussion of risks and benefits
- Patient agreement and interest is paramount
- Patient collaboration on plan including length of taper and perhaps a pause.
- This can take months
- Avoidance of withdrawal symptoms
- Goal may not be cessation but lower dose
- Frequent follow up
- Buprenorphine

The Fumbled Hand-off:

- ER visits and discharge
- Post op pain control
- “Pain contract”
- Discharge of a patient
- Termination of patient after failed UDS
- Transfer of a patient
- Do NOT abandon the patient. Provide for some type of “soft landing”

Characteristics of Ideal Patient

- Well defined pathology
- Good insight and desire to improve
- Willing to “work hard” to improve
- Interested in other modalities and work-up
- Not focused on opioids but desire to improve
- Good understanding that opioids will provide “some” relief to help them improve
- Examples

The Worrisome Patient

- Diffuse and poorly localized pain
- No interest in work-up or other modalities
- Focus is on opioids alone
- Poor insight and unrealistic expectations
- Poorly motivated with no desire to “work hard”
- Poor functionality
- Examples

Patients at Risk

- Psychosocial issues
- History of Substance Use Disorder (SUD)
- Adverse Childhood Experience (ACE)
 - Abuse, neglect, household dysfunction and traumatic stressors
- Poor motivation and lack of insight
- No firm cause of pain delineated
- Disability, Medicaid and prior criminal activity
- Prior overdose

Substance Use Disorder (SUD)

- “The catalyst of the opioid crisis was a denial of the addictive potential of prescription opioids”
- History of alcohol, nicotine, THC, sedatives
- SUD increases risk of developing OUD
- Screening helps identify and reduce risk
- Screening tools for SUD should be incorporated prior to and during opioid therapy
- Beware: flashing light for potential OUD

Opioid Use Disorder

- 3-26% incidence
- Significant impairment or distress
- Poor insight and social support
- Inability to reduce opioids
- Inability to control use
- Often of younger age
- Social function reduced
- Failure to fulfill work, home or school obligations
- Commonly referred to as “abuse” in the literature

Common Pathways to OUD

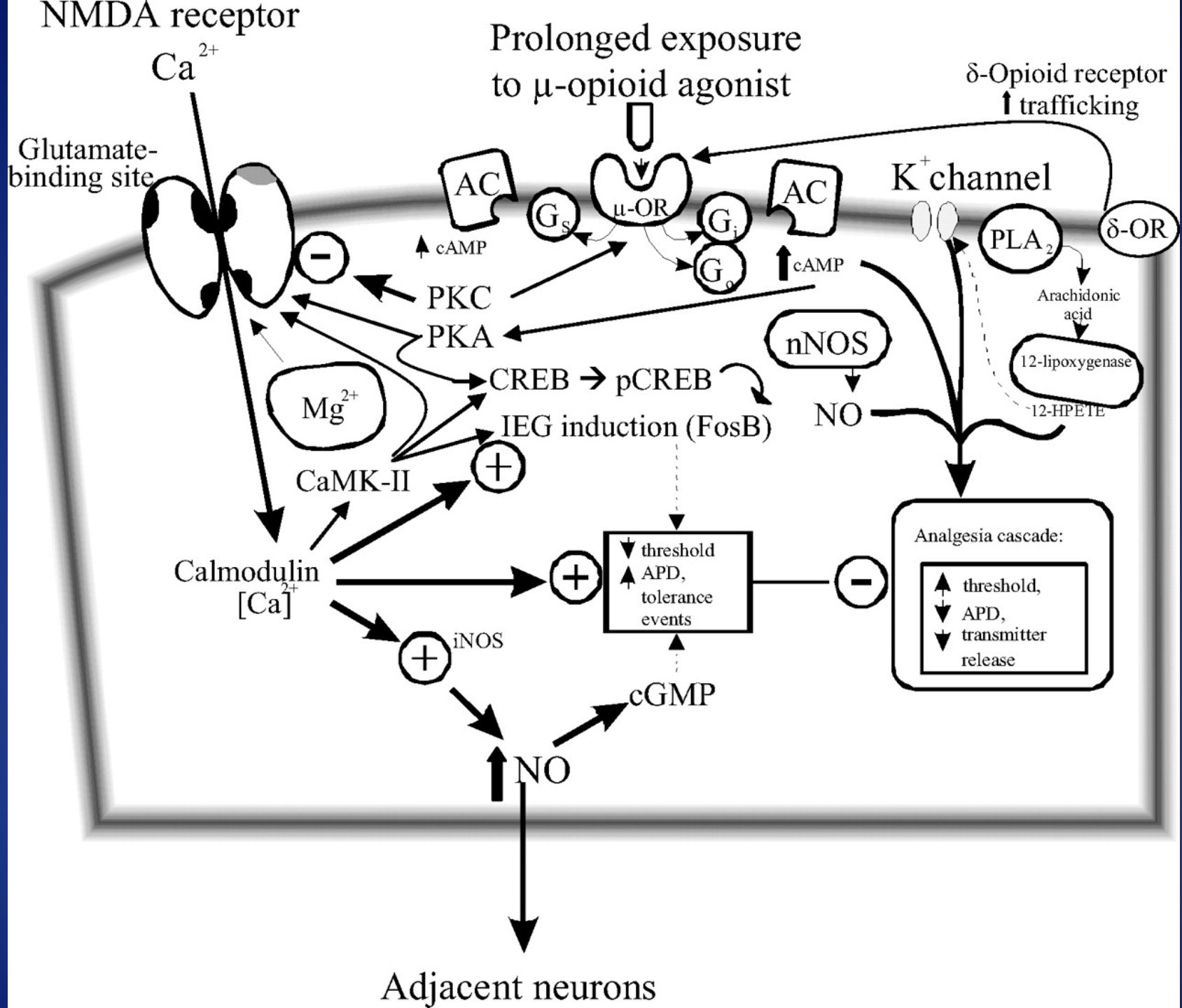
- Poor pain control (often opioids alone)
- Prior history of SUD
- Initial exposure to opioids at a younger age
- Ongoing emotional distress
- Higher opioid doses
- Long term use of opioids
- Misuse of opioids for psychoactive purposes and for unrelieved pain

Medication Assisted Treatment

- Emphasized with patients who display OUD
- Buprenorphine: Partial agonist
- Methadone
- Behavioral therapies
 - Help maintain retention
 - Help reduce relapse rate
- Consensus concerns:
 - Availability
 - Cost

Opioid Induced Hyperalgesia

- Increased sensitivity to noxious or non-noxious stimuli
- Sensitization of pro-nociceptive mechanisms
- Glial cell inflammation at the mu-receptor
- Hypersensitivity and allodynia
- Confused with tolerance
- Caused with rapid escalation and high dose therapy?
- Activity at the NMDA receptor in dorsal horn



Common Errors

- Continued escalation of opioids despite no evidence of improvement in pain or function
- Opioids used in pain syndromes known to be poorly responsive
- Failure to document and monitor
- Not addressing psychosocial issues and OUD
- Comorbid disease states
- Utilization of sedative medications
- Rapid dose increase/decrease

Addressing Worsening Pain

- Evaluate prior to dose increase for OUD
- Common scenarios patient request for opioids or opioid increase
 - Progression of disease
 - New painful diagnosis
 - Psychological issues
 - Unrealistic expectations of pain and opioids
 - Failure to use adjunctives or other therapies
 - OUD or diversion

Risk Mitigation

- Pay attention to a pattern of activity that suggests abuse and address
- Monitor closely through follow up and documentation
- Predicting risk is challenging
- Current tools may not be very reliable
- Not a reason to dismiss patients from care

Prescription Monitoring Program

- Powerful tool
- Physician and staff friendly
- Crosses state lines
- Helpful to determine other scheduled drugs like benzodiazepines
- Good “teaching moment” with the patient
- Ideal to check before every refill
- Unfortunately a high percentage of overdoses are from non-prescribed opioids or illicit

SB1446 and 848: Major Points of Emphasis

- Addiction and abuse
- Dose reduction and cessation
- Emphasis on lower MME's
- Alternative therapies
- Strong focus decreasing the risks of acute pain leading to chronic opioid therapy
- *Strong language for assessing, documenting and specifying your care of the opioid patient*

Prior to Issuing an Initial or Chronic Prescription

- Practitioner shall discuss and *document* with a note in medical record of the risks not limited to
 - Risks of addiction and overdose and risks of combining alcohol and or benzodiazepines
 - The reasons why the prescription is necessary
 - Alternative treatments that may be available
 - Risks associated with the drug being prescribed such as physical and psychological dependence, that “opioids are highly addictive” and overutilization can lead to death

Patient-Provider Agreement

- Provides informed consent
- Essentially an opioid “contract”
- Needed before the 3rd prescription and for chronic pain treatment
- Needed at initial prescription for under 18 and pregnancy
- The Boards have provided an approved agreement for use

Patient-Provider Agreement

- Explains the possible risks
- Document the understanding of patient and physician
- Establishes the rights and obligations of the patient
- Storage of opioids
- Establish specific medications and other treatments
- Specify the measures used by the physician to monitor the patient
- Delineate the process for termination of agreement
- Compliance shall constitute valid informed consent

Chronic Utilization of Opioids

- Review at a minimum every 3 months (first year) or every 6 months if compliant with PPA
 - The course of treatment
 - Any new information about the etiology of the pain
 - Progress of the patient toward treatment objectives
 - Monitor the compliance with the pain management agreement and any recommendations that the patient seek a referral
 - Check PMP (not required BUT encouraged)
 - *Document the results*

Chronic Utilization of Opioids

- Periodically make reasonable efforts, unless clinically contraindicated, to
 - Stop use of controlled substance
 - Decrease the dosage
 - Try other medications and treatment modalities in an effort to reduce the potential for abuse or development of physical or psychological dependence
 - DOCUMENT and SPECIFY the efforts undertaken

Qualifying Opioid Therapy Patient

- *A patient requiring opioid treatment for more than 3 months*
 - Does it matter if low dose or high dose? NO
- *A patient who is prescribed a benzodiazepine and opioid together*
 - What about different doctors prescribing each?
 - Psychiatrist and PCP
- *A patient prescribed a dose of opioids over 100 MME's*

References:

- Proposed 2022 CDC Guidelines. *Federal Register*, Feb 10, 2022.
- Clinical Practice Guidelines Response Draft: *Federal Register*, Feb 2022
- Oklahoma SB 1446 and SB848
- Oklahoma Opioid Overdose Fatality Review Board. Chairman's Report. January 31, 2022