

International Conference on Opioids

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If Not You, Who?

A Call for Informed Professionals To Engage in Opioid-Related Policy Making

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Disclosures

- ★ CLAAD's funders include pharmaceutical companies, treatment centers, and laboratories, and are disclosed on its website, www.claad.org.
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Disclosures

- ★ Braeburn Pharmaceuticals is a pill-free specialty pharmaceutical company committed to developing long-acting implantable and injectable therapies for serious neurological and psychiatric conditions, including for the treatment of opioid use disorder and pain.
- ★ Braeburn's first product, buprenorphine implant (CIII), was approved by FDA on May 26, 2016 for maintenance treatment of opioid dependence in clinically stable patients.

Preview

- ★ Federal opioid prescribing recommendations
- ★ Mandatory prescriber education
- ★ Federal opioid-related legislation
- ★ Buprenorphine patient limit
- ★ Abuse-deterrent opioids
- ★ Other timely opioid-related issues

Federal Opioid Prescribing Recommendations

- ★ CDC guidelines
 - Criticized
 - Lack of transparency and inclusion¹
 - Poor quality evidence²
 - Affiliation with anti-opioid activists³
 - Recommended for primary care⁴
 - CMS and insurer adoption is occurring⁵
- ★ House-passed HR 4641, which creates transparent, inclusive best practice recommendation process
- ★ States regulate the practice of medicine – not the federal government⁶
- ★ State legislatures and medical boards should see federal prescribing recommendations as a starting point

Mandatory Prescriber Education

- ★ Occurring at state level – *e.g.* New Mexico⁷
- ★ Federal mandate through controlled substance registration is widely recommended
 - 30+ non-profit organizations endorsed in 2011⁸
 - FDA⁹
- ★ AMA is now open to discussing the idea¹⁰
- ★ Training should cover more than opioid analgesics
 - Other classes of controlled Rx medications
 - Substance use
 - Prevention
 - Identification
 - Interventions
 - Referrals to treatment

Federal Opioid-Related Legislation

- ★ Senate passed the Comprehensive Addiction and Recovery Act (CARA), S.524, focusing largely on treatment
- ★ House passed 18 bills¹¹
 - Prevention, including a new federal task force to recommend best practices for pain management¹²
 - Law enforcement¹³
 - Treatment
- ★ Debate over federal funding¹⁴
 - House provided \cong \$100 million in funding¹⁵
 - Would otherwise redirect existing funds¹⁶
 - Administration proposed \$1.1 billion in Feb., largely for expanding medication-assisted treatment¹⁷

Federal Opioid-Related Legislation Conferees

- Fred Upton (R-KY, 6th District)
- Joe Pitts (R-PA, 16th District)
- Leonard Lance (R-NJ, 7th District)
- Brett Guthrie, (R-KY, 2nd District)
- Adam Kinzinger (R-IL, 16th District)
- Larry Bucshon (R-IN, 8th District)
- Susan Brooks (R-IN, 5th District)
- Bob Goodlatte (R-VA, 6th District)
- Jim Sensenbrenner (R-WI 5th District)
- Lamar Smith (R-WI 21st District)
- Tom Marino (R-PA, 10th District)
- Doug Collins (R-GA, 9th District)
- Dave Trott (R-MI, 11th District)
- Mike Bishop (R-MI, 8th District)
- Kevin McCarthy (R-CA, 23rd District)
- Frank Pallone (D-NJ, 6th District)
- Ben Ray Lujan (D-NM, 3rd District)
- John Sarbanes (D-MD, 3rd District)
- Gene Green (D-TX, 29th District)
- John Conyers (D-MI, 13th District)
- Sheila Jackson Lee (D-TX, 18th District)
- Judy Chu (D-CA ,27th District)
- Steve Cohen (D-TN 9th District)
- Elizabeth Esty (D-CT, 5th District)
- Ann McLane Kuster (D-NH 2nd District)
- Joe Courtney (D-CT 2nd District)

Buprenorphine Patient Limit

- ★ HHS proposed rule¹⁸
- ★ Federal legislation
 - Senate bill¹⁹
 - House bill²⁰
- ★ American Society of Addiction Medicine recommendations²¹
- ★ American Medical Association recommendations²²

Abuse-Deterrent Opioids

★ Guidance

- Oral opioid analgesics
 - Brand²³
 - Generic²⁴
- Not yet available for controlled Rx medications not dispensed to patients for self-administration, *e.g.*, implants and injectables

★ Insurance coverage

- State abuse-deterrent opioid analgesic parity legislation²⁵
- CMS line extension definition clarified in federal bill now in conference²⁶

★ Federal legislation to foster a broader transition to abuse-deterrent medications²⁷

Other Timely Opioid-Related Issues

- ★ Difficulty of access to medically necessary opioids
 - Pain
 - Opioid use disorder
- ★ Illicit substances
 - Counterfeit/analog fentanyl
 - Heroin price, purity, and availability
- ★ Naloxone
 - Access
 - Pricing
 - Industry petition asking FDA to require offering a prescription for FDA-approved naloxone when prescribing opioids²⁸
- ★ Prescription monitoring programs
 - Optimization
 - Prescriber use
 - Privacy concerns

Professional Engagement in Policy Making

- ★ If not you, who?
 - Non-experts (risk of policy based on ignorance, stereotype, or stigma)
 - Activists with singular focus, e.g., disdain for “big pharma”
- ★ Share your unique perspective
 - Compassion for people on both sides of the issues of opioid abuse, addiction, and overdose
 - Powerful personal stories
- ★ Convey your credibility
 - Medical-scientific credentials
 - Professional licensure
 - Experience managing complex, intertwined issues of pain, addiction, and mental health
 - Understanding of nuance necessary in practice and policy
- ★ Draw on and highlight strong community ties
 - Small business owners
 - High level of trust and respect

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Conclusion

- ★ Professional engagement is essential
- ★ Thanks to IC00 staff and conference sponsors
- ★ Thank you
- ★ Questions and discussion

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