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

If Not You, Who?

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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 inclusion\(^1\)
    • Poor quality evidence\(^2\)
    • Affiliation with anti-opioid activists \(^3\)
  • Recommended for primary care\(^4\)
  • CMS and insurer adoption is occurring\(^5\)

★ House-passed HR 4641, which creates transparent, inclusive best practice recommendation process

★ States regulate the practice of medicine – not the federal government\(^6\)

★ State legislatures and medical boards should see federal prescribing recommendations as a starting point
Mandatory Prescriber Education

★ Occurring at state level – *e.g.* New Mexico\(^7\)
★ Federal mandate through controlled substance registration is widely recommended
  • 30+ non-profit organizations endorsed in 2011\(^8\)
  • FDA\(^9\)
★ AMA is now open to discussing the idea\(^10\)
★ 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 bills
- Prevention, including a new federal task force to recommend best practices for pain management
- Law enforcement
- Treatment

★ Debate over federal funding
- House provided ≈ $100 million in funding
- Would otherwise redirect existing funds
- Administration proposed $1.1 billion in Feb., largely for expanding medication-assisted treatment
Federal Opioid-Related Legislation Conferees

- Fred Upton (R-KY, 6th District)
- Joe Pitts (R-PA, 16th District)
- Leanord 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 Luján (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 rule\textsuperscript{18}
- Federal legislation
  - Senate bill\textsuperscript{19}
  - House bill\textsuperscript{20}
- American Society of Addiction Medicine recommendations\textsuperscript{21}
- American Medical Association recommendations\textsuperscript{22}
Abuse-Deterrent Opioids

★ Guidance
- Oral opioid analgesics
  - Brand\textsuperscript{23}
  - Generic\textsuperscript{24}
- Not yet available for controlled Rx medications not dispensed to patients for self-administration, \textit{e.g.}, implants and injectables

★ Insurance coverage
- State abuse-deterrent opioid analgesic parity legislation\textsuperscript{25}
- CMS line extension definition clarified in federal bill now in conference\textsuperscript{26}

★ Federal legislation to foster a broader transition to abuse-deterrent medications\textsuperscript{27}
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 opioids
★ 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
2. Id. See also Brett Norman, “HHS split on CDC opioid prescription guidelines,” POLITICO PULSE, (Dec. 7, 2015).
3. Id.
7. N.M. STAT. ANN. § 24-2D-5.1 (1978)
9. See FDA Briefing Document Joint Meeting of the Drug Safety and Risk Management (DSaRM) Advisory Committee and the Anesthetic and Analgesic Drug Products Advisory Committee (AADPAC) (“FDA supported a mandatory prescriber training program on responsible opioid prescribing practices that would be linked to DEA registration”), U.S. FOOD AND DRUG ADMINISTRATION, (Apr. 6 2016), http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/AnestheticAndAnalgesicDrugProductsAdvisoryCommittee/UCM497290.pdf.
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14. Id.
15. Id.
16. Id.
17. Id.
22. 2016-5-27 Letter to Enomoto re AMA Comments on SAMHSA NPRM, AMERICAN MEDICAL ASSOCIATION, (May 27, 2016), HTTPS://WWW.REGULATIONS.GOV/#DOCUMENTDETAIL;D=SAMHSA-2016-0001-0391.
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28. Citizen Petition from Lachman Consultant Services, Inc. on behalf of Adapt Pharma (March 24, 2016), https://www.regulations.gov/#/documentDetail;D=FDA-2016-P-1090-0004.
Conclusion

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

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