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Science, Not Stigma, Should Drive Policy: An Update on Medications with Abuse-Deterrent Properties

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Conflict of Interest Disclosure

- CLAAD's funders include members of the pharmaceutical, addiction treatment, and laboratory industries, and are disclosed on its website, www.claad.org.
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Preview

- Context and terminology
- Strategy and principles for policy making
- Medical-scientific overview of opioids with abuse-deterrent properties (co-presenter)
- Policy considerations
  - FDA statements
  - Shortcomings and potential benefits of first-generation medications with abuse-deterrent properties
  - Policy goals
  - Legislation
- Discussion

Current Events

- Division, *e.g.*, by education and cultural perspective
- Painting with a broad brush, *e.g.*, black lives vs. blue lives vs. all lives
- Limited dialogue based on self-identification, spin, and click-bait headlines
- Permeating national discussion re: opioid overdoses
  - Insurers vs. pharmaceutical industry
  - Law enforcement and trial lawyers vs. prescribers
  - Privacy vs. security
  - Appropriate vs. re-allocate funding

Concepts, Terminology, and Implications

Prescription drug abuse

- Controlled medications, e.g., for pain, addiction, anxiety, insomnia, ADHD, low testosterone (not just opioids; look to schedule)
- Non-controlled medications, e.g., biologics and counterfeits
- Prescribing (criminal, negligent, appropriate)
- Misuse, abuse
- Dependence, addiction
- Accidental exposure, diversion
- Intervention, treatment
- Overdose, death
- Related HIV, hepatitis C, neonatal opioid withdrawal syndrome, etc.

Other substance use

- Use
  - Heroin
  - Counterfeits, *e.g.*, fentanyl
  - Other illicit substances
  - Legal substances
- Misuse or abuse
  - OTC medicines

Comprehensive National Strategy

- Prescriber education (covering all controlled medications)
- Public awareness and patient counseling, including safe storage and responsible disposal
- Prescription monitoring programs
- Prosecution of criminals, rehabilitation of negligent prescribers
- Overdose rescues, interventions, and referrals to treatment
- Access to effective treatments for substance use disorder
- Development, use, and coverage of non-pharmacologic treatments; non-controlled, lower scheduled, and abuse-deterrent medications

Principles for Policy Making: American Values

- Compassion
  - People with medical needs for controlled medications, e.g., pain, anxiety, insomnia, ADHD, low testosterone
  - People affected by addiction and overdose
- Defined roles of government
  - State plenary policy powers
  - Federal interstate commerce
- Balancing of privacy and security
- Sound economics and incentives
  - Supply and demand
  - Risk and reward
  - Regulatory clarity and enforcement
- Science, *i.e.*, systematic study and knowledge

Co-Presenter
Medical-Scientific Perspective

FDA Statements

- FDA Commissioner Dr. Robert Califf: “The agency intends to fully support efforts to advance this technology" (AP, 3/1/16)
- FDA’s comprehensive opioid abuse action plan
  - Advisory committee for any non-abuse-deterrent opioid NDA
  - “Formally incorporate the broader public health impact of opioid abuse in approval decisions”
- Draft guidance for generic abuse-deterrent opioids: “The availability of less costly generic products should accelerate prescribers’ [uptake] of abuse deterrent formulations”

Shortcomings of First-Generation Products

- Breadth of “abuse-deterrent” term (employed by critics and regulators)
- Do not prevent:
  - Euphoria, addiction
  - Interactions with other substances, *e.g.*, alcohol
  - All forms of manipulation for abuse or overdose by all means
- Can cost more than conventional counterparts; not yet available as generics
- Difficult to isolate public health benefits
  - Relatively slow market adoption
  - Not supported by adequate demand reduction
  - Impacted by price, purity, and availability of illicit substances
- Are additional opioids coming to market during an opioid overdose epidemic
  - Irrespective in intended safety improvements
  - Despite displacement of conventional opioids in many cases
- [Can yield profits manufacturers at a time of high anti-pharma sentiment]

Potential Benefits of First-Generation Products

Abuse-Deterrent Properties

- May help prevent unintentional overdose
  - Inexperienced persons who alter route of administration
  - Medical misuse, e.g., crushing to take with apple sauce
- May be less desirable for abuse
  - Lower black market demand
  - Less often diverted
- May help thwart the trajectory of abuse

Novel Delivery Systems

- May not be dispensed to patients for self-administration
- May reduce opportunities for diversion, misuse, abuse, and accidental exposure
- May offer continuous medication delivery and greater adherence to medication regimen
- May improve access and convenience, and help reduce stigma

- *Any* reduction in diversion, misuse, abuse, accidental exposure, overdose, or disease transmission is a positive outcome
- Can help fund development of next-generation products

Policy Goals: Reduce Unnecessary Exposure to and Risks of Controlled Medications

- Development and use (when appropriate) of alternatives to commonly abused medications
  - Non-pharmacologic treatments, *e.g.*, virtual reality
  - Non-controlled medications, *e.g.*, biologics
  - Lower risk (lower scheduled) controlled medications
  - Medications with abuse-deterrent properties and novel delivery systems
    - Extended release, immediate release
    - Brand, generic
    - Not just opioids for pain, not just opioids
- Broad market transition
- Regulatory clarity and flexibility
- Recognition of benefits (providers, patients, and public)
- Advance notice of transition deadline to ensure product availability, competition, and lower costs
- Public and private insurance coverage

Legislation

- State legislation
  - Parity of coverage, e.g., prior authorization and co-pays
  - Non-substitution without authorization
- *Why limit to opioid analgesics?*

- Bills introduced in 25 states in 2015 & 2016
- Bills passed in 9 states (CO, IN, MA, MD, ME, MO, NV, TN, UT)
- Bills vetoed in 2 states (NJ & NY)

- Developing consensus on essential elements of 2017 federal legislation

Conclusion

- Thanks to NASCSA, conference sponsors, and co-presenter
- LinkedIn.com/in/michaelcbarnes
- Twitter: @claad_coalition, @mcbtweets
- Thank you
- Questions and discussion