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

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Center for Lawful Access
and Abuse Deterrence

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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



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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



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Co-Presenter Medical-Scientific Perspective



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

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



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?*
- Developing consensus on essential elements of 2017 federal legislation
- 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)



Conclusion

- Thanks to NASCSA, conference sponsors, and co-presenter
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- Thank you
- Questions and discussion



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