Legalizing “Medical Marijuana”- Creating a Slippery Slope?

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Andrea G. Barthwell, MD
Director, Two Dreams

Objectives

- Discuss
  - What impact could legalizing medical marijuana bring?
  - Will it lead us down a path to legalize other “immoral” behaviors?
  - Will it increase recreational marijuana and other illicit drug use?
- Other questions for consideration
  - Tax revenue?
  - Decrease money spent on criminal prosecutions?

What is the “slippery slope?

- Quality standards lessened
- Safety issues ignored
- Accountability requirements set aside
- Delivery system dangerous
- Cost review outside of regulatory control
- Efficacy proof negated
- Needs of prescribers unmet
- Creates a pathway for others to follow

Benefit of FDA review

- Process of drug approval and regulation, including labeling, patient and health care provider education, and marketing restrictions have enabled the realization of benefits of medications to individuals and the public health (Hilts, 2003)
- By way of AE reporting and other systems detect unintended consequences
- CNS drugs have additional requirements of scheduling and schedule specific provisions

Review, continued

- Since 1990s risk management strategies used on drug-by-drug basis to minimize unintended consequences
- Safety and efficacy data sets conditions for access, marketing, and labeling to support appropriate use and discourage inappropriate and harmful use
- Labeling can contain specific claims of medical efficacy

“Accepted Medical Use”

- The drug’s chemistry must be known and reproducible
- There must be adequate safety studies
- There must be adequate and well-controlled studies proving efficacy
- The scientific evidence must be widely available
- *Crude botanical plant material, not standardized by dose and composition, cannot meet these criteria*

Essential Quality Standards

- Composition
- Characterization
- Components
- Standardization/ consistency
- Stability/ storage

Safety

- Lessons learned from recent recalls
  - Never do less testing or lower our standards
- Animal studies
  - Carcinogenic
  - Reproductive
  - Chronic toxicity
  - Genotoxicity
  - Safety

Safety Continued

- Clinical trials
  - Patient years
  - Adverse events
  - Regulatory notification
- Avoids risk of
  - Pesticides, fungi, heavy metals, bird droppings, animal carcasses, etc.
  - Netherlands note- irradiation

Accountability

- Manufacturing process goes awry
  - Company called to task
- Diverted at Pharmacy
  - Practices are reviewed
- Patient injured by improper medication
  - Physician is accountable

Delivery Systems

- Supply chain monitoring
- Pharmacy outlets (or alternative)
- Dispensaries concerns
  - Security
  - Congregation and Congestion
  - Intoxicated consumers coming and going

Cost

- Until we give away 100% pure drugs in unlimited quantities, there will always be a black market
- Price Elasticity Fluctuates -- Addictive substances do not behave in the market the way non-addictive substances do
  - Price elasticity of demand for a highly addictive drug fluctuates – that is, it goes from a perceived luxury with first time use to an inescapable necessity a few uses later

Cost, continued

- Demand is sensitive to changes in price (Williams 2004, Jacobson 2004)
- Prohibition- increases cost, “cost of doing business,” risks on producers and sellers
- Taxation- creates tremendous black market profit potential ex. Tobacco- Canada U.S. border
- Regulation- patients may not choose available product
- Marketing for customers has potential to drive market up

Cost, continued

- Most seriously ill patients cannot cultivate cannabis themselves and purchase it from outside vendors
- Average price is $11/gram (28 grams per ounce), but can be up to $15-$35/gram
- Daily usage is generally 1.8-3.0 grams, but can be as much as 3.0-10.0 grams/day
- At an average of 2.2 grams per day and an average price, cost is $726 per 30-day month
- If use is 4 grams, price can range from $1,320-$4,200 per 30-day month!

Efficacy

- Phase II and III placebo controlled clinical trials for the target
  - Medical scientific evidence where we not only know the number of patients reporting an benefit (numerator), but we also know the number not reporting a benefit (denominator)
- Would not require proof of efficacy, just reports of preference for one substance over approved medications

Prescriber Needs

- Ability to give patients meaningful advice and reliable information
- Ability to review controlled trial results
- Notice of AEs collected after it is on the market
- Ability to send patient to “pharmacy”
- Cost defrayed by health insurance

Pathway Defined

- Biological, botanical, chemical source identified
  - Serendipity note
- Animal studies of characterized material to determine how it works and whether it is likely to work in humans
- Human studies to determine safety when used to treat a certain diagnosis
- Center for Drug Evaluation and Research (CDER) review of safety and efficacy for intended use; benefits > risk
- Note- If accept “no risk” argument, still have to show benefit

Smoke screens and the real slippery slope

- Smoked “medicine”
  - Cite variability in pulmonary studies, develop vaporizers, put in tongue-in-cheek knockoff candy wrappers, avow only end of life use
- “Grow their own” to avoid cost discussion
  - If too ill, then get from club (massive outlet)
- Why treat other crude materials differently
  - Are claims that heroin is better than morphine for my condition next? Where does it end?

If there is no end in sight, and we want to move in this direction with medicine approval, why not start with something without CNS activity and treaty issues?