

The Phenomenology of Prescription Opioid Abuse: What Types of Abuse Do Products Need to Resist?

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October 27, 2005



Historical Perspective

- Prescription opioid abuse an old problem
- Pharmacy Act of 1868 required registration of those dispensing drugs
- Pure Food & Drug Act of 1906 required labeling of products in interstate commerce

Historical Perspective

“At the bottom of the noisome pit of charlantry crawl the drug-habit specialists. They are the scavengers delving amid the carrion of the fraudulent nostrum business for their profits. The human wrecks made by the opium- and cocaine-laden secret “patent medicines” come to them for cure and are wrung dry for the last drop of blood.”

- Muckraker: Samuel Hopkins Adams (1905)

Historical Perspective

- **Harrison Narcotics Act of 1914**
 - Required prescription of narcotics in “good faith”
 - Need to register with Bureau of Internal Revenue (\$1 tax stamp)
 - Required detailed record keeping for dispensed narcotics

Historical Perspective

- **Committee on Problems of Drug Dependence formed in 1929**
 - Develop less abuseable narcotic medication
- **Marijuana Tax Act of 1937**
 - Removed Heroin from US Pharmacopoeia
- **Comprehensive Drug Abuse and Control Act of 1970**

Where Are We Today?

- Prescription drug abuse still a problem
- “It is tragically ironic that, while our streets are awash in prescription medications, the under-treatment of pain in legitimate patients remains a national problem.”

■ Senator Susan Collins, Boston Globe, August 8, 2003

Why New Formulations?

- Patient safety and efficacy
 - Provides alternate delivery systems
 - Patches
 - Nasal sprays
 - Improved pharmacokinetics
 - Longer duration of action
 - More consistent blood levels
 - Reduced pill load for higher blood levels
- Reduced abuse liability

The Talwin Experience

- Launched in 1969
 - Not scheduled
- Marketed as having low abuse potential
- Sporadic IM abuse by health care professional in early 1970s
 - Very little media response to this
- Scheduled in CSA in 1974
 - Schedule IV

The Talwin Experience

- T's and Blues (T's and B's, T's and V's, T's and Rits) street use late '70s to early '80s
 - Localized to Chicago, St Louis and New Orleans
 - Heavy media response
- Talwin NX launched in 1983

The Talwin Experience

- Abuse of T's and blues decreased prior to release of NX formulation
 - Good Heroin increased in areas of T's and Blues abuse prior to release of NX
- DAWN mentions decreased
- Price of old tablets increased
- Prescriptions increased after NX
 - Then dropped precipitously
- Abuse of new preparation reported
- Decreased efficacy of new formulation reported

**Talwin NX only
addressed the problem
in IV abuse.**

Does one size fit all?

**Abuse is not abuse
is not abuse!**

With sincerest apologies to Gertrude Stein.

Types of Abusers

- **Hard core opioid (heroin) addict**
 - Primarily IV abuser
 - May snort or smoke
 - Wants intense heroin like high
 - Often has high tolerance
 - Attracted to areas where overdoses occur
 - Urban dweller
 - Only uses Rx drugs when good cheap heroin not available

Types of Abusers

- **Hard core opioid (Rx) addict**
 - Primarily oral or intranasal abuser
 - Tries to convert CR formulation to IR
 - Wants intense high
 - Will use heroin if available
 - Often has high tolerance
 - Suburban or rural dweller
 - Will use lots of IR drugs if that is all that is available

Types of Abusers

- **Polydrug abuser**
 - Will smoke, snort and swallow
 - IV use rare
 - Takes any type of drug available
 - Likes to mix multiple drugs together including alcohol
 - Often has high tolerance to multiple drugs
 - Lives everywhere
 - Likes all types of Rx drugs
 - Will empty your medicine cabinet

Types of Abusers

- **Rave abuser**
 - Will smoke, snort and swallow
 - Takes any type of drug available
 - Likes to mix multiple drugs together including alcohol
 - Often has high tolerance to multiple drugs
 - Lives everywhere
 - Likes all types of Rx drugs
 - Will empty your medicine cabinet
 - Prefers long acting drugs

Types of Abusers

- **Inexperienced abuser**
 - Primarily has experience with alcohol and marijuana
 - Will abuse Rx drugs if available
 - Will mix with alcohol and marijuana
 - Has no tolerance
 - High school or college student
 - THIS IS THE POSTER CHILD

Types of Abusers

- **Patient abuser/addict**
 - Commonly has history of abuse or mental illness
 - True iatrogenic addiction rare
 - “Pseudoaddiction” must be ruled out
 - Misuse should not be confused with abuse
 - May be a scammer/diverter
 - Should not confuse physical dependence with abuse or addiction

Tamper Resistance Scale

Curtis Wright, IV, MD, MPH

- Level 0 – no preparation needed for abuse
- Level 1- readily prepared for abuse by all routes
- Level 2 – readily prepared for abuse by some routes
- Level 3 – requires extraction with simple solvents
- Level 4 – extracted only with advanced solvents
- Level 5 – not readily recovered with common methods
- Level 6 – resistant to remanufacture

Abuse Liability Matrix

Tamper Resistance	Efficacy related to IR	Safety related to IR	Drug interactions	Abuse type affected
Level 0	↑ ↓	↑ ↓	↑ ↓	None
Level 1	↑ ↓	↑ ↓	↑ ↓	None
Level 2	↑ ↓	↑ ↓	↑ ↓	IV
Level 3	↑ ↓	↑ ↓	↑ ↓	IV, nasal
Level 4	↑ ↓	↑ ↓	↑ ↓	All but intact abuser
Level 5	↑ ↓	↑ ↓	↑ ↓	All but intact abuser
Level 6	↑ ↓	↑ ↓	↑ ↓	All but intact abuser

Where Do We Go from Here?

- How do we balance the benefit/risk ratio?
 - Who should take precedence?
 - Patient?
 - Addict?
 - Abuser?
- If we make a true abuse resistant formulation, will abuse and addiction go away?
- We need consistent definitions and diagnostic criteria that address the difference between illicit and licit drugs

Some Other Thoughts

- Should abuse resistance be used for marketing?
- Do we need better definitions for misuse, abuse, addiction, dependence, etc.?
- Do we need a change in the DSM with new criteria for prescription drug problems?