

Goals of an Opioid Risk Management Plan

Tufts Health Care Institute Program on Risk Management:

Responding to Signals of Prescription Opioid Abuse and Diversion

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Consider the Precursors

- Early RMP's were designed to prevent spread of abuse from medications used to treat addiction (opioid, nicotine)
- Second generation programs focused on specific risks and their prevention
- Third generation programs proposed to address all identifiable product risks

Mechanisms Underlying the Early RMPs

- Statutory
- Non Statutory
 - Informally linked to approval
 - Formally linked to approval (subpart H)

RMP's to prevent spread of abuse from medications for addiction treatment

- 1970s to 1990s Methadone, LAAM
 - NATA---prohibited prescription of controlled substances for addiction. Only legal mechanism—dispensing drug in treatment centers (Methadone Clinics)
 - administered by FDA
 - GOAL: prevent diversion to nonaddicts by “containing” the availability of drug
- 1990s Nicotine replacement products
 - Prohibition on underage sales
 - Early active surveillance (media reporting)
 - “informally” linked to approval
 - Feeble attempts to make oral drugs nonpalatable
 - *GOAL: to prevent NRTs from becoming “gateway” to smoking among minors*

RMP's to prevent spread of abuse from medications for addiction treatment

- 2002 Buprenorphine SL
 - Statutory components in place (DATA) at time of approval
 - DEA registration linked to special training
 - Limits on number of patients treated by a single physician
 - FDA imposed additional RMP “informally” linked to approval
 - Focus on particulars of prescription and distribution chain
 - Active surveillance and Reporting requirements
 - GOAL: to prevent diversion to substance abusing population or beyond

Opioid RMPs for Pain Medications

- Evolved as the FDA's Risk Management Focus was developing for all therapeutic products
- GOAL: protect risk to the vulnerable population for which drug not prescribed
- Examples
 - Thalidomide
 - Isotretinoin
 - Actiq
- It would not be until OxyContin abuse was perceived as a serious problem that FDA expanded its focus to preventing abuse and diversion