TAKE BACK SUMMIT

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Overdose: A Public Health Epidemic

• Prescription opioids are potentially dangerous drugs – overdoses involving these drugs claimed more than 175,000 lives between 1999 and 2013.

• From 1999 to 2010, a 4-fold increase in opioid sales paralleled a more than 4-fold increase in prescription opioid-involved overdose deaths.
National Drug Control Strategy

• The President’s science-based plan to reform drug policy:
  1) Prevent drug use before it ever begins through education
  2) Expand access to treatment for Americans struggling with addiction
  3) Reform our criminal justice system
  4) Support Americans in recovery

• Coordinated Federal effort on 112 action items

• Signature initiatives:
  – Prescription Drug Abuse
  – Prevention
  – Drugged Driving
Rx Elements of the 2010 National Drug Control Strategy

– Prevention
  • School Based and Community
  • Media Campaign

– Opioid Use/Nonmedical Prescription Use
  • Early Intervention, Treatment and Recovery
  • Naloxone for First Responders including law enforcement
  • Syringe Exchange Services
Prescription Drug Abuse Prevention Plan

• Coordinated effort across the Federal Government

• Four focus areas:
  1) Education
  2) Prescription Drug Monitoring Programs
  3) Proper Disposal of Medication
  4) Enforcement
• In September 2014, we joined the Drug Enforcement Administration to announce the final rule of the Safe Drug Disposal Act of 2010.
Drug Disposal Accomplishments and Remaining Action Items

- Congress passed the *Secure and Responsible Drug Disposal Act of 2010*¹
- FDA website on safe disposal of unused medicines²
- DEA conducted interim take back activities
  - 9 National Take-Back Days/over 2,100 tons returned
- DEA *Published Disposal of Controlled Substances Final Rule*³
- Final rule went into effect October 9, 2014³
- Promote community-based medication disposal programs⁴

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¹ http://www.deadiversion.usdoj.gov/drug_disposal/non_registrant/s_3397.pdf
² http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/EnsuringSafeUseofMedicine/SafeDisposalofMedicines/ucm186187.htm#MEDICINES
Community Efforts

Educate the Community: DEA encourages voluntary, educational outreach to the public on the abuse potential and proper disposal of pharmaceutical controlled substances, whether it be through law enforcement, community groups, or professional organizations.

Conduct Take-Back Events: Entities may choose to establish disposal programs for various reasons, including for profit, to build goodwill in the community, to attract customers, to advertise businesses, and to preserve the environment.
The Rule Allows

- Mail-back programs
- All means of disposal allowed previously (e.g., take-back by DEA)
- Drop boxes in pharmacies
- Drop boxes in law enforcement agencies
Bill Pollack, Program Manager, Household Hazardous Waste Program

- County Drug Take-Back Program
- Pre DEA Regulations: 31 sites, managed & funded by nine agencies: Wastewater, LEA’s Recycling & HHW program. One is a law enforcement controlled substances site
Safe Drug Disposal Ordinance
Alameda County, California

Kathleen Pacheco, Senior Deputy County Counsel

- Lawsuit filed in federal court by pharmaceutical trade groups alleging unconstitutional burden on interstate commerce, violating the dormant commerce clause.
  
  Pharmaceutical Research And Manufacturers Of America; Generic Pharmaceutical Association; Biotechnology Industry Organization v. County Of Alameda

- Summary Judgment in favor of Alameda County
  
  “Defendants have adequately shown that the Ordinance serves a legitimate public health and safety interest, and that the relatively modest compliance costs producers will incur should they choose to sell their products in the county do not unduly burden interstate commerce.”  Pharma v. County Of Alameda (2013) 967 F.Supp.2d 1339, 1346.

- Appealed to US Court of Appeals, Ninth Circuit which upholds lower court
  
  “However, there is nothing unusual or unconstitutional per se about a state or county regulating the in-state conduct of an out-of-state entity when the out-of-state entity chooses to engage the state or county through interstate commerce.”  Pharma, et al v. County Of Alameda (2014) 768 F.3d 1037, 1043.

  “The fact that the county could run a similar program does not nullify the program's benefits. ... Moreover, even if the Ordinance did nothing other than save the county money, that is not equivalent to “no public benefits.”  768 F.3d at 1045.
Safe Storage and Drug Disposal

- Prescribers should talk to patients about controlled substance storage and disposal

- DEA’s new rule allows
  - Mail-back programs
  - All means of disposal allowed previously (e.g., take-back by law enforcement)
  - Drop boxes in pharmacies & law enforcement agencies
  - Drug Deactivation Systems that meet the DEA Standard

- Parents and Pharmacists can work with local law enforcement and community coalitions to support safe disposal
Disposal Needs Today – National Plan

• DOJ (DEA) has conducted an additional Take Back Day.

• However:
  – A comprehensive National safe storage/disposal rollout plan is still needed
    • Environmental groups and waste disposal
    • Law enforcement
    • Pharmacies
    • Prescribers
For More Information

whitehouse.gov/ONDCP