Disposal of Controlled Substances

Cathy A. Gallagher
Associate Section Chief Liaison and Policy Section Office of Diversion Control

October 12, 2010
Office of Diversion Control

Mission

To prevent, detect, and investigate the diversion of controlled substances from legitimate sources

while

Ensuring an adequate and uninterrupted supply for legitimate medical and scientific purposes
Controlled Substances Act of 1970

• Established system for U.S. compliance with international treaties.

• Serves as the legal foundation of the Federal government’s authority over controlled substances and listed chemicals.

• Consolidated over 50 laws regulating the manufacture, distribution, import/export, and dispensing of controlled substances and listed chemicals.
The CSA’s Closed System of Distribution

Manufacturer

Distributor

Pharmacy

Importer

Practitioner

Patient

The CSA’s Closed System of Distribution

Manufacturer

Distributor

Pharmacy

Importer

Practitioner

Patient
Active DEA Registrants

as of 6/8/10

- Practitioners 1,045,080
- MLP – Nurse Practitioners 92,107
- MLP – Physician Assistants 54,255
- Pharmacies 65,863
- Hospitals/Clinics 15,606
- Researchers 6,147
- All Others 5,676

- Approximate Total: 1.3 million - 2010
- Approximate Total: 480,000 - 1973
Disposal of Controlled Substances
CSA Limitations

- Under the Controlled Substances Act, Congress established a "closed system" of distribution designed to prevent the diversion of controlled substances.

- All persons who lawfully handle controlled substances must be registered with DEA or exempt from registration.

- Ultimate users are not required to register with DEA to possess controlled substances.
CSA Definitions

Under the Controlled Substances Act...

- An “ultimate user” is a person who has lawfully obtained, and who possesses, a controlled substance for his own use or for the use of a member of his household or for an animal owned by him or by a member of his household.
DEA Regulatory Action

- Entitled, “Disposal of Controlled Substances by Persons Not Registered With the Drug Enforcement Administration.”
- Seeking options for the safe and responsible disposal of patient owned controlled substances consistent with CSA.
- Comment period ended March 23, 2009.
Solicited information on the disposal of CS dispensed to ultimate user from:

- ultimate users
- law enforcement
- interest groups
- long-term care facilities
- hospices and in-home care groups
- pharmacies
- reverse distributor
- state regulatory agencies
- other interested parties

158 Comments Received (Regulations.gov)
Safe Disposal Act of 2009

- **House Resolution 5809**
  - Introduced on 7/21/2010 by Rep Inslee (WA)
  - Amend the CSA to permit ultimate user disposal
  - Passed House on 9/22/2010

- **Companion Senate Bill 1336**
  - Introduced on 6/24/2009 by Sen Murray (WA)
  - Referred to Committee 6/24/2009
Secure and Responsible Drug Disposal Act of 2009

- **House Resolution 1359**
  - Amend the CSA to permit ultimate user disposal
  - Referred to committee April 2009

- **Senate Bill 3397**
  - Introduced on 6/18/2009 by Sen Klobuchar (MN) and Sen Grassley (IA)
  - Passed Senate on 8/3/2010
  - Amended on 9/30/2010, sent to President for signature

DEA - Office of Diversion Control
Law Enforcement Involvement

Registration is waived for “Any officer or employee of any State, or any political subdivision or agency thereof, who is engaged in the enforcement of any State or local law relating to controlled substances and is duly authorized to possess controlled substances in the course of his/her official duties.”

21 CFR 1301.24(a)(2)
DEA National Take Back Day

- September 25, 10:00 am-2:00 pm
- More than 4,000 collection sites
- Approximately 3,000 state and local agency participants
- Collections in all 50 states, Puerto Rico, Guam, and the Virgin Islands
Got Drugs?

Turn in your unused or expired medication for safe disposal
Saturday, Sept. 25th
Visit www.dea.gov for a collection site near you.
Got Drugs?

Turn in your unused or expired medication for safe disposal Saturday, Sept. 25th

Visit www.dea.gov for a collection site near you.
Got Drugs?

Make your home medicine cabinet safe

Saturday, Sept. 25th

Visit www.dea.gov for a collection site near you.

Visit www.dea.gov for a collection site near you.

Turn in your unused or expired medication for safe disposal.

Visit www.dea.gov for a collection site near you.
Results

Approximately 242,000 lbs of unwanted medications were collected.
Lessons Learned