## PTCE DUMP SHEET

## Federal laws



• The Poison Prevention Packaging Act (1970)

Mandates child-resistant packaging.

- The Resource Conservation and Recovery Act (RCRA,1976)
  Regulates the disposal of solid waste and hazardous waste.
- The Occupational Safety and Health Administration (OSHA, 1970)

Assures safe and healthful working conditions.

The Controlled Substances Act (CSA)

Creates five schedules for controlled medications.

- The Combat Methamphetamine Epidemic Act (CMEA, 2005) Limits sales of ephedrine, pseudoephedrine, and phenylpropanolamine. Sets a daily limit of 3.6 grams and a 30-day limit of 9 grams per purchaser.
- The Ryan Haight Online Pharmacy Consumer Protection Act (Ryan Haight Act, 2008)

Prevents the illegal distribution and dispensing of controlled substances through the Internet.

The Risk Evaluation and Mitigation Strategy (REMS)

Monitors certain medications with serious safety concerns to help ensure the benefits of the medication outweigh its risks, like isotretinoin, clozapine, and thalidomide.

• The Durham-Humphrey Amendment (1951)

Distinguishes between over-the-counter and prescription drugs.

• The Kefauver-Harris Amendment (1962)

Enacted in response to the thalidomide tragedy.

Refilling controlled medications

Schedule II medications cannot be refilled. Instead, they need a new prescription for every fill. Schedule III and IV cannot be refilled after six months or five times, whichever is earlier.