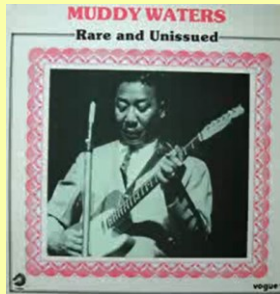




Theme: History of US Drug Legislation



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### Chapter 3

### Drug Products and Their Regulations



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### Early U.S. Reformism

- Current laws trace back to two pieces of legislation from the early 1900s
- Racist fears about deviant behavior, including drug misuse, played a role in the development of drug regulation
- Laws were developed to regulate undesirable behaviors



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## Issues Leading to Legislation

### 1. Fraud in patent medicines that were sold directly to the public

- False therapeutic claims
- Habit-forming drug content



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## Issues Leading to Legislation

### 2. Opium and the Chinese

- U.S. was involved in international drug trade
- Opium smoking brought to U.S. by Chinese workers
- Laws passed against the importation, manufacture, and use of opium—racism involved?



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## Issues Leading to Legislation

### 3. Cocaine

- Present in many patent medicines (and, yes, Coca-Cola!)
- Viewed as a cause of increasing crime
- Racist connections



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## 1906 Pure Food and Drugs Act

- Required **accurate labeling** and listing of ingredients
- Later amended to require safety testing and testing for effectiveness

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## Harrison Act of 1914

- A law that required those who “produce, import, manufacture, compound, deal in, dispense, or give away” certain drugs to **register and pay a special tax**
- Later expanded to include other federal controlled-substance regulations

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## Two Bureaus, Two Types of Regulation

- **The Pure Food and Drugs Act (1906)**
  - U.S. Department of Agriculture
  - Goal: drugs are pure and honestly labeled
- **Harrison Act (1914)**
  - U.S. Treasury Department
  - Goal: taxation of drugs to restrict commerce in opioids and cocaine to authorized physicians, pharmacists, and legitimate manufacturers

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## 1920s Prohibition

- In **1919**, laws were created making **alcohol sale, manufacture and transportation illegal (18<sup>th</sup> Amendment)**
- Contemporary prohibitionists ("dries") labeled this as the "Noble Experiment"<sup>[2]</sup> and presented it as a victory for public morals and health. The **consumption of alcohol overall went down by half in the 1920s**

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## ZDOGG MD

"Big Pharma"



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## Regulation of Pharmaceuticals

Today, the industry is a **\$180 billion market**

1. **Purity** – 1912 *Sherley Act*
2. **Safety** – 1938 *Food, Drug, and Cosmetic Act*
3. **Effectiveness** – 1962 *Kefauver-Harris Amendments*

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## Regulation of Pharmaceuticals

### 1. Purity

- **1912 Sherley Amendment** outlawed “false and fraudulent” therapeutic claims on labels
  - The contents of the product must be accurately listed on the label
  - FDA encouraged voluntary cooperation and compliance

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## Regulation of Pharmaceuticals

### 2. Safety

- Originally no legal requirement that medications be safe; but then came “*Elixir Sulfanilamide*” (107 deaths) p.58
- **1938 Food, Drug, and Cosmetic Act** required pre-market testing for toxicity
- Companies required to submit a New Drug Application (NDA) to the **FDA** (*Food and Drug Administration*)
  - FDA became a gatekeeper and expanded greatly
- Directions must be included
  - Adequate instructions for consumer **OR**
  - Drug can be used only with physician prescription

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## Regulation of Pharmaceuticals

### 3. Effectiveness

- **1962 Kefauver-Harris Amendments**
  - *Thalidomide*: caused birth defects in W. Germany
  - Pre-approval required before human testing
  - Advertising for prescription drugs must include information about adverse reactions;
  - Every new drug must be demonstrated to be effective for the illnesses mentioned on label.

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## Marketing a New Drug

- May require 10+ years and costs \$1+billion
- Preclinical research and development
  - **IND** submitted to the FDA (notice for new drug investigation)
- **Clinical trials:** human research and development
  - *Three Phases*, from low doses to a few healthy volunteers to higher doses for typically 1,000-5,000 patients
- Permission to market after *many* years
- **Fraud?** July '12, *Glaxo-Smith-Kline, \$3 bil. settlement* - *Avandia* (diabetes drug) re-evaluated

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## Marketing a New Drug

- **Orphan Drug Act of 1983** — tax and other financial incentives for developing rare disease drugs
- **Prescription Drug Marketing Act of 1988** — regulation of free samples, imports, etc.
- **1997 FDA Modernization Act** — new guidelines for postmarketing reporting, distribution of information on off-label uses

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## Dietary Supplements

Dietary Supplement Health and Marketing Act

- **Regulated more like food** than drugs
- Labels must be accurate
- Products can't make unsubstantiated *direct* claims
- Products can make general health claims
- Products can be marketed without first proving safety



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## Controlled Substances

Parched land no desert sand, sun was just a dot  
And a little bit of water goes a long way, 'cause it's hot  
Three good buddies were laughing and smoking in the back  
Of a rented ford  
They couldn't know they weren't going far

Each one with the money in his pocket  
Could go out and buy himself a brand new car  
But they all had the money they had  
Money they hoped would take them very far

The sky was bright, a traffic light, now and then a truck  
And they hadn't seen a cop around all day  
They brought everything they needed  
Bags and scales to weigh the stuff  
The driver said the border's just over the bluff

It wasn't until the car suddenly stopped  
In the middle of a cold and barren place  
And the other guy turned and spilled  
Three boys blood, did they know a trap had been lain?

They're ok the last days of may, I'll be breathing dry air  
I'm leaving soon, the others are already there  
You wouldn't be interested in coming along, instead of staying here  
They say the west is nice this time of year



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## Controlled Substances

- **Early enforcement: 1920s**
  - 18th Amendment (Alcohol Prohibition)
  - Physicians and pharmacists arrested; growth of illegal drug trade
  - Stiffer penalties
    - **1922 Jones-Miller Act** – doubled penalties for dealing
    - Prohibition on importation of opium for heroin
  - **Prison vs. rehabilitation**
    - Punishment seemed not to be working
    - "Narcotic farms" – 1935, Lexington KY (1000 patients, 2/3 of whom were prisoners)

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## Controlled Substance

- **1930 Bureau of Narcotics** (Treasury Department)
  - First "Drug Czar" (Harry Anslinger) – control until 1962
  - 1937 - Marijuana Tax Act
  - 1951 - Mandatory minimum sentences (1951)
  - 1956 - Narcotic Drug Control Act toughened penalties again; link to McCarthyism
- **Drug Abuse Control Act Amendments of 1965**
  - Added new classes of drugs (hallucinogens like LSD)

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## Comprehensive Drug Abuse Prevention and Control Act of 1970

- Replaced or updated all previous laws
- Drugs controlled by the Act are under federal jurisdiction (The DEA - *Drug Enforcement Agency* - is created)
  - In some cases, state and federal laws conflict; CA mj
- **The goal:** direct control of drugs, not control through taxation
- Enforcement separated from scientific and medical decisions
- Prevention and treatment funding increased

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## Summary of Controlled Substance Schedules

Schedule	Criteria	Examples
I	a. High potential for abuse b. No accepted medical use c. Lack of accepted safety	Heroin, marijuana, MDMA (Ecstasy), LSD
II	a. High potential for abuse b. Currently accepted medical use c. Abuse may lead to severe dependence	Morphine, cocaine, methamphetamine
III	a. Potential for abuse less than I and II b. Currently accepted medical use c. Abuse may lead to moderate physical dependence or high psychological dependence	Anabolic steroids, most barbiturates, Dronabinol (THC in pill form)
IV	a. Low potential for abuse relative to III b. Currently accepted medical use c. Abuse may lead to limited physical or psychological dependence relative to III	Xanax, barbitol, chloral hydrate, fenfluramine
V	a. Low potential for abuse relative to IV b. Currently accepted medical use c. Abuse may lead to limited physical or psychological dependence relative to IV	Mixture with small amounts of codeine or opium

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## Comprehensive Drug Abuse Prevention and Control Act of 1970

- Set new possession and selling penalties – 15 year max.
- Made illegal:
  - Drug precursors (raw form)
  - Drug paraphernalia
- **Office of National Drug Control Policy** established
- Further legislation has muddled the 1970 act; for example, **Anti-Drug Abuse Acts of 1986 & 1988**, and other Congressional mandates



*It is illegal to sell narcotics paraphernalia; these items were seized in a raid. So how can "head shops" sell them?*

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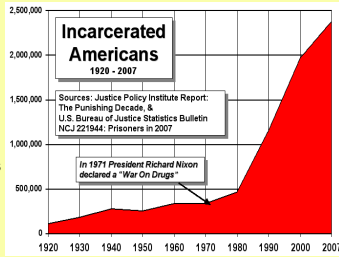
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## State and Local Regulations

- Difference in penalties from state to state
  - Federal law overrides state law
  - Significant growth in number of Americans in prison
  - In 2007 the number rose to 5.06 prisoners per thousand and in 2008 it dropped slightly to 5.04 per thousand.



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## Federal Support for Drug Screening

- Military and federal employees
- Transportation workers
- Employees at private companies
- Public schools employees
- Testing methods
  - Different test = different results
  - Different levels of sensitivity
  - Different detection ability



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## Impact of Drug Enforcement

- Budget
- International programs
- Other federal agencies



*In this raid, an international task force seized two tons of cocaine in the Caribbean Basin.*

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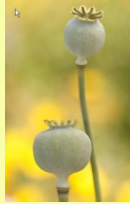
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## Impact of Drug Enforcement

- Other costs
  - Cost of prison population
  - Crimes committed to purchase drugs
  - Corruption in law enforcement
  - Conflicting international policy goals ([Afghanistan](#))
  - Loss of individual freedom
- Drug use has not been eliminated



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## Effectiveness of Control

- About 10-15 percent of illegal drug supply is seized each year
- When supplies are restricted, prices go up
- Higher prices and increased difficulty in obtaining drugs may deter some would-be users, but also may lead to more crime, poverty and other social problems



Seized Ecstasy

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