CHAPTER

Drug Use, Regulation, and the Law

The chapter outline provides you with an organizational guide to the topics and ideas presented in this chapter of the text.

Introduction

Cultural Attitudes About Drug Use The Road to Regulation and the FDA

Prescription Versus OTC Drugs
The Rising Demand for Effectiveness in
Medicinal Drugs
Regulating the Development of New Drugs
The Effects of the OTC Review on Today's
Medications

The Regulation of Drug Advertising

Federal Regulation and Quality Assurance

Drug Laws and Deterrence Factors in Controlling Drug Abuse

Strategies for Preventing Drug Abuse

Supply Reduction Strategy Demand Reduction Strategy Inoculation Strategy Drug Courts

Current and Future Drug Use

Drug Legalization Debate Drug Testing Pragmatic Drug Policies

■ Kev Terms

Ι	Define the following terms:
	1. Thalidomide
	2. Phocomelia
	3. Switching policy
	4. Supply reduction
	5. Interdiction
	6. Inoculation
	7. Drug courts
	8. Demand reduction
	O Harrison Act of 1014

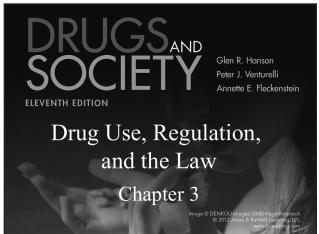
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■ Fill-in-the-Blank required manufacturers to **1.** The indicate the amounts of alcohol, morphine, opium, cocaine, heroin, and marijuana extract on the label of each product. is a birth defect that involves impaired development of the arms, legs, or both. **3.** The first legitimate effort by the U.S. government to regulate addicting substances was the _____ **4.** The ______ allows drug companies to receive tax advantages if they develop drugs that are not very profitable. involves attempts to decrease individuals' tendencies to use drugs with emphasis on reformulating values and behaviors. **6.** The policy of cutting off or destroying supplies of illicit drugs is called _____ Identify 1. Identify society's two major guidelines for controlling drug development and marketing. a. _____ 2. The Durham-Humphrey Amendment to the Food, Drug, and Cosmetic Act established criteria for determining whether a drug should be classified as prescription or nonprescription. Identify the three categories that determine whether a drug is considered nonprescription. **3.** Identify and explain the regulatory steps for developing new prescription drugs.

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4.	Identify the criteria that must be satisfied if a drug is to be switched to OTC status.
	a
	b
	c
	Discussion Questions
1.	Name and explain an example of a law or an amendment that has been passed to allow an exception to
	FDA new prescription drug regulations. Explain why the regulation is important.
2	Discuss the effects of advertising on the drug industry.
۷.	Discuss the effects of advertising on the drug industry.
3.	Why are drug laws not always a satisfactory deterrent against the use of illicit drugs?
4.	Discuss the drug legalization debate. What are the arguments being presented for and against the
	legalization of drugs? What are some possible compromises? What do you think is the best option?
5.	Discuss the pros and cons of drug testing.
	Discuss the prosenia consorting testing.

Notes	
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	Drug Use and Ch
	Guidelines for Developmen
	 Society has the righthe damaging impact Society has the right effective drugs.
	criccity diags.
	Patent
	 The term patent m the ingredients wer The patent medicin
	early 1900s demon insufficient regulat



Controlling Drug t and Marketing

- t to protect itself from ct of drug use.
- t to demand safe and

Medicines

- edicines signified that e secret, not patented.
- es of the late 1800s and strated the problems of ion of the drug industry.

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The 1906 Pure Food and Drug Act

- Required manufacturers to include on labels the amounts of alcohol, morphine, opium, cocaine, heroin, or marijuana extract in each product
- Made misrepresentation of drugs as "nonhabit forming" illegal
- Did not prohibit distribution of dangerous preparations

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The Sherley Amendment in 1912

- Accuracy of manufacturers' therapeutic claims was not controlled by the Pure Food and Drug Act
- The Sherley Amendment in 1912 was passed to strengthen existing laws and required that labels should not contain "any statement ... regarding the curative or therapeutic effect ... which is false and fraudulent."

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Food, Drug, and Cosmetic Act

- The sale and use of Elixir Sulfanilamide led to a tragic accident that killed over 100 people.
- Companies required to file applications with the government showing that new drugs were safe.

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Food, Drug, and Cosmetic Act (continued)

- Defined drugs to include products that affect bodily structure or function even in the absence of disease.
- Drug labels had to list all ingredients as well as provide instructions regarding correct use and warnings about its dangers.

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Durham-Humphrey Amendment

- Made formal distinction between prescription and nonprescription drugs
- Established drug classification categories
 - Drug is habit-forming
 - Drug is not safe for self-medication
 - Drug is a new drug and not shown to be completely safe

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Kefauver-Harris Amendments

- Passed, in part, as a consequence of the thalidomide tragedy
- Drug manufacturers had to demonstrate the efficacy and safety of drugs
- The FDA was empowered to withdraw approval of a drug that was already being marketed
- The FDA was permitted to regulate and evaluate drug testing by pharmaceutical companies

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Regulating New Drug Development

• The amended Food, Drug, and Cosmetic Act requires that all new drugs be registered with and approved by the FDA.

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Regulating New Drug Development (continued)

- The FDA is mandated by Congress to:
 - Ensure the rights and safety of human subjects during clinical testing
 - Evaluate the safety and efficacy of new treatments
 - Compare benefits and risks of new drugs and determine if approval for marketing is appropriate

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Regulatory Steps for New Prescription Drugs Clinical Research and Development (Human Testing) Phase 2 Phase 3 Postmarketing aurveillance Phase 4 Phase 4 Phase 4 Phase 3

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Notes	
	Regulatory Steps for In Prescription Drugs (consistence) • Step 1: Preclinical research and decelused in the step 2: Clinical research and develused in the step 2: Clinical stage • Clinical pharmacological evaluation • Step 3: Permission to market • Postmarketing surveillance
	New Drug Application (• If there is sufficient data to demons a drug is safe and effective, the consubmits an NDA as a formal reques FDA approve it for marketing.
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	 Exceptions: Special D Marketing Laws "Fast-track" rule Applied to testing of certain drug ones for rare cancers and AIDS Orphan Drug Law Tax advantages for development treat "rare diseases" since this can otherwise unprofitable Prescription Drug User Fee Act of Increase reviewers and decrease in
	- Therease reviewers and decrease

New tinued)

- evelopment
- lopment
 - ation stage

(NDA)

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The Regulation of Nonprescription Drugs

- In 1972, the FDA initiated a program to evaluate the effectiveness and safety of nonprescription drugs.
- The FDA evaluated each active ingredient in OTC medications and placed ingredients into three categories:
 - I. Safe and effective
 - II. Not safe and effective or unacceptable indications
 - III. Insufficient data to permit final classification

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Switching Policy

- The drug must have been used by prescription for 3 years.
- Use must have been relatively high during the time it was used by prescription.
- Adverse drug reactions must not be alarming, and the frequency of side effects must not have increased during the time the drug was available to the public.

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Drug Advertising

- Promotional efforts by pharmaceutical companies have a large impact on the drug-purchasing habits of the general public and health professionals.
- As a general rule, the FDA oversees most issues related to advertising of prescription products. The FTC regulates OTC and dietary supplement advertising.

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	Direct-to-Consumer (DTC) Advertising
	 Most physicians surveyed agreed that because their patient saw a DTC advertisement, he/she asked thoughtful questions during the visit. Approximately the same percentage of physicians thought the advertisements made their patients more aware of possible treatments. The physicians surveyed indicated that the advertisements did not convey information about risks and benefits equally well.
	Direct-to-Consumer (DTC)
	 Advertising (continued) Approximately 75% of physicians surveyed indicated that DTC ads cause patients to think that the drug works better than it does, and many physicians felt some pressure to prescribe something when patients mentioned DTC ads. The physicians surveyed reported that patients understand that they need to consult a health care provider concerning appropriate treatments.
	The Harrison Act of 1914
	Marked the first legitimate effort by the federal government to regulate and control the production and importation of addicting substances
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The Comprehensive Drug Abuse Prevention and Control Act

- This 1970 act divided substances with abuse potential into categories based on the degree of their abuse potential and clinical usefulness.
- Schedules I, II, III, IV, and V

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"Scheduling"

- Schedule I substances have high-abuse potential and no currently approved medicinal uses; they cannot be prescribed.
- Schedule II substances have high-abuse potential but are approved for medical uses and can be prescribed.
- Schedule II–V substances reflect the likelihood of abuse and clinical usefulness.

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Factors Determining Scheduling

- The actual or relative potential for abuse of the drug.
- Scientific evidence of the pharmacological effects of the drug.
- The state of current scientific knowledge regarding the substance.
- Its history and current pattern of abuse.
- What, if any, risk there is to the public health.

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 Factors Determi
 (conti
 • The psychological or pliability of the drug.
The scope, duration, anWhether the substance precursor of a substance
Principal Issues Regarding Su
• If a person abuses a dr treated as a criminal or with a disease?
 How is the user (support distinguished from the criminal) of an illicit d more harshly punished
Are the laws and associate deterrents against drug effectiveness determin
Strategies fo
 Drug
 • Supply Reduction - Attempts to curtail the
or their precursors and other, more therapeutic – Includes interdiction
 or destroying supplies - Limited success

ining Scheduling inued)

- hysiological dependence
- nd significance of abuse.
- is an immediate e already controlled.

Influencing Laws ubstance Abuse

- ug, should he or she be as a sick person inflicted
- sedly the victim) pusher (supposedly the rug, and who should be
- iated penalties effective use or abuse, and how is

r Preventing Abuse

- ne supply of illegal drugs exert greater control over drugs
- , the policy of cutting off of illicit drugs

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Strategies for Preventing Drug Abuse (continued)

• Inoculation

 Aims to protect drug users by teaching them responsibility and explaining the effects of drugs on bodily and mental functioning

• Demand Reduction

– Aims to reduce the actual demand for drugs

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Suggestions for Reducing Demand

- A top priority of prevention is to reduce demand by youth.
- Education must be carefully designed for the target population.
- Attitudes toward drug abuse must be changed.
- Replacement therapy can be useful.

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Drug Courts

- Designed to deal with nonviolent, drug-abusing offenders
- Integrate mandatory drug testing, substance abuse treatment, sanctions, and incentives in a judicially supervised setting



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	 Drug Legalization Debate Violence and crime would decrease/increase? Profits associated with illegal trade would decrease/increase? Law enforcement costs would decrease/increase? Addiction would decrease/increase? Societal/health costs would decrease/increase? Consumption would increase/decrease?
	 Drug Testing In response to the demand by society to stop the spread of drug abuse and its adverse consequences, drug testing has been implemented in some situations to detect drug users. Breathalyzers Urine, blood, and hair specimens
	Pragmatic Drug Policies • The government must develop programs that are consistent with the desires of the majority of the population. • Programs must consider de-emphasizing interdiction and stress programs that reduce demand.

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Pragmatic Drug Policies (continued)

- Government and society must better understand how laws, used properly and selectively, can reinforce and communicate expected social behavior and values.
- Programs, such as anti-smoking campaigns, should be implemented that employ "public consensus" more effectively.

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