INTERVIEWEE BACKGROUND INFORMATION

Name: James Franklin Robinson M/F: M

Address: 200 South Main Avenue, Sylacauga, Alabama, 35150

Phone number(s): (205) 245-3304

Approximate age or date of birth: 10-19-27

Mothers name: Ola Mae Robinson

Father's name: James Almon Robinson

Places lived and when: Born and raised in Sylacauga, Alabama; 1963 - Waukeegan, Illinois 1964 - 1971 Dubuque, Iowa; 1971 - 1976 Bynum, Alabama; 1976 - 1985 Oak Level, Al.; 1985 - Present Sylacauga, Alabama

Education: Columbia Military Acadamy - Graduated 1945; Howard College Graduated 1960 with a B.S. Degree

Religion: Christian

Business, political and social memberships (past and present): Alabama Pharmacutical Association, American Pharmacutical Association

Present occupation: Pharmasist

Former occupations: Pharmasist

Special Skills: Forensic Testing for drug identification

Major Accomplishments: Expert Witness , Editor Piedmont Hospital Newsletter, Articles published in various Pharmacutical publications

National Events in which interviewee has participated: World War II and Korean War

Local Events in which interviewee has participated:

National born U.S. citizen? Yes/No Naturalized Citizen: Yes/No

Country from which he/she emigrated:

Documents, photographs, and artifacts which are in the possession of the interviewee:

Individuals recommended by the interviewee who might be candidates for an oral history interview:

Additional information:

Gift and Release Agreement

We James F. Robinson (Interviewee (print)) and Tracy K. Lewis (Interviewer (print))

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200 South Main Avenue, Sylacauga, Alabama,

on the date(s) of March 27, 1996

for the oral history collection being compiled by Dr. Marshall.

James F. Robinson
Interviewee's Signature

Date: March 27, 1996

Address 200 South Main Avenue
Sylacauga, Alabama 35150

Phone (205) 245-3304

Date March 27, 1996

Interviewer's Signature

Address 644 West 44th Street
Anniston, Alabama 36206

Phone (205) 237-7443

James F. Robinson

James Robinson was born on October 19, 1927 the son of a pharmacist, James Almon Robinson, and a domestic engineer, Ola Mae Robinson. Raised in Sylacauga, Alabama, James Robinson grew up in and around the drug store environment of the mid 1900's with his brother Tom Robinson. In this environment James Robinson was able to watch as his father compounded drugs to make the pharmaceutical medicines of the mid 1900's. Finding the process fascinating and being encouraged by his father, James Robinson decided to go into the same field of endeavor as his father.

Attending Columbia Military Academy -- finishing in 1945 -- and then going on to Howard College (now called Samford University in Birmingham, Al) James Robinson found his education interrupted by his call to the United States Navy, he served in the U.S. Navy at the end of WWII and during the Korean War. Throughout his years of college James Robinson also worked various jobs including manufacturing, wholesaling, and retailing -- all in the drug field.

During this interim in his education, James Robinson married Carol Dale Roberts the daughter of a Navy Leiutentant Commander on Jan 20, 1952. From this union four

children were born, the firstborn Bruce Emerson Robinson born on Feb. 11, 1953, the second child Amy Jo Robinson born on Nov. 29, 1955, the third child Tracy Kathyrn Robinson born on September 24, 1957 and the fourth child James Scott Robinson born on Nov. 14, 1959. Mr. Robinson continued his education with much difficulty, raising a family and working full time, but finish it he did, in 1960 with a BS in Pharmacy.

James Robinson continued working in retail stores as a pharmacist. Working in retail pharmacies took James Robinson and family to Waukeegan, Illinois and then on to Dubuque, Iowa. In 1964 when the Robinson family moved to Dubuque, James Robinson started working in hospital pharmacy and as an expert witness in the identification of "street drugs".

In an effort to curb the use of street Drugs -- narcotics -- the Harrison Act of 1914 was passed by the Federal Government; this Act made it illegal to obtain narcotic drugs without a prescription. In 1927 the Food, Drug, and Insecticide Administration was formed; in 1930 this agency became known as the Food and Drug Administration (FDA). Although the Harrison Act and the formation of the FDA were beginnings, there were not any major steps toward drug control until 1965 when the Drug Abuse Control Amendments were enacted to deal with problems of addiction. Until 1968 there were two Federal Agencies that dealt with drug and narcotic control -- FDA Bureau of Drug Abuse Control and Treasury Department Bureau of Narcotics -- these

were transferred to the Department of Justice thus consolidating the policing of drug traffic. With the laws changing quickly, control of this epidemic was left to the courts, the police, and the expert witness.

In the state of Iowa at the time there was only one chemist available to identify "street drugs"; an agricultural chemist who had to get his other work done before he could start the process of identifying these street drugs. "Pushers" of street drugs were arrested and in order to get a conviction, positive identification of these drugs was a necessity. James Robinson is a community minded person who wanted to help cut down the crime of drug abuse, so while attending a pharmacy meeting in Dubuque, Mr. Robinson asked, "Is there anything I can do to help identify street drugs so we can get quicker court action?" The answer to this question was yes. James Robinson was trained to identify street drugs; he was also given a special license to handle these drugs. At this time James Robinson was considered an expert witness, called upon to identify street drugs and to give witness as to the contents of these drugs.

When an opportunity arose in 1971 to purchase his own retail drug store in Alabama, James Robinson moved his family to Bynum, Alabama. Pharmaceutical companies have by this time come along way in research and production of drugs, because of this rapid advance it was not necessary for pharmacists to be trained in compounding drugs as they had been in the past. James Robinson had been trained in

compounding drugs during his pharmaceutical training and was often asked to compound special products that were not available from pharmaceutical companies. I watched as Mr. Robinson mixed with his spatchula the creams of one of these compounds; a fascinating process, it is a shame to see the art of compounding fall to the wayside as we see advances in the pharmaceutical field.

In 1976 James Robinson was informed by his doctor that he would need to get off his feet or end up in a wheel chair, this is a problem caused by the many hours of standing on his feet filling prescriptions. James Robinson then sold his drug store and went back into hospital pharmacy as the Director of Pharmacy for the hospital in Piedmont, Alabama.

In 1985 James Robinson discovered that his father was getting sick enough to warrant continuous care, so he moved back to his hometown of Sylacauga, Alabama to stay with his father and care for him. Carol Robinson was a LPN and she cared for the senior Mr. Robinson until his death in 1989. James Robinson worked at the hospital in Talladega, Alabama -- about 30 miles North of Sylacauga -- as the Director of Pharmacy for several years and then moved to the hospital in Sylacauga, Alabama when the opportunity arose.

James Robinson retired from the hospital in Sylacauga this year -- 1996 -- and is now working part time at a retail drug store. James Robinson is currently writing a book on his life as a pharmacist.

am*phet*amine

(noun)

: a racemic sympathomimetic amine or one of its derivatives (as dextroamphetamine or methamphetamine) frequently abused as a stimulant of the central nervous system but used clinically esp. as the sulfate or hydrochloride salt to treat hyperactive children and the symptoms of narcolepsy and as a short-term appetite suppressant in dieting -- compare BENZEDRINE

antibiotic

(noun)

: a substance produced by or a semisynthetic substance derived from a microorganism and able in dilute solution to inhibit or kill another microorganism

bar*bi*tu*rate

(noun)

1 : a salt or ester of barbituric acid

2 : any of various derivatives of barbituric acid used esp. as sedatives, hypnotics, and antispasmodics

co*deine

(noun)

: a morphine derivative that is found in opium, is weaker in action than morphine, and is used esp. in cough remedies

di*az*e*pam

(noun)

: a synthetic tranquilizer used esp. to relieve anxiety and tension and as a muscle relaxant -- see VALIUM

Val*ium

(trademark)

-- used for a preparation of diazepam

her*o*in

(noun)

: a strongly physiologically addictive narcotic that is made by acetylation of but is more potent than morphine and that is prohibited for medical use in the U.S. but is used illicitly for its euphoric effects -- called also diacetylmorphine, diamorphine

LSD

(noun)

: an organic compound that induces psychotic symptoms similar to those of schizophrenia --called also acid, lysergic acid diethylamide, lysergide

meth*a*done

also meth*a*don

(noun)

: a synthetic addictive narcotic drug used esp. in the form of its hydrochloride for the relief of pain and as a substitute narcotic in the treatment of heroin addiction -- called also amidone

mor*phine

(noun)

: a bitter crystalline addictive narcotic base that is the principal alkaloid of opium and is used in the form of a soluble salt (as a hydrochloride or a sulfate) as an analgesic and sedative

opi*um

(noun)

: a highly addictive drug that consists of the dried milky juice from the seed capsules of the opium poppy, that is a stimulant narcotic causing coma or death if the dose is excessive, that was formerly used in medicine to soothe pain, and that is smoked as an intoxicant

phe*no*bar*bi*tal

(noun)

: a crystalline barbiturate used as a hypnotic and sedative

THC

(noun)

: a physiologically active chemical from hemp plant resin that is the chief intoxicant in marijuana --called also tetrahydrocannabinol

[U.S. Food and Drug Administration] *August 1995*

Milestones in U.S. Food and Drug Law History

From the beginnings of civilization people have been concerned about the quality and safety of foods and medicines. In 1202, King John of England proclaimed the first English food law, the Assize of Bread, which prohibited adulteration of bread with such ingredients as ground peas or beans. Regulation of food in the United States dates from early colonial times. Federal controls over the drug supply began with inspection of imported drugs in 1848. The following chronology describes some of the milestones in the history of food and drug regulation in the United States.

1785
MASSACHUSETTS enacts the first general food adulteration law in the United States.

1820
Eleven physicians meet in the capitol at Washington to establish the U.S. PHARMACOPEIA, first compendium of standard drugs for the United States.

1848
DRUG IMPORTATION ACT passed by Congress requires U.S. Customs inspection to stop entry of adulterated drugs from overseas.

1850
CALIFORNIA passes a pure food and drink law, one year after the gold rush.

1862
PRESIDENT LINCOLN appoints a chemist, Charles M. Wetherill, to serve in the new Department of Agriculture. This was the beginning of the Bureau of Chemistry, now the Food and Drug Administration in the Department of Health and Human Services.

1879
PETER COLLIER, chief chemist, U.S. Department of Agriculture, begins investigating food adulteration. The following year he recommends a national food and drug law. In the next 25 years more than 100 food and drug bills were introduced in Congress.

1883
DR. HARVEY W. WILEY becomes chief chemist of the USDA. He immediately assigns members of his staff to expand the studies of food adulteration.

1897
TEA IMPORTATION ACT passed, providing for Customs inspection of all tea entering U.S. ports, at the expense of the importers.

1898
PURE FOOD CONGRESS in Washington focuses attention on the growing national movement to secure a federal law against the misbranding and adulteration of foods and drugs. Its leader is Dr. Wiley.

1902
The BIOLOGICS CONTROL ACT is passed to insure purity and safety of serums, vaccines, and similar products used to prevent or treat diseases in humans.

Congress appropriates funds to establish FOOD STANDARDS and to study the effects of chemicals on digestion and health.

1906
The original FOOD AND DRUGS ACT of 1906 is passed by Congress and signed by President Theodore Roosevelt. It prohibits interstate commerce in misbranded and adulterated foods, drinks and drugs.

The MEAT INSPECTION ACT is passed the same day, June 30. Shocking disclosures of insanitary conditions in meat- packing plants, the use of poisonous preservatives and dyes in foods, and cure-all claims for worthless and dangerous patent medicines were the major problems leading to the enactment of these laws.

1907

First CERTIFIED COLOR REGULATIONS, requested by manufacturers and users, list seven found suitable for use in foods.

1911
In U.S. v. JOHNSON, the Supreme Court rules that the 1906 Food and Drugs Act did not prohibit false therapeutic claims but only false and misleading statements about the ingredients or identity of a drug. Congress enacts the SHERLEY AMENDMENT to overcome the ruling in U.S. v. Johnson. It prohibits labeling medicines with false therapeutic claims intended to defraud the purchaser, a standard difficult to prove.

1912
After 29 years, Dr. Wiley retires as chief of the Bureau of Chemistry, and is succeeded by Dr. Carl L. Alsberg.

1913
GOULD AMENDMENT is enacted, requiring quantity of contents to be stated on food packages.

1914
In U.S. v. LEXINGTON MILL AND ELEVATOR COMPANY, the Supreme Court rules that foods containing poisonous or deleterious ingredients are illegal when the quantity of such ingredients may be injurious. Although the law does not require proof of actual injury, the mere presence of such an ingredient is not sufficient to make a food illegal.

1921
WALTER G. CAMPBELL becomes acting chief of the Bureau of Chemistry.

1924
In U.S. v. 95 BARRELS ALLEGED APPLE CIDER VINEGAR, the Supreme Court rules that the Food and Drugs Act condemns every statement, design or device which may mislead or deceive, even if technically true.

1927
A separate law enforcement agency is formed, first known as the Food, Drug, and Insecticide Administration and then, in 1930, as the Food and Drug Administration (FDA).

The CAUSTIC POISON ACT requires warning labels and antidotes to protect children from being injured by lye and other dangerous chemicals.

1930
McNARY-MAPES AMENDMENT authorizes FDA standards of quality and fill-of-container for canned food.

1933
FDA recommends a complete revision of the obsolete 1906 Food and Drugs Act. The first bill is introduced into the Senate, launching a five-year legislative battle.

1937
An ELIXIR OF SULFANILAMIDE containing a poisonous solvent kills 107 persons, mostly children, dramatizing the need to establish drug safety before marketing and to enact the pending food and drug law.

1938
THE FEDERAL FOOD, DRUG, AND COSMETIC (FDC) ACT of 1938 is passed by Congress, containing new provisions:

- Extending control to cosmetics and therapeutic devices.
- Requiring new drugs to be shown safe before marketing-- starting a new system of drug regulation.
- Eliminating the Sherley Amendment requirement to prove intent to defraud in drug misbranding cases.
- Providing that safe tolerances be set for unavoidable poisonous substances.
- Authorizing standards of identity, quality, and fill-of- container for foods.
- Authorizing factory inspections.
- Adding the remedy of court injunctions to the previous penalties of seizures and prosecutions.

1939
FIRST FOOD STANDARDS issued (canned tomatoes, tomato puree, and tomato paste).

1940
FDA TRANSFERRED from the Department of Agriculture to the Federal Security Agency, with Walter G. Campbell appointed as the first Commissioner of Food and Drugs.

1941

INSULIN AMENDMENT requires FDA to test and certify purity and potency of this life-saving drug for diabetes.

1943
In U.S. v. DOTTERWEICH, the Supreme Court rules that the responsible officials of a corporation, as well as the corporation itself, may be prosecuted for violations. It need not be proven that the officials intended, or even to know, of the violations.

1944
PUBLIC HEALTH SERVICE ACT was passed, covering a broad spectrum of health concerns, including regulation of biological products and control of communicable diseases.

1945
PENICILLIN AMENDMENT requires FDA testing and certification of safety and effectiveness of all penicillin products. Later amendments extended this requirement to all antibiotics. In 1983 such control was found no longer needed and was abolished.

1948
MILLER AMENDMENT AFFIRMS that the Federal Food, Drug, and Cosmetic Act applies to goods that have moved in interstate commerce all the way to the ultimate consumer.

1950
In ALBERTY FOOD PRODUCTS CO. v. U.S., the court of appeals rules that the directions for use on a drug label must include the purpose for which the drug is offered. Therefore, a worthless remedy cannot escape the law by not stating the condition it is supposed to treat.

OLEOMARGARINE ACT requires prominent labeling of colored oleomargarine, to distinguish it from butter.

1951
"DELANEY COMMITTEE" starts congressional investigation of the safety of chemicals in foods and cosmetics, laying the foundation for effective controls over pesticides, food additives, and colors.

DURHAM-HUMPHREY AMENDMENT defines the kinds of drugs that cannot be safely used without medical supervision and restricts their sale to prescription by a licensed practitioner.

1952
In U.S. v. CARDIFF, the Supreme Court rules that the factory inspection provision of the 1938 act is too vague to be enforced as criminal law (see factory inspection amendment, 1953).

FDA CONSUMER CONSULTANTS are appointed in each field district to maintain communications with consumers and insure that FDA considers their needs and problems.

1953
FEDERAL SECURITY AGENCY becomes the Department of Health, Education, and Welfare (HEW).

FACTORY INSPECTION AMENDMENT clarifies previous law and requires FDA to give manufacturers written reports of conditions observed during inspections and analyses of factory samples.

1954
PESTICIDES AMENDMENT spells out procedures for setting safety limits for pesticide residues on raw agricultural commodities.

1955
HEW SECRETARY OVETA CULP HOBBY appoints a committee of 14 citizens to study the adequacy of FDA's facilities and programs. The committee recommends a substantial expansion of FDA staff and facilities, a new headquarters building, and more use of educational and informational programs.

1958
FOOD ADDITIVES AMENDMENT enacted, requiring manufacturers of new food additives to establish safety. The Delaney proviso prohibits the approval of any food additive shown to induce cancer in humans or animals.

1959
U.S. CRANBERRY CROP recalled three weeks before Thanksgiving for FDA tests to insure freedom from aminotriazole, a weedkiller found to cause cancer in laboratory animals.

THE FIRST NEW FDA DISTRICT OFFICE in 24 years, and the first in a building designed for scientific enforcement, opens in Detroit, Mich.

1960
COLOR ADDITIVE AMENDMENTS enacted, requiring manufacturers to establish the safety of color additives in foods, drugs and cosmetics.

FEDERAL HAZARDOUS SUBSTANCES LABELING ACT, enforced by FDA, requires prominent label warnings on hazardous household chemical products.

1962
THALIDOMIDE, a new sleeping pill, is found to have caused birth defects in thousands of babies born in western Europe. News reports on the role of Dr. Frances Kelsey, FDA medical officer, in keeping the drug off the U.S. market, arouse public support for stronger drug regulation.

KEFAUVER-HARRIS DRUG AMENDMENTS PASSED to ensure greater drug safety. For the first time, drug manufacturers are required to prove to FDA the effectiveness of their products before marketing them. The amendments also exempt from the Delaney proviso animal drugs that are shown to induce cancer. CONSUMER BILL OF RIGHTS is proclaimed by President John F. Kennedy in a message to Congress. Included are the right to safety, the right to be informed, the right to choose, the right to be heard.

1965
DRUG ABUSE CONTROL AMENDMENTS are enacted to deal with problems caused by abuse of depressants, stimulants and hallucinogens.

NEW FDA WASHINGTON headquarters laboratory is occupied and dedicated.

1966
FDA CONTRACTS with the National Academy of Sciences/National Research Council to evaluate the effectiveness of 4,000 drugs approved on the basis of safety alone between 1938 and 1962.

CHILD PROTECTION ACT enlarges the scope of the Federal Hazardous Substances Labeling Act to ban hazardous toys and other articles so hazardous that adequate label warnings could not be written.

FAIR PACKAGING AND LABELING ACT requires all consumer products in interstate commerce to be honestly and informatively labeled, with FDA enforcing provisions on foods, drugs, cosmetics, and medical devices.

1968
FDA BUREAU OF DRUG ABUSE CONTROL and Treasury Department Bureau of Narcotics are transferred to the Department of Justice to consolidate policing of traffic in drugs that are abused.

REORGANIZATION of federal health programs places FDA in the Public Health Service.

ANIMAL DRUG AMENDMENTS place all new animal drug regulation under one section of the Food, Drug, and Cosmetic Act--Section 512--making approval of animal drugs and medicated feeds more efficient.

1969
FDA begins administration of sanitation programs for milk, shellfish, food service, and interstate travel facilities, and for poisoning and accident prevention, transferred from other units of the Public Health Service.

1970
In UPJOHN v. FINCH the Court of Appeals upholds enforcement of the 1962 drug effectiveness amendments by ruling that commercial success alone does not constitute substantial evidence of drug safety and efficacy.

ENVIRONMENTAL PROTECTION AGENCY established; takes over FDA program for setting pesticide tolerances.

1971
BUREAU OF RADIOLOGICAL HEALTH transferred to FDA. Its mission: protection against unnecessary human exposure to radiation from electronic products in the home, industry, and the healing arts.

NATIONAL CENTER FOR TOXICOLOGICAL RESEARCH is established in the biological facilities of the Pine Bluff Arsenal in Arkansas. Its mission is to examine biological effects of chemicals in the environment, extrapolating data from experimental

animals to human health.

1972

OVER-THE-COUNTER DRUG review begun to enhance the safety, effectiveness and appropriate labeling of drugs sold without prescription.

REGULATION OF BIOLOGICS--including serums, vaccines, and blood products--is transferred to FDA.

1973

THE SUPREME COURT upholds the 1962 drug effectiveness law and endorses FDA action to control entire classes of products by regulations rather than to rely only on time- consuming litigation.

LOW-ACID FOOD PROCESSING regulations issued to insure that low-acid packaged foods have adequate heat treatment and are not hazardous.

CONSUMER PRODUCT SAFETY COMMISSION created by Congress; takes over programs pioneered by FDA under 1927 Caustic Poison Act, 1960 Hazardous Substances Labeling Act, 1966 Child Protection Act, and PHS accident prevention activities for safety of toys, home appliances, etc.

1976

MEDICAL DEVICE AMENDMENTS passed to ensure safety and effectiveness of medical devices, including diagnostic products. The amendments require manufacturers to register with FDA and follow quality control procedures. Some products must have pre-market approval by FDA; others must meet performance standards before marketing.

VITAMINS AND MINERALS AMENDMENTS stop FDA from establishing standards limiting potency of vitamins and minerals in food supplements or regulating them as drugs based solely on potency.

1977

SACCHARIN STUDY AND LABELING ACT passed by Congress to stop FDA from banning the chemical sweetener but requiring a label warning that it has been found to cause cancer in laboratory animals.

1980

INFANT FORMULA ACT establishes special FDA controls to insure necessary nutritional content and safety.

1982

TAMPER-RESISTANT PACKAGING REGULATIONS issued by FDA to prevent poisonings such as deaths from cyanide placed in Tylenol capsules. The Federal Anti-Tampering Act passed in 1983 makes it a crime to so tamper with packaged consumer products.

1983

ORPHAN DRUG ACT enables FDA to promote research and approval and marketing of drugs needed for treating rare diseases, which otherwise would not be profitable.

1984

FINES ENHANCEMENT LAWS of 1984 and 1987 amend the U.S. Code to greatly increase penalties for all federal offenses. The maximum fine for individuals is now $100,000 for each offense and $250,000 if the violation is a felony or causes death. For corporations, the amounts are doubled.

DRUG PRICE COMPETITION AND PATENT TERM RESTORATION ACT expedites the availability of less costly generic drugs by permitting FDA to approve applications to market generic versions of brand-name drugs without repeating the research done to prove them safe and effective. At the same time, the brand-name companies can apply for up to five years longer patent protection for the new medicines they developed to make up for time lost while their products were going through FDA's approval process.

1985

AIDS TEST FOR BLOOD approved by FDA in its first major action to protect patients from infected donors.

1986

CHILDHOOD VACCINE ACT requires patient information on vaccines, gives FDA authority to recall biologics, and authorizes civil penalties.

1987

THE PRESCRIPTION DRUG MARKETING ACT bans the diversion of prescription drugs from legitimate commercial channels. Congress finds that the resale of such drugs leads to the distribution of mislabeled, adulterated, subpotent, or counterfeit drugs to the public. The new law requires drug wholesalers to be licensed by the states; restricts reimportation from other countries; and bans sale, trade or purchase of drug samples, and traffic or counterfeiting of redeemable drug coupons.

1988

FOOD AND DRUG ADMINISTRATION ACT of 1988 officially establishes FDA as an agency of the Department of Health and Human Services with a Commissioner of Food and Drugs appointed by the President with the advice and consent of the Senate, and spells out broadly the responsibilities of the Secretary and the Commissioner for research, enforcement, education, and information.

GENERIC ANIMAL DRUG AND PATENT TERM RESTORATION ACT extends to veterinary products benefits given to human drugs under the 1984 Drug Price Competition and Patent Term Restoration Act. Companies can produce and sell generic versions of animal drugs approved after October 1962 without duplicating research done to prove them safe and effective. The act also authorizes extension of animal drug patents.

1990 NUTRITION LABELING AND EDUCATION ACT requires all packaged foods to bear nutrition labeling and all health claims for foods to be consistent with terms defined by the Secretary of Health and Human Services. The law preempts state requirements as to food standards, nutrition labeling, and health claims.

SAFE MEDICAL DEVICES ACT of 1990 requires medical device user facilities such as hospitals and nursing homes to report promptly to FDA incidents that reasonably suggest a probability that a medical device caused or contributed to the death, serious illness, or serious injury of a patient. The act requires manufacturers to conduct post-market surveillance on devices that are permanent implants and whose failure may cause serious health consequences or death, and to establish methods for tracing and locating patients depending on such devices. The act authorizes FDA to order device product recalls, to issue "stop use" notices to health professionals and user facilities, and to impose civil penalties (fines) after hearings before an Administrative Law Judge.

1992

GENERIC DRUG ENFORCEMENT ACT imposes debarment and other penalties for illegal acts involving approval of abbreviated drug applications.

PRESCRIPTION DRUG USER FEE ACT OF 1992 requires drug and biologics manufacturers to pay fees for drug and biologics applications and supplements. In addition, these firms must pay an annual establishment fee and annual product fees. FDA will use these funds to hire more reviewers to assess applications. Unless Congress renews the act, the user fee law will expire at the end of FY 1997.

MAMMOGRAPHY QUALITY STANDARDS ACT of 1992 required all mammography facilities in the United States to be accredited and federally certified as meeting quality standards effective Oct. 1, 1994. After initial certification, facilities must pass annual inspections by approved federal or state inspectors.

1994

DIETARY SUPPLEMENT HEALTH AND EDUCATION ACT establishes specific labeling requirements, provides a regulatory framework, and authorizes FDA to promulgate good manufacturing practice regulations for "dietary supplements" and "dietary ingredients" and classifies them as food. The act also establishes a commission to recommend how to regulate label claims.

ANIMAL MEDICINAL DRUG USE CLARIFICATION ACT allows veterinarians to prescribe extra-label use of veterinary drugs for animals under specific circumstances. In addition, the legislation allows licensed veterinarians to prescribe human drugs for use in animals under certain conditions.

[FDA Home Page]

BG 95-1
(Replaces BG90-5.1)

New Search

drug abuse

The term **drug abuse** most often refers to the use of a **drug** with such frequency that it causes physical or mental harm to the user or impairs social functioning. Although the term seems to imply that users **abuse** the **drugs** they take, in fact, it is themselves or others they **abuse** by using **drugs**.
Traditionally, the term **drug abuse** referred to the use of any **drug** prohibited by law, regardless of whether it was actually harmful or not. This meant that any use of MARIJUANA, for example, even if it occurred only once in a while, would constitute **abuse**, while the same level of alcohol consumption would not. In 1973 the National Commission on Marihuana and **Drug Abuse** declared that this definition was illogical. The term **abuse**, the commission stated, "has no functional utility and has become no more than an arbitrary codeword for that **drug** which is presently considered wrong." As a result, this definition fell into disuse.

The term **drug** is commonly associated with substances that may be purchased legally with prescription for medical use, such as penicillin, which is almost never abused, and VALIUM, which is frequently abused, or illegal substances, such as ANGEL DUST, which are taken for the purpose of getting high, or intoxicated, but actually have no medical use. Other substances that may be purchased legally and are commonly abused include alcohol (see ALCOHOLISM) and NICOTINE, contained in tobacco cigarettes. In addition, in recent years, chemists working in illegal, clandestine laboratories have developed new chemicals that have been used for the purpose of getting high. (These are called "designer **drugs**".) All of these substances are psychoactive. Such substances--legal and illegal--influence or alter the workings of the mind; they affect moods, emotions, feelings, and thinking processes. For a general description of **drug** types, including an outline of their historical development and use, and their effects on the human body, see the article DRUG.

Drug Dependence

Drug abuse must be distinguished from **drug** dependence. **Drug** dependence, formerly called **drug** addiction, is defined by three basic characteristics. First, users continue to take a **drug** over an extended period of time. Just how long this period is depends on the **drug** and the user. Second, users find it difficult to stop using the **drug**. They seem powerless to quit. Users take extraordinary and often harmful measures to continue using the **drug**. How dependency-producing a **drug** is can be measured by how much users go through to continue taking it. Third, if users stop taking their **drug**--if their supply of the **drug** is cut off, or if they are forced to quit for any reason-- they will undergo painful physical or mental distress. The experience of withdrawal distress, called the withdrawal syndrome, is a sure sign that **drug** is dependency-producing and that a given user is dependent on a particular **drug**. **Drug** dependence may lead to **drug abuse**--especially of illegal **drugs**.
Psychoactive, or mind-altering, substances are found the world over. The coca plant grows in the Andes of South America and contains 1 to 2 percent COCAINE. The marijuana plant, Cannabis sativa, contains a group of chemicals called tetrahydrocannabinol, or THC. This plant grows wild in most countries, including the United States. The opium poppy is the source for OPIUM, MORPHINE, HEROIN, and CODEINE. It grows in the Middle East and the Far East. HALLUCINOGENS (such as LSD), the amphetamines (see AMPHETAMINE), and sedatives (see SEDATIVE), such as methaqualone (Quaalude, or ludes) and barbiturates (see BARBITURATE), are manufactured in clandestine laboratories worldwide. As a result, psychoactive **drugs** are used for the purpose of intoxication practically everywhere. (See also DRUG TRAFFICKING.)

Classification of Psychoactive **Drugs**

Pharmacologists, who study the effects of **drugs**, classify psychoactive **drugs** according to what they do to those who take them. **Drugs** that speed up signals passing through the NERVOUS SYSTEM, which is made up of the brain and spinal cord, and produce alertness and arousal and, in higher doses, excitability, and inhibit fatigue and sleep, are called stimulants (see STIMULANT). They include the amphetamines, cocaine, caffeine, and nicotine. **Drugs** that retard, slow down, or depress signals passing through the central nervous system and produce relaxation, a lowering of anxiety, and, at higher doses, drowsiness and sleep, are called depressants. They include sedatives, such as barbiturates, methaqualone, and alcohol, and tranquilizers (see TRANQUILIZER), such as Valium. Constituting one distinct kind of depressants are those which dull the mind's perception of pain and in medicine are used as painkillers, or analgesics (see ANALGESIC). These **drugs** are called narcotics. They include heroin, morphine, opium, and codeine. In addition to their painkilling properties, these depressants also

produce a strong high and are intensely dependency-producing. Some **drugs** cannot be placed neatly in this stimulant-depressant spectrum. Hallucinogens include LSD, mescaline, and psilocybin. Such **drugs** produce unusual mental states, such as psychedelic visions. Marijuana is generally regarded as not belonging to any of these categories but as a **drug** type unto itself.

History of **Drug Abuse** in the United States

During the 19th century there were virtually no controls on the importation, sale, purchase, possession, or use of psychoactive **drugs**. Dangerous substances such as opium, cocaine, and morphine were basic ingredients in patent medicines that could be purchased by anyone for any reason, without a prescription. These nostrums were used to cure headaches, toothaches, depression, nervousness, alcoholism, menstrual cramps--in fact, practically every human ailment.

As a result of the ready availability of addicting **drugs**, and as a result of their heavy use for medical problems, many individuals became addicted to the narcotics contained in these patent medicines. In fact, in 1900, there were more narcotics addicts, proportionate to the population, than there are today. At that time, most of the users who became addicts were medical addicts. Very few abusers took **drugs** for "recreational" purposes. In 1914, in an effort to curb the indiscriminate use of narcotics, the federal government passed the Harrison Act, making it illegal to obtain a narcotic **drug** without a prescription. During the 1920s the Supreme Court ruled that maintaining addicts on narcotic **drugs**, even by prescription, was in violation of the Harrison Act. Approximately 30,000 physicians were arrested during this period for dispensing narcotics, and some 3,000 actually served prison sentences. Consequently, doctors all but abandoned the treatment of addicts for nearly half a century in the United States.

The use of narcotic **drugs** dropped sharply in the United States between the 1920s, when there were as many as half a million addicts, and 1945, when the addict population was roughly 40,000 to 50,000. The recreational use of other **drugs**, such as marijuana, cocaine, stimulants, hallucinogens, and sedatives, which are used so frequently today, also remained at extremely low levels during this period. The 1960s, however, was a watershed decade. The widening use of illegal **drugs** accompanied increased tolerance for a wide range of unconventional behavior. The period saw the growth of movements that stood in opposition to the war in Vietnam and to mainstream American culture, the coming into popularity of rock music, and enormous publicity devoted to **drugs**, their users and proselytizers. During this time some social groups viewed **drug** use in positive terms and believed it a virtue to "turn on" someone who did not use **drugs**. Although media attention to **drugs** and **drug** use declined between the late 1960s and late 1970s, the use of **drugs** did not. The late 1970s and 1980s represent another turning point in the recreational use of marijuana, hallucinogens, sedatives, and amphetamines. Studies show a considerable drop in the use of most **drug** types through the 1980s, but a slight increase since 1990.
Cocaine and its derivative crack, the smokable form of cocaine, seem to be major exceptions; while their casual (weekly or less) use declined throughout the 1980s, their heavy or daily use rose during this period. Crack first appeared in the mid- 1980s and rapidly became one of the most widely abused illicit **drugs** in the United States. New forms of older **drugs** continue to appear: "Ecstasy" (see MDMA) is a methamphetamine analog that was first synthesized some 70 years ago as an appetite suppressant.

Patterns of **Drug** Use

The illegal use of psychoactive **drugs** is extensive in the United States. Some 75 million Americans age 12 and over have tried at least one or more prohibited **drugs** for the purpose of getting high. The illegal **drug** trade represents an enormous economic enterprise, with annual gross sales estimated to be $40 to $100 billion--more than the total net sales of the largest U.S. corporation. About 60 percent of the illegal **drugs** sold worldwide end up in the United States.
By far the most commonly used illegal **drug** is marijuana. Roughly half of the total of all illegal **drug** use involves marijuana alone. There was a substantial decline in daily or near-daily use of marijuana throughout the 1980s; in 1985 roughly 75 percent of all Americans under the age of 26 had at least tried marijuana; in 1988, that proportion had shrunk to 56 percent. Since 1990 marijuana use has risen slightly. Cocaine is the second most commonly used **drug** in the United States. In 1988, 13 percent of Americans aged 12 to 25 had used cocaine at least once. Heroin is one of the least-often used of the well-known **drugs**. It has been used at least once by fewer than 1 American in 100.

Most people who have taken illegal **drugs** have done so on an experimental basis. They typically try the **drug** once to a dozen times and then cease using it. Of all illegal **drugs**, marijuana is the one users are most likely to continue using. Discontinuation rates are very high for **drugs** such as methaqualone, sedatives, barbiturates, heroin, and LSD. Even most regular users of illegal **drugs** are moderate in their use. The typical regular marijuana smoker is an occasional user. Still, a sizable minority does use the **drug** frequently, to the point of **abuse**. About 2 percent of all high school seniors used marijuana daily or nearly daily in 1993. A pattern of episodic, regular use characterizes nearly all **drug** use for the purpose of recreation. This does not deny the problem of the heavy, chronic abuser of these **drugs**.

Drug Law Enforcement

In 1970 the U.S. Congress passed the Comprehensive **Drug Abuse** Prevention and Control Act (**Drug** Control Act). Most of the states followed suit, basing their state legislation on the federal model. The **Drug** Control Act distinguishes among several categories of **drugs** based on their supposed **abuse** potential and medical utility. **Drugs** that supposedly have a high potential for **abuse** and no currently accepted medical use, including heroin, LSD and the other hallucinogens, and marijuana, may be used legally only in federally approved scientific research. Because some authorities think of these **drugs** as having a high **abuse** potential, they are tightly controlled by federal and state laws. In practice, the criminal justice system distinguishes between "hard" and "soft" **drugs**; it is unlikely that a first-time offender arrested for marijuana possession will serve a prison sentence. **Drugs** such as morphine, cocaine, methaqualone, the amphetamines, and short-acting barbiturates are also regarded as having great **abuse** potential, even though they do have accepted uses in medicine. Rigid prescription procedures maintain extremely tight controls over their use. Such medically prescribed **drugs** as long-acting barbiturates and nonnarcotic painkillers are considered to have a lesser **abuse** potential, although they may lead to low physical dependence or high psychological dependence. These **drugs** have more relaxed controls, as do tranquilizers, and are classified as having low **abuse** potential. There has been a remarkable drop in the number of prescriptions written for psychoactive **drugs** from the early 1970s into the 1990s. In the mid-1990s, the prescription use of the barbiturates and the amphetamines is barely one-tenth of what it was in 1970. Many other countries have also placed severe restrictions on the prescribing of **drugs** by doctors and have thus greatly reduced the frequency of the **abuse** of amphetamines.

Restricting psychoactive pharmaceuticals has brought about a reduction in the number of legal prescriptions written for them. A decline in the illegal street use of these same **drugs** lagged a few years behind the decline in legal prescription use. Even so, the illegal use of prescription **drugs** for the purpose of getting high has declined since the restrictions on psychoactive pharmaceuticals went into effect. In 1975, 11 percent of high school seniors said that they had taken barbiturates for nonmedical purposes during the previous year; in 1993, that figure was only 3 percent. Methaqualone was used annually by 5-8 percent of high school seniors during the late 1970s and early 1980s; in 1985 it was completely outlawed, and each year in the early 1990s, only a fraction of 1 percent had used methaqualone recreationally. Clearly legal restriction on prescription **drugs** has brought about a decline in illegal street use.

The demand for **drugs** for illegal purposes remains high in spite of law-enforcement efforts. In 1991, there were slightly over one million arrests on **drug** violations in the United States, an increase of more than 50 percent over the previous decade. Only one-third of these arrests were on sale or manufacture charges, while two-thirds were on the charge of simple possession. About 285,000 of these arrests were for marijuana violations, of which nearly 80 percent entailed simple possession. The risk of arrest does not appear to deter substantial numbers of Americans from selling and using illegal **drugs**.

Drug Testing in the Workplace

Drinking on the job is a social and economic problem with a long history. With the growing popularity of illegal **drugs** in the 1960s and 1970s, testing for their use in the workplace became a major issue in the 1980s. The main issues were safety versus the risk to individual rights. In addition, the tests were (and are) not completely accurate or reliable. Some companies and government agencies have instituted **drug**-testing programs for their employees. By the early 1990s, **drug** testing in the workplace was no longer a big issue. Testing is commonplace in the armed forces and is often cited as a major factor in reducing the use of **drugs** among military personnel. Some businesses ask for **drug** tests before a person is hired.

Treatment

From the 1920s until the 1960s, treatment of **drug abuse** in the United States was practically nonexistent. Following the enforcement of the Harrison Act during the 1920s, few physicians were willing to treat addicts. During the 1930s two Public Health Service prison hospitals were opened, but the relapse rate of their released patients was roughly 80 percent, and during the 1970s, the federal government closed them down. For most addicts since the 1920s, the primary treatment program has been no treatment at all; until recently, arrest has simply resulted in incarceration and therefore forcible detoxification. The dramatic explosion in the use and **abuse** of a number of illegal **drugs** during the 1960s demonstrated the weakness of this approach. As a result, a range of treatment programs, developed largely in the 1960s, have been widely used to treat **drug abuse**.

METHADONE is an addictive synthetic narcotic used to combat narcotic addiction. A hospital or a clinic administers the **drug**, which is taken orally, usually dissolved in artificial orange juice. Taken this way, the addict does not get high. Methadone also blocks the action of narcotic **drugs** so that addicts cannot become high, even if they were to inject heroin. According to the program's rationale, addicts will then stop taking heroin. Although they will still be addicted to methadone, they can live a normal life, since their supply of methadone is steady and secure. Plus, they are no longer exposed to health risks like AIDS and HEPATITIS from shared needles used for injecting **drugs**. Because the program is inexpensive to administer, methadone has become a very popular form of treatment; roughly 100,000 narcotic addicts in the United States are treated in the methadone maintenance program. Perhaps four or five out of every 10 addicts show significant improvement: their use of narcotics and other **drugs** declines, and their crime rate is cut by 50 to 75 percent.

The **drug** naltrexone has been approved by the U.S. FOOD AND DRUG ADMINISTRATION for treating alcoholism and heroin addiction, in concert with an appropriate counseling program. Naltrexone reduces cravings for alcohol and heroin, thereby decreasing relapse rates.

Therapeutic communities (TCs), such as Daytop Village in New York and Walden House in San Francisco, advocate a completely **drug**- and alcohol-free existence. Addicts live in the therapeutic communities, and many of the administrators are ex-addicts, who can best understand the addict residents. The view of all TCs is that the addict uses **drugs** as a crutch. TCs attempt to resocialize the addict by inculcating a value system that is the opposite of that which prevailed on the street: no **drugs**, no deception, no stealing; emphasizing honesty, responsibility, and treating others as human beings rather than as objects to be exploited.

Discipline in therapeutic communities is strict, penalties for breaking rules are severe, peer pressure is unrelenting, and the program assumes the role of a benevolent dictator. Because of the strictness of the program, many residents leave against the advice, and without the permission, of the staff. The therapeutic community is an effective program for a limited segment of the addict population, usually those who are young, come from a middle-class background, and are highly motivated to discontinue **drug abuse**. TCs are expensive programs to administer; there are far fewer patients in them than in methadone-maintenance programs.

The Legalization Debate

Recently, there has been a strong call among some experts, as well as a few politicians, judges, and government officials, for the removal of all criminal penalties for the sale, possession, and use of currently illegal **drugs**. The legalization or decriminalization program rests on three basic assumptions: one, that **drug abuse** will not rise significantly under legalization; two, that currently illegal **drugs** are less harmful than currently legal alcohol and tobacco and are less harmful than is generally believed; and three, that the current policy of arresting and imprisoning for **drug** possession and sale does more harm than good. No one can know for sure whether **drug** use and **abuse** would rise, fall, or remain stable under legalization. In nine U.S. states and in the Netherlands, where small-quantity marijuana possession has been partially decriminalized, no sharp rise in the use of this **drug** has taken place. However, evidence suggests that for some **drugs**, criminalization has produced lower use and **abuse**, and that legalization, if accompanied by lower cost and ready availability, would result in a significant rise in use and **abuse**. For example, the continuance rates of alcohol and tobacco are strikingly higher than they are for illegal **drugs**. For the most part, the use of the illegal **drugs** tends to be more likely to be sporadic and occasional, and more likely to be given up, than is true for the use of legal **drugs**. In addition, in the United States, outlawing the sale of alcohol to persons under the age of 21 has accompanied a significant decline in the number of alcohol- related fatalities in this age group. Many current users, abusers, and addicts state that they would take **drugs** more frequently and heavily than they do now if **drugs** were legalized and readily available. And last, contrary to the stereotype, evidence suggests that, during national alcohol PROHIBITION (1920-33), alcohol consumption actually declined significantly.

The pro-legalization groups are almost certainly right that crime and certain medical maladies among **drug** abusers would decline if **drugs** were legalized. Perhaps a "third path" between the current punitive policy and full legalization would be most effective, with the guiding policy on **drug** use and **abuse** focusing on harm reduction rather than waging an unwinnable "war" on **drug abuse**. This policy could include flexible or selective enforcement, vastly expanding **drug** treatment programs, using arrest primarily to get **drug** abusers into treatment programs, needle exchange programs, a distinction between the "hard" and "soft" **drugs**, expanding anti-**drug** educational efforts, and focusing on reducing the use and **abuse** of tobacco and alcohol.
Erich Goode

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DEA Mission Statement

The mission of the Drug Enforcement Administration is to enforce the controlled substances laws and regulations of the United States and to bring to the criminal and civil justice system of the United States or any other competent jurisdiction, those organizations, and principal members of organizations, involved in the growing, manufacture, or distribution of controlled substances appearing in or destined for illicit traffic in the United States; and to recommend and support nonenforcement programs aimed at reducing the availability of illicit controlled substances on the domestic and international markets. In carrying out its mission, DEA is the lead agency responsible for the development of overall Federal drug enforcement strategy, programs, planning, and evaluation. DEA's primary responsibilities include:

- Investigation and preparation for prosecution of major violators of controlled substances laws operating at interstate and international levels;
- Management of a national drug intelligence system in cooperation with Federal, state, local, and foreign officials to collect, analyze, and disseminate strategic and operational drug intelligence information;
- Seizure and forfeiture of assets derived from, traceable to, or intended to be used for illicit drug trafficking;
- Enforcement of the provisions of the Controlled Substances Act as they pertain to the manufacture, distribution, and dispensing of legally produced controlled substances;
- Coordination and cooperation with Federal, state and local law enforcement officials on mutual drug enforcement efforts and enhancement of such efforts through exploitation of potential interstate and international investigations beyond local or limited Federal jurisdictions and resources;
- Coordination and cooperation with other Federal, state, and local agencies, and with foreign governments, in programs designed to reduce the availability of illicit abuse-type drugs on the United States market through nonenforcement methods such as crop eradication, crop substitution, and training of foreign officials;
- Responsibility, under the policy guidance of the Secretary of State and U.S. Ambassadors, for all programs associated with drug law enforcement counterparts in foreign countries; and
- Liaison with the United Nations, Interpol, and other organizations on matters relating to international drug control programs.

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21 CFR Sec. 1306.07

-EXPCITE-

Title 21-Food and Drugs
CHAPTER II
PART 1306

-HEAD-

Sec. 1306.07 Administering or dispensing of **narcotic** drugs.

-TEXT-

(a) The administering or dispensing directly (but not prescribing) of **narcotic** drugs listed in any schedule to a **narcotic** drug dependent person for 'detoxification treatment' or 'maintenance treatment' as defined in section 102 of the **Act** (21 U.S.C. 802) shall be deemed to be within the meaning of the term 'in the course of his professional practice or research' in section 308(e) and section 102(20) of the **Act** (21 U.S.C. 828 (e)): Provided, That the practitioner is separately registered with the Attorney General as required by section 303(g) of the **Act** (21 U.S.C. 823(g)) and then thereafter complies with the regulatory standards imposed relative to treatment qualification, security, records and unsupervised use of drugs pursuant to such **Act**.

(b) Nothing in this section shall prohibit a physician who is not specifically registered to conduct a **narcotic** treatment program from administering (but not prescribing) **narcotic** drugs to a person for the purpose of relieving acute withdrawal symptoms when necessary while arrangements are being made for referral for treatment. Not more than one day's medication may be administered to the person or for the person's use at one time. Such emergency treatment may be carried out for not more than three days and may not be renewed or extended.

(c) This section is not intended to impose any limitations on a physician or authorized hospital staff to administer or dispense **narcotic** drugs in a hospital to maintain or detoxify a person as an incidental adjunct to medical or surgical treatment of conditions other than addiction, or to administer or dispense **narcotic** drugs to persons with intractable pain in which no relief or cure is possible or none has been found after reasonable efforts.

(39 FR 37986, Oct. 25, 1974)

CONTROLLED SUBSTANCES LISTED IN SCHEDULE II

- UNITED STATES CODE
  - TITLE 21 - FOOD AND DRUGS
    - CHAPTER 13 - DRUG ABUSE PREVENTION AND CONTROL
      - SUBCHAPTER I - CONTROL AND ENFORCEMENT
        - Part A - Introductory Provisions

§ 802. Definitions

As used in this subchapter:

- (1) The term "addict" means any individual who habitually uses any narcotic drug so as to endanger the public morals, health, safety, or welfare, or who is so far addicted to the use of narcotic drugs as to have lost the power of self-control with reference to his addiction.
- (2) The term "administer" refers to the direct application of a controlled substance to the body of a patient or research subject by -
  - (A) a practitioner (or, in his presence, by his authorized agent), or
  - (B) the patient or research subject at the direction and in the presence of the practitioner, whether such application be by injection, inhalation, ingestion, or any other means.
- (3) The term "agent" means an authorized person who acts on behalf of or at the direction of a manufacturer, distributor, or dispenser; except that such term does not include a common or contract carrier, public warehouseman, or employee of the carrier or warehouseman, when acting in the usual and lawful course of the carrier's or warehouseman's business.
- (4) The term "Drug Enforcement Administration" means the Drug Enforcement Administration in the Department of Justice.
- (5) The term "control" means to add a drug or other substance, or immediate precursor, to a schedule under part B of this subchapter, whether by transfer from another schedule or otherwise.
- (6) The term "controlled substance" means a drug or other substance, or immediate precursor, included in schedule I, II, III, IV, or V of part B of this subchapter. The term does not include distilled spirits, wine, malt beverages, or tobacco, as those terms are defined or used in subtitle E of the Internal Revenue Code of 1986.
- (7) The term "counterfeit substance" means a controlled substance which, or the container or labeling of which, without authorization, bears the trademark, trade name, or other identifying mark, imprint, number, or device, or any likeness thereof, of a manufacturer, distributor, or dispenser other than the person or persons who in fact manufactured, distributed, or dispensed such substance and which thereby falsely purports or is represented to be the product of, or to have been distributed by, such other manufacturer, distributor, or dispenser.
- (8) The terms "deliver" or "delivery" mean the actual, constructive, or attempted transfer of a controlled substance or a listed chemical, whether or not there exists an agency relationship.
- (9) The term "depressant or stimulant substance" means -
  - (A) a drug which contains any quantity of (i) barbituric acid or any of the salts of barbituric acid; or (ii) any derivative of barbituric acid which has been designated by the Secretary as habit forming under section 352(d) of this title; or
  - (B) a drug which contains any quantity of (i) amphetamine or any of its optical isomers; (ii) any salt of amphetamine or any salt of an optical isomer of amphetamine; or (iii) any substance which the Attorney General, after investigation, has found to be, and by regulation designated as, habit forming because of its stimulant effect on the central nervous systems; or
  - (C) lysergic acid diethylamide; or
  - (D) any drug which contains any quantity of a substance which the Attorney General, after investigation, has found to have, and by regulation designated as having, a potential for abuse because of its depressant or stimulant effect on the central nervous system or its hallucinogenic effect.
- (10) The term "dispense" means to deliver a controlled substance to an ultimate user or research subject by, or pursuant to the lawful order of, a practitioner, including the prescribing and administering of a controlled substance and the packaging, labeling or compounding necessary to prepare the substance for such delivery. The term "dispenser" means a practitioner who so delivers a controlled substance to an ultimate user or research subject.
- (11) The term "distribute" means to deliver (other than by administering or dispensing) a controlled substance or a listed chemical. The term "distributor" means a person who so delivers a controlled substance or a listed chemical.
- (12) The term "drug" has the meaning given that term by section 321(g)(1) of this title.

- (13) The term "felony" means any Federal or State offense classified by applicable Federal or State law as a felony.
- (14) The term "isomer" means the optical isomer, except as used in schedule I(c) and schedule II(a)(4). As used in schedule I(c), the term "isomer" means any optical, positional, or geometric isomer. As used in schedule II(a)(4), the term "isomer" means any optical or geometric isomer.
- (15) The term "manufacture" means the production, preparation, propagation, compounding, or processing of a drug or other substance, either directly or indirectly or by extraction from substances of natural origin, or independently by means of chemical synthesis or by a combination of extraction and chemical synthesis, and includes any packaging or repackaging of such substance or labeling or relabeling of its container; except that such term does not include the preparation, compounding, packaging, or labeling of a drug or other substance in conformity with applicable State or local law by a practitioner as an incident to his administration or dispensing of such drug or substance in the course of his professional practice. The term "manufacturer" means a person who manufactures a drug or other substance.
- (16) The term "marihuana" means all parts of the plant Cannabis sativa L., whether growing or not; the seeds thereof; the resin extracted from any part of such plant; and every compound, manufacture, salt, derivative, mixture, or preparation of such plant, its seeds or resin. Such term does not include the mature stalks of such plant, fiber produced from such stalks, oil or cake made from the seeds of such plant, any other compound, manufacture, salt, derivative, mixture, or preparation of such mature stalks (except the resin extracted therefrom), fiber, oil, or cake, or the sterilized seed of such plant which is incapable of germination.
- (17) The term "narcotic drug" means any of the following whether produced directly or indirectly by extraction from substances of vegetable origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis:
  - (A) Opium, opiates, derivatives of opium and opiates, including their isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, whenever the existence of such isomers, esters, ethers, and salts is possible within the specific chemical designation. Such term does not include the isoquinoline alkaloids of opium.
  - (B) Poppy straw and concentrate of poppy straw.
  - (C) Coca leaves, except coca leaves and extracts of coca leaves from which cocaine, ecgonine, and derivatives of ecgonine or their salts have been removed.
  - (D) Cocaine, its salts, optical and geometric isomers, and salts of isomers.
  - (E) Ecgonine, its derivatives, their salts, isomers, and salts of isomers.
  - (F) Any compound, mixture, or preparation which contains any quantity of any of the substances referred to in subparagraphs (A) through (E).
- (18) The term "opiate" means any drug or other substance having an addiction-forming or addiction-sustaining liability similar to morphine or being capable of conversion into a drug having such addiction-forming or addiction-sustaining liability.
- (19) The term "opium poppy" means the plant of the species Papaver somniferum L., except the seed thereof.
- (20) The term "poppy straw" means all parts, except the seeds, of the opium poppy, after mowing.
- (21) The term "practitioner" means a physician, dentist, veterinarian, scientific investigator, pharmacy, hospital, or other person licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he practices or does research, to distribute, dispense, conduct research with respect to, administer, or use in teaching or chemical analysis, a controlled substance in the course of professional practice or research.
- (22) The term "production" includes the manufacture, planting, cultivation, growing, or harvesting of a controlled substance.
- (23) The term "immediate precursor" means a substance -
  - (A) which the Attorney General has found to be and by regulation designated as being the principal compound used, or produced primarily for use, in the manufacture of a controlled substance;
  - (B) which is an immediate chemical intermediary used or likely to be used in the manufacture of such controlled substance; and
  - (C) the control of which is necessary to prevent, curtail, or limit the manufacture of such controlled substance.
- (24) The term "Secretary", unless the context otherwise indicates, means the Secretary of Health and Human Services.
- (25) The term "serious bodily injury" means bodily injury which involves -
  - (A) a substantial risk of death;
  - (B) protracted and obvious disfigurement; or
  - (C) protracted loss or impairment of the function of a bodily member, organ, or mental faculty.
- (26) The term "State" means any State, territory, or possession of the United States, the District of Columbia, the Commonwealth of Puerto Rico, the Trust Territory of the Pacific Islands, and the Canal Zone.
- (27) The term "ultimate user" means 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.

- (28) The term "United States", when used in a geographic sense, means all places and waters, continental or insular, subject to the jurisdiction of the United States.
- (29) The term "maintenance treatment" means the dispensing, for a period in excess of twenty-one days, of a narcotic drug in the treatment of an individual for dependence upon heroin or other morphine-like drugs.
- (30) The term "detoxification treatment" means the dispensing, for a period not in excess of one hundred and eighty days, of a narcotic drug in decreasing doses to an individual in order to alleviate adverse physiological or psychological effects incident to withdrawal from the continuous or sustained use of a narcotic drug and as a method of bringing the individual to a narcotic drug-free state within such period.
- (31) The term "Convention on Psychotropic Substances" means the Convention on Psychotropic Substances signed at Vienna, Austria, on February 21, 1971; and the term "Single Convention on Narcotic Drugs" means the Single Convention on Narcotic Drugs signed at New York, New York, on March 30, 1961.
- (32)
  - (A) Except as provided in subparagraph (B), the term "controlled substance analogue" means a substance -
    - (i) the chemical structure of which is substantially similar to the chemical structure of a controlled substance in schedule I or

II;

- (ii) which has a stimulant, depressant, or hallucinogenic effect on the central nervous system that is substantially similar to or greater than the stimulant, depressant, or hallucinogenic effect on the central nervous system of a controlled substance in schedule I or II; or
- (iii) with respect to a particular person, which such person represents or intends to have a stimulant, depressant, or hallucinogenic effect on the central nervous system that is substantially similar to or greater than the stimulant, depressant, or hallucinogenic effect on the central nervous system of a controlled substance in schedule I or II.
- (B) Such term does not include -
  - (i) a controlled substance;
  - (ii) any substance for which there is an approved new drug application;
  - (iii) with respect to a particular person any substance, if an exemption is in effect for investigational use, for that person, under section 355 of this title to the extent conduct with respect to such substance is pursuant to such exemption; or
  - (iv) any substance to the extent not intended for human consumption before such an exemption takes effect with respect to that substance.
- (33) The term "listed chemical" means any list I chemical or any list II chemical.
- (34) The term "list I chemical" means a chemical specified by regulation of the Attorney General as a chemical that is used in manufacturing a controlled substance in violation of this subchapter and is important to the manufacture of the controlled substances, and such term includes (until otherwise specified by regulation of the Attorney General, as considered appropriate by the Attorney General or upon petition to the Attorney General by any person) the following:
  - (A) Anthranilic acid, its esters, and its salts.
  - (B) Benzyl cyanide.
  - (C) Ephedrine, its salts, optical isomers, and salts of optical isomers.
  - (D) Ergonovine and its salts.
  - (E) Ergotamine and its salts.
  - (F) N-Acetylanthranilic acid, its esters, and its salts.
  - (G) Norpseudoephedrine, its salts, optical isomers, and salts of optical isomers.
  - (H) Phenylacetic acid, its esters, and its salts.
  - (I) Phenylpropanolamine, its salts, optical isomers, and salts of optical isomers.
  - (J) Piperidine and its salts.
  - (K) Pseudoephedrine, its salts, optical isomers, and salts of optical isomers.
  - (L) 3,4-Methylenedioxyphenyl-2-propanone.
  - (M) Methylamine.
  - (N) Ethylamine.
  - (O) Propionic anhydride.
  - (P) Insosafrole.
  - (Q) Safrole.
  - (R) Piperonal.
  - (S) N-Methylepherdrine. (FOOTNOTE 1) (FOOTNOTE 1) So in original. Probably should be "N-Methylephedrine."

- (T) N-methylpseudoephedrine.
- (U) Hydriotic acid.
- (V) benzaldehyde.
- (W) nitroethane.
- (X) Any salt, optical isomer, or salt of an optical isomer of the chemicals listed in subparagraphs (M) through (U) of this paragraph.

- (35) The term "list II chemical" means a chemical (other than a list I chemical) specified by regulation of the Attorney General as a chemical that is used in manufacturing a controlled substance in violation of this subchapter, and such term includes (until otherwise specified by regulation of the Attorney General, as considered appropriate by the Attorney General or upon petition to the Attorney General by any person) the following chemicals:
  - (A) Acetic anhydride.
  - (B) Acetone.
  - (C) Benzyl chloride.
  - (D) Ethyl ether.
  - (E) Repealed. Pub. L. 101-647, title XXIII, Sec. 2301(b), Nov. 29, 1990, 104 Stat. 4858.
  - (F) Potassium permanganate.
  - (G) 2-Butanone.
  - (H) Toluene.
- (36) The term "regular customer" means, with respect to a regulated person, a customer with whom the regulated person has an established business relationship that is reported to the Attorney General.
- (37) The term "regular importer" means, with respect to a listed chemical, a person that has an established record as an importer of that listed chemical that is reported to the Attorney General.
- (38) The term "regulated person" means a person who manufactures, distributes, imports, or exports a listed chemical, a tableting machine, or an encapsulating machine or who acts as a broker or trader for an international transaction involving a listed chemical, a tableting machine, or an encapsulating machine.
- (39) The term "regulated transaction" means -
  - (A) a distribution, receipt, sale, importation, or exportation of, or an international transaction involving shipment of, a listed chemical, or if the Attorney General establishes a threshold amount for a specific listed chemical, a threshold amount, including a cumulative threshold amount for multiple transactions (as determined by the Attorney General, in consultation with the chemical industry and taking into consideration the quantities normally used for lawful purposes), of a listed chemical, except that such term does not include -
    - (i) a domestic lawful distribution in the usual course of business between agents or employees of a single regulated person;
    - (ii) a delivery of a listed chemical to or by a common or contract carrier for carriage in the lawful and usual course of the business of the common or contract carrier, or to or by a warehouseman for storage in the lawful and usual course of the business of the warehouseman, except that if the carriage or storage is in connection with the distribution, importation, or exportation of a listed chemical to a third person, this clause does not relieve a distributor, importer, or exporter from compliance with section 830 of this title;
    - (iii) any category of transaction or any category of transaction for a specific listed chemical or chemicals specified by regulation of the Attorney General as excluded from this definition as unnecessary for enforcement of this subchapter or subchapter II of this chapter;
    - (iv) any transaction in a listed chemical that is contained in a drug that may be marketed or distributed lawfully in the United States under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) unless -
      - (I)
        - (aa) the drug contains ephedrine or its salts, optical isomers, or salts of optical isomers as the only active medicinal ingredient or contains ephedrine or its salts, optical isomers, or salts of optical isomers and therapeutically insignificant quantities of another active medicinal ingredient; or

          (bb) the Attorney General has determined under section 814 of this title that the drug or group of drugs is being diverted to obtain the listed chemical for use in the illicit production of a controlled substance; and
      - (II) the quantity of ephedrine or other listed chemical contained in the drug included in the transaction or multiple transactions equals or exceeds the threshold established for that chemical by the Attorney General. (FOOTNOTE 2) (FOOTNOTE 2) So in original. The period probably should be "; or".
    - (v) any transaction in a chemical mixture which the Attorney General has by regulation designated as exempt from

the application of this subchapter and subchapter II of this chapter based on a finding that the mixture is formulated in such a way that it cannot be easily used in the illicit production of a controlled substance and that the listed chemical or chemicals contained in the mixture cannot be readily recovered; and

- (B) a distribution, importation, or exportation of a tableting machine or encapsulating machine.

- (40) The term "chemical mixture" means a combination of two or more chemical substances, at least one of which is not a list I chemical or a list II chemical, except that such term does not include any combination of a list I chemical or a list II chemical with another chemical that is present solely as an impurity.
- (41)
  - (A) The term "anabolic steroid" means any drug or hormonal substance, chemically and pharmacologically related to testosterone (other than estrogens, progestins, and corticosteroids) that promotes muscle growth, and includes -
    - (i) boldenone,
    - (ii) chlorotestosterone,
    - (iii) clostebol,
    - (iv) dehydrochlormethyltestosterone,
    - (v) dihydrotestosterone,
    - (vi) drostanolone,
    - (vii) ethylestrenol,
    - (viii) fluoxymesterone,
    - (ix) formebulone,
    - (x) mesterolone,
    - (xi) methandienone,
    - (xii) methandranone,
    - (xiii) methandriol,
    - (xiv) methandrostenolone,
    - (xv) methenolone,
    - (xvi) methyltestosterone,
    - (xvii) mibolerone,
    - (xviii) nandrolone,
    - (xix) norethandrolone,
    - (xx) oxandrolone,
    - (xxi) oxymesterone,
    - (xxii) oxymetholone,
    - (xxiii) stanolone,
    - (xxiv) stanozolol,
    - (xxv) testolactone,
    - (xxvi) testosterone,
    - (xxvii) trenbolone, and
    - (xxviii) any salt, ester, or isomer of a drug or substance described or listed in this paragraph, if that salt, ester, or isomer promotes muscle growth.
  - (B)
    - (i) Except as provided in clause (ii), such term does not include an anabolic steroid which is expressly intended for administration through implants to cattle or other nonhuman species and which has been approved by the Secretary of Health and Human Services for such administration.
    - (ii) If any person prescribes, dispenses, or distributes such steroid for human use, such person shall be considered to have prescribed, dispensed, or distributed an anabolic steroid within the meaning of subparagraph (A).
- (42) The term "international transaction" means a transaction involving the shipment of a listed chemical across an international border (other than a United States border) in which a broker or trader located in the United States participates.
- (43) The terms "broker" and "trader" mean a person that assists in arranging an international transaction in a listed chemical by -
  - (A) negotiating contracts;
  - (B) serving as an agent or intermediary; or
  - (C) bringing together a buyer and seller, a buyer and transporter, or a seller and transporter.

[Credits and Conditions] [Structure] [Your Comments]

- UNITED STATES CODE
  - TITLE 21 - FOOD AND DRUGS
    - CHAPTER 9 - FEDERAL FOOD, DRUG, AND COSMETIC ACT
      - SUBCHAPTER V - DRUGS AND DEVICES
        - Part A - Drugs and Devices

§ 355. New drugs

- (a) Necessity of effective approval of application
  No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) or (j) of this section is effective with respect to such drug.
- (b) Filing application; contents
  - (1) Any person may file with the Secretary an application with respect to any drug subject to the provisions of subsection (a) of this section. Such person shall submit to the Secretary as a part of the application (A) full reports of investigations which have been made to show whether or not such drug is safe for use and whether such drug is effective in use; (B) a full list of the articles used as components of such drug; (C) a full statement of the composition of such drug; (D) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug; (E) such samples of such drug and of the articles used as components thereof as the Secretary may require; and (F) specimens of the labeling proposed to be used for such drug. The applicant shall file with the application the patent number and the expiration date of any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug. If an application is filed under this subsection for a drug and a patent which claims such drug or a method of using such drug is issued after the filing date but before approval of the application, the applicant shall amend the application to include the information required by the preceding sentence. Upon approval of the application, the Secretary shall publish information submitted under the two preceding sentences.
  - (2) An application submitted under paragraph (1) for a drug for which the investigations described in clause (A) of such paragraph and relied upon by the applicant for approval of the application were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted shall also include -
    - (A) a certification, in the opinion of the applicant and to the best of his knowledge, with respect to each patent which claims the drug for which such investigations were conducted or which claims a use for such drug for which the applicant is seeking approval under this subsection and for which information is required to be filed under paragraph (1) or subsection (c) of this section -
      - (i) that such patent information has not been filed,
      - (ii) that such patent has expired,
      - (iii) of the date on which such patent will expire, or
      - (iv) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted; and
    - (B) if with respect to the drug for which investigations described in paragraph (1)(A) were conducted information was filed under paragraph (1) or subsection (c) of this section for a method of use patent which does not claim a use for which the applicant is seeking approval under this subsection, a statement that the method of use patent does not claim such a use.
  - (3)
    - (A) An applicant who makes a certification described in paragraph (2)(A)(iv) shall include in the application a statement that the applicant will give the notice required by subparagraph (B) to -
      - (i) each owner of the patent which is the subject of the certification or the representative of such owner designated to receive such notice, and
      - (ii) the holder of the approved application under subsection (b) of this section for the drug which is claimed by the patent or a use of which is claimed by the patent or the representative of such holder designated to receive such notice.
    - (B) The notice referred to in subparagraph (A) shall state that an application has been submitted under this

subsection for the drug with respect to which the certification is made to obtain approval to engage in the commercial manufacture, use, or sale of the drug before the expiration of the patent referred to in the certification. Such notice shall include a detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid or will not be infringed.

- (C) If an application is amended to include a certification described in paragraph (2)(A)(iv), the notice required by subparagraph (B) shall be given when the amended application is submitted.

- (c) Period for approval of application; period for, notice, and expedition of hearing; period for issuance of order
  - (1) Within one hundred and eighty days after the filing of an application under subsection (b) of this section, or such additional period as may be agreed upon by the Secretary and the applicant, the Secretary shall either -
    - (A) approve the application if he then finds that none of the grounds for denying approval specified in subsection (d) of this section applies, or
    - (B) give the applicant notice of an opportunity for a hearing before the Secretary under subsection (d) of this section on the question whether such application is approvable. If the applicant elects to accept the opportunity for hearing by written request within thirty days after such notice, such hearing shall commence not more than ninety days after the expiration of such thirty days unless the Secretary and the applicant otherwise agree. Any such hearing shall thereafter be conducted on an expedited basis and the Secretary's order thereon shall be issued within ninety days after the date fixed by the Secretary for filing final briefs.
  - (2) If the patent information described in subsection (b) of this section could not be filed with the submission of an application under subsection (b) of this section because the application was filed before the patent information was required under subsection (b) of this section or a patent was issued after the application was approved under such subsection, the holder of an approved application shall file with the Secretary the patent number and the expiration date of any patent which claims the drug for which the application was submitted or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug. If the holder of an approved application could not file patent information under subsection (b) of this section because it was not required at the time the application was approved, the holder shall file such information under this subsection not later than thirty days after September 24, 1984, and if the holder of an approved application could not file patent information under subsection (b) of this section because no patent had been issued when an application was filed or approved, the holder shall file such information under this subsection not later than thirty days after the date the patent involved is issued. Upon the submission of patent information under this subsection, the Secretary shall publish it.
  - (3) The approval of an application filed under subsection (b) of this section which contains a certification required by paragraph (2) of such subsection shall be made effective on the last applicable date determined under the following:
    - (A) If the applicant only made a certification described in clause (i) or (ii) of subsection (b)(2)(A) of this section or in both such clauses, the approval may be made effective immediately.
    - (B) If the applicant made a certification described in clause (iii) of subsection (b)(2)(A) of this section, the approval may be made effective on the date certified under clause (iii).
    - (C) If the applicant made a certification described in clause (iv) of subsection (b)(2)(A) of this section, the approval shall be made effective immediately unless an action is brought for infringement of a patent which is the subject of the certification before the expiration of forty-five days from the date the notice provided under paragraph (3)(B) is received. If such an action is brought before the expiration of such days, the approval may be made effective upon the expiration of the thirty-month period beginning on the date of the receipt of the notice provided under paragraph (3)(B) or such shorter or longer period as the court may order because either party to the action failed to reasonably cooperate in expediting the action, except that -
      - (i) if before the expiration of such period the court decides that such patent is invalid or not infringed, the approval may be made effective on the date of the court decision,
      - (ii) if before the expiration of such period the court decides that such patent has been infringed, the approval may be made effective on such date as the court orders under section 271(e)(4)(A) of title 35, or
      - (iii) if before the expiration of such period the court grants a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug until the court decides the issues of patent validity and infringement and if the court decides that such patent is invalid or not infringed, the approval shall be made effective on the date of such court decision. In such an action, each of the parties shall reasonably cooperate in expediting the action. Until the expiration of forty-five days from the date the notice made under paragraph (3)(B) is received, no action may be brought under section 2201 of title 28 for a declaratory judgment with respect to the patent. Any action brought under such section 2201 shall be brought in the judicial district where the defendant has its principal place of

business or a regular and established place of business.

- (D)
  - (i) If an application (other than an abbreviated new drug application) submitted under subsection (b) of this section for a drug, no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under subsection (b) of this section, was approved during the period beginning January 1, 1982, and ending on September 24, 1984, the Secretary may not make the approval of another application for a drug for which the investigations described in clause (A) of subsection (b)(1) of this section and relied upon by the applicant for approval of the application were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted effective before the expiration of ten years from the date of the approval of the application previously approved under subsection (b) of this section.
  - (ii) If an application submitted under subsection (b) of this section for a drug, no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under subsection (b) of this section, is approved after September 24, 1984, no application which refers to the drug for which the subsection (b) application was submitted and for which the investigations described in clause (A) of subsection (b)(1) of this section and relied upon by the applicant for approval of the application were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted may be submitted under subsection (b) of this section before the expiration of five years from the date of the approval of the application under subsection (b) of this section, except that such an application may be submitted under subsection (b) of this section after the expiration of four years from the date of the approval of the subsection (b) application if it contains a certification of patent invalidity or noninfringement described in clause (iv) of subsection (b)(2)(A) of this section. The approval of such an application shall be made effective in accordance with this paragraph except that, if an action for patent infringement is commenced during the one-year period beginning forty-eight months after the date of the approval of the subsection (b) application, the thirty-month period referred to in subparagraph (C) shall be extended by such amount of time (if any) which is required for seven and one-half years to have elapsed from the date of approval of the subsection (b) application.
  - (iii) If an application submitted under subsection (b) of this section for a drug, which includes an active ingredient (including any ester or salt of the active ingredient) that has been approved in another application approved under subsection (b) of this section, is approved after September 24, 1984, and if such application contains reports of new clinical investigations (other than bioavailability studies) essential to the approval of the application and conducted or sponsored by the applicant, the Secretary may not make the approval of an application submitted under subsection (b) of this section for the conditions of approval of such drug in the approved subsection (b) application effective before the expiration of three years from the date of the approval of the application under subsection (b) of this section if the investigations described in clause (A) of subsection (b)(1) of this section and relied upon by the applicant for approval of the application were not conducted by or for the applicant and if the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted.
  - (iv) If a supplement to an application approved under subsection (b) of this section is approved after September 24, 1984, and the supplement contains reports of new clinical investigations (other than bioavailabilty (FOOTNOTE 1) studies) essential to the approval of the supplement and conducted or sponsored by the person submitting the supplement, the Secretary may not make the approval of an application submitted under subsection (b) of this section for a change approved in the supplement effective before the expiration of three years from the date of the approval of the supplement under subsection (b) of this section if the investigations described in clause (A) of subsection (b)(1) of this section and relied upon by the applicant for approval of the application were not conducted by or for the applicant and if the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted.

    (FOOTNOTE 1) So in original. Probably should be "bioavailability".
  - (v) If an application (or supplement to an application) submitted under subsection (b) of this section for a drug, which includes an active ingredient (including any ester or salt of the active ingredient) that has been approved in another application under subsection (b) of this section, was approved during the period beginning January 1, 1982, and ending on September 24, 1984, the Secretary may not make the approval

of an application submitted under this subsection and for which the investigations described in clause (A) of subsection (b)(1) of this section and relied upon by the applicant for approval of the application were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted and which refers to the drug for which the subsection (b) application was submitted effective before the expiration of two years from September 24, 1984.

- (d) Grounds for refusing application; approval of application; "substantial evidence" defined
  If the Secretary finds, after due notice to the applicant in accordance with subsection (c) of this section and giving him an opportunity for a hearing, in accordance with said subsection, that (1) the investigations, reports of which are required to be submitted to the Secretary pursuant to subsection (b) of this section, do not include adequate tests by all methods reasonably applicable to show whether or not such drug is safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof; (2) the results of such tests show that such drug is unsafe for use under such conditions or do not show that such drug is safe for use under such conditions; (3) the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug are inadequate to preserve its identity, strength, quality, and purity; (4) upon the basis of the information submitted to him as part of the application, or upon the basis of any other information before him with respect to such drug, he has insufficient information to determine whether such drug is safe for use under such conditions; or (5) evaluated on the basis of the information submitted to him as part of the application and any other information before him with respect to such drug, there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof; or (6) the application failed to contain the patent information prescribed by subsection (b) of this section; or (7) based on a fair evaluation of all material facts, such labeling is false or misleading in any particular; he shall issue an order refusing to approve the application. If, after such notice and opportunity for hearing, the Secretary finds that clauses (1) through (6) do not apply, he shall issue an order approving the application. As used in this subsection and subsection (e) of this section, the term "substantial evidence" means evidence consisting of adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and responsibly be concluded by such experts that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling or proposed labeling thereof.
- (e) Withdrawal of approval; grounds; immediate suspension upon finding imminent hazard to public health
  The Secretary shall, after due notice and opportunity for hearing to the applicant, withdraw approval of an application with respect to any drug under this section if the Secretary finds (1) that clinical or other experience, tests, or other scientific data show that such drug is unsafe for use under the conditions of use upon the basis of which the application was approved; (2) that new evidence of clinical experience, not contained in such application or not available to the Secretary until after such application was approved, or tests by new methods, or tests by methods not deemed reasonably applicable when such application was approved, evaluated together with the evidence available to the Secretary when the application was approved, shows that such drug is not shown to be safe for use under the conditions of use upon the basis of which the application was approved; or (3) on the basis of new information before him with respect to such drug, evaluated together with the evidence available to him when the application was approved, that there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling thereof; or (4) the patent information prescribed by subsection (c) of this section was not filed within thirty days after the receipt of written notice from the Secretary specifying the failure to file such information; or (5) that the application contains any untrue statement of a material fact: Provided, That if the Secretary (or in his absence the officer acting as Secretary) finds that there is an imminent hazard to the public health, he may suspend the approval of such application immediately, and give the applicant prompt notice of his action and afford the applicant the opportunity for an expedited hearing under this subsection; but the authority conferred by this proviso to suspend the approval of an application shall not be delegated. The Secretary may also, after due notice and opportunity for hearing to the applicant, withdraw the approval of an application submitted under subsection (b) or (j) of this section with respect to any drug under this section if the Secretary finds (1) that the applicant has failed to establish a system for maintaining required records, or has repeatedly or deliberately failed to maintain such records or to make required reports, in accordance with a regulation or order under subsection (k) of this section or to comply with the notice requirements of section 360(k)(2) of this title, or the applicant has refused to permit access to, or copying or verification of, such records as required by paragraph (2) of such subsection; or (2) that on the basis of new information before him, evaluated together with the evidence before him when the application was approved, the methods used in, or the facilities and controls used for, the manufacture, processing, and packing of such drug are inadequate to assure and preserve its identity, strength, quality, and purity and were not made adequate within a reasonable time after receipt of written notice from the Secretary specifying the matter

complained of; or (3) that on the basis of new information before him, evaluated together with the evidence before him when the application was approved, the labeling of such drug, based on a fair evaluation of all material facts, is false or misleading in any particular and was not corrected within a reasonable time after receipt of written notice from the Secretary specifying the matter complained of. Any order under this subsection shall state the findings upon which it is based.

- (f) Revocation of order refusing, withdrawing or suspending approval of application
  Whenever the Secretary finds that the facts so require, he shall revoke any previous order under subsection (d) or (e) of this section refusing, withdrawing, or suspending approval of an application and shall approve such application or reinstate such approval, as may be appropriate.
- (g) Service of orders
  Orders of the Secretary issued under this section shall be served (1) in person by any officer or employee of the department designated by the Secretary or (2) by mailing the order by registered mail or by certified mail addressed to the applicant or respondent at his last-known address in the records of the Secretary.
- (h) Appeal from order
  An appeal may be taken by the applicant from an order of the Secretary refusing or withdrawing approval of an application under this section. Such appeal shall be taken by filing in the United States court of appeals or the circuit wherein such applicant resides or has his principal place of business, or in the United States Court of Appeals for the District of Columbia Circuit, within sixty days after the entry of such order, a written petition praying that the order of the Secretary be set aside. A copy of such petition shall be forthwith transmitted by the clerk of the court to the Secretary, or any officer designated by him for that purpose, and thereupon the Secretary shall certify and file in the court the record upon which the order complained of was entered, as provided in section 2112 of title 28. Upon the filing of such petition such court shall have exclusive jurisdiction to affirm or set aside such order, except that until the filing of the record the Secretary may modify or set aside his order. No objection to the order of the Secretary shall be considered by the court unless such objection shall have been urged before the Secretary or unless there were reasonable grounds for failure so to do. The finding of the Secretary as to the facts, if supported by substantial evidence, shall be conclusive. If any person shall apply to the court for leave to adduce additional evidence, and shall show to the satisfaction of the court that such additional evidence is material and that there were reasonable grounds for failure to adduce such evidence in the proceeding before the Secretary, the court may order such additional evidence to be taken before the Secretary and to be adduced upon the hearing in such manner and upon such terms and conditions as to the court may seem proper. The Secretary may modify his findings as to the facts by reason of the additional evidence so taken, and he shall file with the court such modified findings which, if supported by substantial evidence, shall be conclusive, and his recommendation, if any, for the setting aside of the original order. The judgment of the court affirming or setting aside any such order of the Secretary shall be final, subject to review by the Supreme Court of the United States upon certiorari or certification as provided in section 1254 of title 28. The commencement of proceedings under this subsection shall not, unless specifically ordered by the court to the contrary, operate as a stay of the Secretary's order.
- (i) Exemptions of drugs for research; discretionary and mandatory conditions; direct reports to Secretary
  The Secretary shall promulgate regulations for exempting from the operation of the foregoing subsections of this section drugs intended solely for investigational use by experts qualified by scientific training and experience to investigate the safety and effectiveness of drugs. Such regulations may, within the discretion of the Secretary, among other conditions relating to the protection of the public health, provide for conditioning such exemption upon -
  - (1) the submission to the Secretary, before any clinical testing of a new drug is undertaken, of reports, by the manufacturer or the sponsor of the investigation of such drug, of preclinical tests (including tests on animals) of such drug adequate to justify the proposed clinical testing;
  - (2) the manufacturer or the sponsor of the investigation of a new drug proposed to be distributed to investigators for clinical testing obtaining a signed agreement from each of such investigators that patients to whom the drug is administered will be under his personal supervision, or under the supervision of investigators responsible to him, and that he will not supply such drug to any other investigator, or to clinics, for administration to human beings; and
  - (3) the establishment and maintenance of such records, and the making of such reports to the Secretary, by the manufacturer or the sponsor of the investigation of such drug, of data (including but not limited to analytical reports by investigators) obtained as the result of such investigational use of such drug, as the Secretary finds will enable him to evaluate the safety and effectiveness of such drug in the event of the filing of an application pursuant to subsection (b) of this section. Such regulations shall provide that such exemption shall be conditioned upon the manufacturer, or the sponsor of the investigation, requiring that experts using such drugs for investigational purposes certify to such manufacturer or sponsor that they will inform any human beings to whom such drugs, or any controls used in connection therewith, are being administered, or their representatives, that such drugs are being used for

investigational purposes and will obtain the consent of such human beings or their representatives, except where they deem it not feasible or, in their professional judgment, contrary to the best interests of such human beings. Nothing in this subsection shall be construed to require any clinical investigator to submit directly to the Secretary reports on the investigational use of drugs.

- (j) Abbreviated new drug applications
  - (1) Any person may file with the Secretary an abbreviated application for the approval of a new drug.
  - (2)
    - (A) An abbreviated application for a new drug shall contain -
      - (i) information to show that the conditions of use prescribed, recommended, or suggested in the labeling proposed for the new drug have been previously approved for a drug listed under paragraph (6) (hereinafter in this subsection referred to as a "listed drug");
      - (ii)
        - (I) if the listed drug referred to in clause (i) has only one active ingredient, information to show that the active ingredient of the new drug is the same as that of the listed drug;
        - (II) if the listed drug referred to in clause (i) has more than one active ingredient, information to show that the active ingredients of the new drug are the same as those of the listed drug, or
        - (III) if the listed drug referred to in clause (i) has more than one active ingredient and if one of the active ingredients of the new drug is different and the application is filed pursuant to the approval of a petition filed under subparagraph (C), information to show that the other active ingredients of the new drug are the same as the active ingredients of the listed drug, information to show that the different active ingredient is an active ingredient of a listed drug or of a drug which does not meet the requirements of section 321(p) of this title, and such other information respecting the different active ingredient with respect to which the petition was filed as the Secretary may require;
      - (iii) information to show that the route of administration, the dosage form, and the strength of the new drug are the same as those of the listed drug referred to in clause (i) or, if the route of administration, the dosage form, or the strength of the new drug is different and the application is filed pursuant to the approval of a petition filed under subparagraph (C), such information respecting the route of administration, dosage form, or strength with respect to which the petition was filed as the Secretary may require;
      - (iv) information to show that the new drug is bioequivalent to the listed drug referred to in clause (i), except that if the application is filed pursuant to the approval of a petition filed under subparagraph (C), information to show that the active ingredients of the new drug are of the same pharmacological or therapeutic class as those of the listed drug referred to in clause (i) and the new drug can be expected to have the same therapeutic effect as the listed drug when administered to patients for a condition of use referred to in clause (i);
      - (v) information to show that the labeling proposed for the new drug is the same as the labeling approved for the listed drug referred to in clause (i) except for changes required because of differences approved under a petition filed under subparagraph (C) or because the new drug and the listed drug are produced or distributed by different manufacturers;
      - (vi) the items specified in clauses (B) through (F) of subsection (b)(1) of this section;
      - (vii) a certification, in the opinion of the applicant and to the best of his knowledge, with respect to each patent which claims the listed drug referred to in clause (i) or which claims a use for such listed drug for which the applicant is seeking approval under this subsection and for which information is required to be filed under subsection (b) or (c) of this section -
        - (I) that such patent information has not been filed,
        - (II) that such patent has expired,
        - (III) of the date on which such patent will expire, or
        - (IV) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted; and
      - (viii) if with respect to the listed drug referred to in clause (i) information was filed under subsection (b) or (c) of this section for a method of use patent which does not claim a use for which the applicant is seeking approval under this subsection, a statement that the method of use patent does not claim such a use. The Secretary may not require that an abbreviated application contain information in addition to that required by clauses (i) through (viii).
    - (B)

- (i) An applicant who makes a certification described in subparagraph (A)(vii)(IV) shall include in the application a statement that the applicant will give the notice required by clause (ii) to -
  - (I) each owner of the patent which is the subject of the certification or the representative of such owner designated to receive such notice, and
  - (II) the holder of the approved application under subsection (b) of this section for the drug which is claimed by the patent or a use of which is claimed by the patent or the representative of such holder designated to receive such notice.
- (ii) The notice referred to in clause (i) shall state that an application, which contains data from bioavailability or bioequivalence studies, has been submitted under this subsection for the drug with respect to which the certification is made to obtain approval to engage in the commercial manufacture, use, or sale of such drug before the expiration of the patent referred to in the certification. Such notice shall include a detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid or will not be infringed.
- (iii) If an application is amended to include a certification described in subparagraph (A)(vii)(IV), the notice required by clause (ii) shall be given when the amended application is submitted.

(C) If a person wants to submit an abbreviated application for a new drug which has a different active ingredient or whose route of administration, dosage form, or strength differ from that of a listed drug, such person shall submit a petition to the Secretary seeking permission to file such an application. The Secretary shall approve or disapprove a petition submitted under this subparagraph within ninety days of the date the petition is submitted. The Secretary shall approve such a petition unless the Secretary finds -

- (i) that investigations must be conducted to show the safety and effectiveness of the drug or of any of its active ingredients, the route of administration, the dosage form, or strength which differ from the listed drug; or
- (ii) that any drug with a different active ingredient may not be adequately evaluated for approval as safe and effective on the basis of the information required to be submitted in an abbreviated application.

(3) Subject to paragraph (4), the Secretary shall approve an application for a drug unless the Secretary finds -

(A) the methods used in, or the facilities and controls used for, the manufacture, processing, and packing of the drug are inadequate to assure and preserve its identity, strength, quality, and purity;

(B) information submitted with the application is insufficient to show that each of the proposed conditions of use have been previously approved for the listed drug referred to in the application;

(C)

- (i) if the listed drug has only one active ingredient, information submitted with the application is insufficient to show that the active ingredient is the same as that of the listed drug;
- (ii) if the listed drug has more than one active ingredient, information submitted with the application is insufficient to show that the active ingredients are the same as the active ingredients of the listed drug, or
- (iii) if the listed drug has more than one active ingredient and if the application is for a drug which has an active ingredient different from the listed drug, information submitted with the application is insufficient to show -
  - (I) that the other active ingredients are the same as the active ingredients of the listed drug, or
  - (II) that the different active ingredient is an active ingredient of a listed drug or a drug which does not meet the requirements of section 321(p) of this title, or no petition to file an application for the drug with the different ingredient was approved under paragraph (2)(C);

(D)

- (i) if the application is for a drug whose route of administration, dosage form, or strength of the drug is the same as the route of administration, dosage form, or strength of the listed drug referred to in the application, information submitted in the application is insufficient to show that the route of administration, dosage form, or strength is the same as that of the listed drug, or
- (ii) if the application is for a drug whose route of administration, dosage form, or strength of the drug is different from that of the listed drug referred to in the application, no petition to file an application for the drug with the different route of administration, dosage form, or strength was approved under paragraph (2)(C);

(E) if the application was filed pursuant to the approval of a petition under paragraph (2)(C), the application did not contain the information required by the Secretary respecting the active ingredient, route of administration, dosage form, or strength which is not the same;

(F) information submitted in the application is insufficient to show that the drug is bioequivalent to the listed

drug referred to in the application or, if the application was filed pursuant to a petition approved under paragraph (2)(C), information submitted in the application is insufficient to show that the active ingredients of the new drug are of the same pharmacological or therapeutic class as those of the listed drug referred to in paragraph (2)(A)(i) and that the new drug can be expected to have the same therapeutic effect as the listed drug when administered to patients for a condition of use referred to in such paragraph;

- (G) information submitted in the application is insufficient to show that the labeling proposed for the drug is the same as the labeling approved for the listed drug referred to in the application except for changes required because of differences approved under a petition filed under paragraph (2)(C) or because the drug and the listed drug are produced or distributed by different manufacturers;
- (H) information submitted in the application or any other information available to the Secretary shows that (i) the inactive ingredients of the drug are unsafe for use under the conditions prescribed, recommended, or suggested in the labeling proposed for the drug, or (ii) the composition of the drug is unsafe under such conditions because of the type or quantity of inactive ingredients included or the manner in which the inactive ingredients are included;
- (I) the approval under subsection (c) of this section of the listed drug referred to in the application under this subsection has been withdrawn or suspended for grounds described in the first sentence of subsection (e) of this section, the Secretary has published a notice of opportunity for hearing to withdraw approval of the listed drug under subsection (c) of this section for grounds described in the first sentence of subsection (e) of this section, the approval under this subsection of the listed drug referred to in the application under this subsection has been withdrawn or suspended under paragraph (5), or the Secretary has determined that the listed drug has been withdrawn from sale for safety or effectiveness reasons;
- (J) the application does not meet any other requirement of paragraph (2)(A); or
- (K) the application contains an untrue statement of material fact.

- (4)
  - (A) Within one hundred and eighty days of the initial receipt of an application under paragraph (2) or within such additional period as may be agreed upon by the Secretary and the applicant, the Secretary shall approve or disapprove the application.
  - (B) The approval of an application submitted under paragraph (2) shall be made effective on the last applicable date determined under the following:
    - (i) If the applicant only made a certification described in subclause (I) or (II) of paragraph (2)(A)(vii) or in both such subclauses, the approval may be made effective immediately.
    - (ii) If the applicant made a certification described in subclause (III) of paragraph (2)(A)(vii), the approval may be made effective on the date certified under subclause (III).
    - (iii) If the applicant made a certification described in subclause (IV) of paragraph (2)(A)(vii), the approval shall be made effective immediately unless an action is brought for infringement of a patent which is the subject of the certification before the expiration of forty-five days from the date the notice provided under paragraph (2)(B)(i) is received. If such an action is brought before the expiration of such days, the approval shall be made effective upon the expiration of the thirty-month period beginning on the date of the receipt of the notice provided under paragraph (2)(B)(i) or such shorter or longer period as the court may order because either party to the action failed to reasonably cooperate in expediting the action, except that -
      - (I) if before the expiration of such period the court decides that such patent is invalid or not infringed, the approval shall be made effective on the date of the court decision,
      - (II) if before the expiration of such period the court decides that such patent has been infringed, the approval shall be made effective on such date as the court orders under section 271(e)(4)(A) of title 35, or
      - (III) if before the expiration of such period the court grants a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug until the court decides the issues of patent validity and infringement and if the court decides that such patent is invalid or not infringed, the approval shall be made effective on the date of such court decision. In such an action, each of the parties shall reasonably cooperate in expediting the action. Until the expiration of forty-five days from the date the notice made under paragraph (2)(B)(i) is received, no action may be brought under section 2201 of title 28, for a declaratory judgment with respect to the patent. Any action brought under section 2201 shall be brought in the judicial district where the defendant has its principal place of business or a regular and established place of business.

- (iv) If the application contains a certification described in subclause (IV) of paragraph (2)(A)(vii) and is for a drug for which a previous application has been submitted under this subsection continuing such a certification, the application shall be made effective not earlier than one hundred and eighty days after -
  - (I) the date the Secretary receives notice from the applicant under the previous application of the first commercial marketing of the drug under the previous application, or
  - (II) the date of a decision of a court in an action described in clause (iii) holding the patent which is the subject of the certification to be invalid or not infringed, whichever is earlier.

- (C) If the Secretary decides to disapprove an application, the Secretary shall give the applicant notice of an opportunity for a hearing before the Secretary on the question of whether such application is approvable. If the applicant elects to accept the opportunity for hearing by written request within thirty days after such notice, such hearing shall commence not more than ninety days after the expiration of such thirty days unless the Secretary and the applicant otherwise agree. Any such hearing shall thereafter be conducted on an expedited basis and the Secretary's order thereon shall be issued within ninety days after the date fixed by the Secretary for filing final briefs.
- (D)
  - (i) If an application (other than an abbreviated new drug application) submitted under subsection (b) of this section for a drug, no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under subsection (b) of this section, was approved during the period beginning January 1, 1982, and ending on September 24, 1984, the Secretary may not make the approval of an application submitted under this subsection which refers to the drug for which the subsection (b) application was submitted effective before the expiration of ten years from the date of the approval of the application under subsection (b) of this section.
  - (ii) If an application submitted under subsection (b) of this section for a drug, no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under subsection (b) of this section, is approved after September 24, 1984, no application may be submitted under this subsection which refers to the drug for which the subsection (b) application was submitted before the expiration of five years from the date of the approval of the application under subsection (b) of this section, except that such an application may be submitted under this subsection after the expiration of four years from the date of the approval of the subsection (b) application if it contains a certification of patent invalidity or noninfringement described in subclause (IV) of paragraph (2)(A)(vii). The approval of such an application shall be made effective in accordance with subparagraph (B) except that, if an action for patent infringement is commenced during the one-year period beginning forty-eight months after the date of the approval of the subsection (b) application, the thirty-month period referred to in subparagraph (B)(iii) shall be extended by such amount of time (if any) which is required for seven and one-half years to have elapsed from the date of approval of the subsection (b) application.
  - (iii) If an application submitted under subsection (b) of this section for a drug, which includes an active ingredient (including any ester or salt of the active ingredient) that has been approved in another application approved under subsection (b) of this section, is approved after September 24, 1984, and if such application contains reports of new clinical investigations (other than bioavailability studies) essential to the approval of the application and conducted or sponsored by the applicant, the Secretary may not make the approval of an application submitted under this subsection for the conditions of approval of such drug in the subsection (b) application effective before the expiration of three years from the date of the approval of the application under subsection (b) of this section for such drug.
  - (iv) If a supplement to an application approved under subsection (b) of this section is approved after September 24, 1984, and the supplement contains reports of new clinical investigations (other than bioavailability studies) essential to the approval of the supplement and conducted or sponsored by the person submitting the supplement, the Secretary may not make the approval of an application submitted under this subsection for a change approved in the supplement effective before the expiration of three years from the date of the approval of the supplement under subsection (b) of this section.
  - (v) If an application (or supplement to an application) submitted under subsection (b) of this section for a drug, which includes an active ingredient (including any ester or salt of the active ingredient) that has been approved in another application under subsection (b) of this section, was approved during the period beginning January 1, 1982, and ending on September 24, 1984, the Secretary may not make the approval of an application submitted under this subsection which refers to the drug for which the subsection (b) application was submitted or which refers to a change approved in a supplement to the subsection (b)

application effective before the expiration of two years from September 24, 1984.

- (5) If a drug approved under this subsection refers in its approved application to a drug the approval of which was withdrawn or suspended for grounds described in the first sentence of subsection (e) of this section or was withdrawn or suspended under this paragraph or which, as determined by the Secretary, has been withdrawn from sale for safety or effectiveness reasons, the approval of the drug under this subsection shall be withdrawn or suspended -
  - (A) for the same period as the withdrawal or suspension under subsection (e) of this section or this paragraph, or
  - (B) if the listed drug has been withdrawn from sale, for the period of withdrawal from sale or, if earlier, the period ending on the date the Secretary determines that the withdrawal from sale is not for safety or effectiveness reasons.
- (6)
  - (A)
    - (i) Within sixty days of September 24, 1984, the Secretary shall publish and make available to the public -
      - (I) a list in alphabetical order of the official and proprietary name of each drug which has been approved for safety and effectiveness under subsection (c) of this section before September 24, 1984;
      - (II) the date of approval if the drug is approved after 1981 and the number of the application which was approved; and
      - (III) whether in vitro or in vivo bioequivalence studies, or both such studies, are required for applications filed under this subsection which will refer to the drug published.
    - (ii) Every thirty days after the publication of the first list under clause (i) the Secretary shall revise the list to include each drug which has been approved for safety and effectiveness under subsection (c) of this section or approved under this subsection during the thirty-day period.
    - (iii) When patent information submitted under subsection (b) or (c) of this section respecting a drug included on the list is to be published by the Secretary, the Secretary shall, in revisions made under clause (ii), include such information for such drug.
  - (B) A drug approved for safety and effectiveness under subsection (c) of this section or approved under this subsection shall, for purposes of this subsection, be considered to have been published under subparagraph (A) on the date of its approval or September 24, 1984, whichever is later.
  - (C) If the approval of a drug was withdrawn or suspended for grounds described in the first sentence of subsection (e) of this section or was withdrawn or suspended under paragraph (5) or if the Secretary determines that a drug has been withdrawn from sale for safety or effectiveness reasons, it may not be published in the list under subparagraph (A) or, if the withdrawal or suspension occurred after its publication in such list, it shall be immediately removed from such list -
    - (i) for the same period as the withdrawal or suspension under subsection (e) of this section or paragraph

- UNITED STATES CODE
  - TITLE 21 - FOOD AND DRUGS
    - CHAPTER 13 - DRUG ABUSE PREVENTION AND CONTROL
      - SUBCHAPTER I - CONTROL AND ENFORCEMENT
        - Part B - Authority To Control; Standards and Schedules

§ 812. Schedules of controlled substances

- (a) Establishment
  There are established five schedules of controlled substances, to be known as schedules I, II, III, IV, and V. Such schedules shall initially consist of the substances listed in this section. The schedules established by this section shall be updated and republished on a semiannual basis during the two-year period beginning one year after October 27, 1970, and shall be updated and republished on an annual basis thereafter.
- (b) Placement on schedules; findings required
  Except where control is required by United States obligations under an international treaty, convention, or protocol, in effect on October 27, 1970, and except in the case of an immediate precursor, a drug or other substance may not be placed in any schedule unless the findings required for such schedule are made with respect to such drug or other substance. The findings required for each of the schedules are as follows:
  - (1) Schedule I. -
    - (A) The drug or other substance has a high potential for abuse.
    - (B) The drug or other substance has no currently accepted medical use in treatment in the United States.
    - (C) There is a lack of accepted safety for use of the drug or other substance under medical supervision.
  - (2) Schedule II. -
    - (A) The drug or other substance has a high potential for abuse.
    - (B) The drug or other substance has a currently accepted medical use in treatment in the United States or a currently accepted medical use with severe restrictions.
    - (C) Abuse of the drug or other substances may lead to severe psychological or physical dependence.
  - (3) Schedule III. -
    - (A) The drug or other substance has a potential for abuse less than the drugs or other substances in schedules I and II.
    - (B) The drug or other substance has a currently accepted medical use in treatment in the United States.
    - (C) Abuse of the drug or other substance may lead to moderate or low physical dependence or high psychological dependence.
  - (4) Schedule IV. -
    - (A) The drug or other substance has a low potential for abuse relative to the drugs or other substances in schedule III.
    - (B) The drug or other substance has a currently accepted medical use in treatment in the United States.
    - (C) Abuse of the drug or other substance may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in schedule III.
  - (5) Schedule V. -
    - (A) The drug or other substance has a low potential for abuse relative to the drugs or other substances in schedule IV.
    - (B) The drug or other substance has a currently accepted medical use in treatment in the United States.
    - (C) Abuse of the drug or other substance may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in schedule IV.
- (c) Initial schedules of controlled substances
  Schedules I, II, III, IV, and V shall, unless and until amended (FOOTNOTE 1) pursuant to section 811 of this title, consist of the following drugs or other substances, by whatever official name, common or usual name, chemical name, or brand name designated:

(FOOTNOTE 1) Revised schedules are published in the Code of Federal Regulations, Part 1308 of Title 21, Food and Drugs.

SCHEDULE I

- (a) Unless specifically excepted or unless listed in another schedule, any of the following opiates, including their isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, whenever the existence of such isomers, esters, ethers, and salts is possible within the specific chemical designation:
  - (1) Acetylmethadol.
  - (2) Allylprodine.
  - (3) Alphacetylmathadol. (FOOTNOTE 2) (FOOTNOTE 2) So in original. Probably should be "Alphacetylmethadol."
  - (4) Alphameprodine.
  - (5) Alphamethadol.
  - (6) Benzethidine.
  - (7) Betacetylmethadol.
  - (8) Betameprodine.
  - (9) Betamethadol.
  - (10) Betaprodine.
  - (11) Clonitazene.
  - (12) Dextromoramide.
  - (13) Dextrorphan.
  - (14) Diampromide.
  - (15) Diethylthiambutene.
  - (16) Dimenoxadol.
  - (17) Dimepheptanol.
  - (18) Dimethylthiambutene.
  - (19) Dioxaphetyl butyrate.
  - (20) Dipipanone.
  - (21) Ethylmethylthiambutene.
  - (22) Etonitazene.
  - (23) Etoxeridine.
  - (24) Furethidine.
  - (25) Hydroxypethidine.
  - (26) Ketobemidone.
  - (27) Levomoramide.
  - (28) Levophenacylmorphan.
  - (29) Morpheridine.
  - (30) Noracymethadol.
  - (31) Norlevorphanol.
  - (32) Normethadone.
  - (33) Norpipanone.
  - (34) Phenadoxone.
  - (35) Phenampromide.
  - (36) Phenomorphan.
  - (37) Phenoperidine.
  - (38) Piritramide.
  - (39) Propheptazine.
  - (40) Properidine.
  - (41) Racemoramide.
  - (42) Trimeperidine.
- (b) Unless specifically excepted or unless listed in another schedule, any of the following opium derivatives, their salts, isomers, and salt of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:
  - (1) Acetorphine.
  - (2) Acetyldihydrocodeine.
  - (3) Benzylmorphine.
  - (4) Codeine methylbromide.

- (5) Codeine-N-Oxide.
- (6) Cyprenorphine.
- (7) Desomorphine.
- (8) Dihydromorphine.
- (9) Etorphine.
- (10) Heroin.
- (11) Hydromorphinol.
- (12) Methyldesorphine.
- (13) Methylhydromorphine.
- (14) Morphine methylbromide.
- (15) Morphine methylsulfonate.
- (16) Morphine-N-Oxide.
- (17) Myrophine.
- (18) Nicocodeine.
- (19) Nicomorphine.
- (20) Normorphine.
- (21) Pholcodine.
- (22) Thebacon.

- (c) Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation, which contains any quantity of the following hallucinogenic substances, or which contains any of their salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:
  - (1) 3,4-methylenedioxy amphetamine.
  - (2) 5-methoxy-3,4-methylenedioxy amphetamine.
  - (3) 3,4,5-trimethoxy amphetamine.
  - (4) Bufotenine.
  - (5) Diethyltryptamine.
  - (6) Dimethyltryptamine.
  - (7) 4-methyl-2,5-diamethoxyamphetamine.
  - (8) Ibogaine.
  - (9) Lysergic acid diethylamide.
  - (10) Marihuana.
  - (11) Mescaline.
  - (12) Peyote.
  - (13) N-ethyl-3-piperidyl benzilate.
  - (14) N-methyl-3-piperidyl benzilate.
  - (15) Psilocybin.
  - (16) Psilocyn.
  - (17) Tetrahydrocannabinols.

SCHEDULE II

(a) Unless specifically excepted or unless listed in another schedule, any of the following substances whether produced directly or indirectly by extraction from substances of vegetable origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis:

(1) Opium and opiate, and any salt, compound, derivative, or preparation of opium or opiate.

(2) Any salt, compound, derivative, or preparation thereof which is chemically equivalent or identical with any of the substances referred to in clause (1), except that these substances shall not include the isoquinoline alkaloids of opium.

(3) Opium poppy and poppy straw. (4) coca (FOOTNOTE 3) leaves, except coca leaves and extracts of coca leaves from which cocaine, ecgonine, and derivatives of ecgonine or their salts have been removed; cocaine, its salts, optical and geometric isomers, and salts of isomers; ecgonine, its derivatives, their salts, isomers, and salts of isomers; or any compound, mixture, or preparation which contains any quantity of any of the substances referred to in this paragraph.

(FOOTNOTE 3) So in original. Probably should be capitalized. (b) Unless specifically excepted or unless listed in another

schedule, any of the following opiates, including their isomers, esters, ethers, salts, and salts of isomers, esters and ethers, whenever the existence of such isomers, esters, ethers, and salts is possible within the specific chemical designation:

(1) Alphaprodine. (2) Anileridine. (3) Bezitramide. (4) Dihydrocodeine. (5) Diphenoxylate. (6) Fentanyl. (7) Isomethadone. (8) Levomethorphan. (9) Levorphanol. (10) Metazocine. (11) Methadone. (12) Methadone-Intermediate, 4-cyano-2-dimethylamino-4,4-diphenyl butane.

(13) Moramide-Intermediate, 2-methyl-3-morpholino-1, 1-diphenylpropane-carboxylic acid.

(14) Pethidine. (15) Pethidine-Intermediate-A, 4-cyano-1-methyl-4-phenylpiperidine.

(16) Pethidine-Intermediate-B, ethyl-4-phenylpiperidine-4-carboxylate.

(17) Pethidine-Intermediate-C, 1-methyl-4-phenylpiperidine-4-carboxylic acid.

- (18) Phenazocine.
- (19) Piminodine.
- (20) Racemethorphan.
- (21) Racemorphan. (c) Unless specifically excepted or unless listed in another schedule, any injectable liquid which contains any quantity of methamphetamine, including its salts, isomers, and salts of isomers.

SCHEDULE III

(a) Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system:

(1) Amphetamine, its salts, optical isomers, and salts of its optical isomers.

(2) Phenmetrazine and its salts. (3) Any substance (except an injectable liquid) which contains any quantity of methamphetamine, including its salts, isomers, and salts of isomers.

(4) Methylphenidate. (b) Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a depressant effect on the central nervous system:

(1) Any substance which contains any quantity of a derivative of barbituric acid, or any salt of a derivative of barbituric acid.

(2) Chorhexadol. (3) Glutehimide. (4) Lysergic acid. (5) Lysergic acid amide. (6) Methyprylon. (7) Phencyclidine. (8) Sulfondiethylmethane. (9) Sulfonethylmethane. (10) Sulfonmethane. (c) Nalorphine.

- (d) Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation containing limited quantities of any of the following narcotic drugs, or any salts thereof:
  - (1) Not more than 1.8 grams of codeine per 100 milliliters or not more than 90 milligrams per dosage unit, with an equal or greater quantity of an isoquinoline alkaloid of opium.
  - (2) Not more than 1.8 grams of codeine per 100 milliliters or not more than 90 milligrams per dosage unit, with one or more active, non-narcotic ingredients in recognized therapeutic amounts.
  - (3) Not more than 300 milligrams of dihydrocodeinone per 100 milliliters or not more than 15 milligrams per dosage unit, with a fourfold or greater quantity of an isoquinoline alkaloid of opium.
  - (4) Not more than 300 milligrams of dihydrocodeinone per 100 milliliters or not more than 15 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.
  - (5) Not more than 1.8 grams of dihydrocodeine per 100 milliliters or not more than 90 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.
  - (6) Not more than 300 milligrams of ethylmorphine per 100 milliliters or not more than 15 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.
  - (7) Not more than 500 milligrams of opium per 100 milliliters or per 100 grams, or not more than 25 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.
  - (8) Not more than 50 milligrams of morphine per 100 milliliters or per 100 grams with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.
- (e) Anabolic steroids.

SCHEDULE IV

(1) Barbital. (2) Chloral betaine. (3) Chloral hydrate. (4) Ethchlorvynol. (5) Ethinamate. (6) Methohexital. (7) Meprobamate. (8) Methylphenobarbital. (9) Paraldehyde. (10) Petrichloral. (11) Phenobarbital.

SCHEDULE V

Any compound, mixture, or preparation containing any of the following limited quantities of narcotic drugs, which shall include one or more nonnarcotic active medicinal ingredients in sufficient proportion to confer upon the compound, mixture, or preparation valuable medicinal qualities other than those possessed by the narcotic drug alone:

- (1) Not more than 200 milligrams of codeine per 100 milliliters or per 100 grams.
- (2) Not more than 100 milligrams of dihydrocodeine per 100 milliliters or per 100 grams.
- (3) Not more than 100 milligrams of ethylmorphine per 100 milliliters or per 100 grams.
- (4) Not more than 2.5 milligrams of diphenoxylate and not less than 25 micrograms of atropine sulfate per dosage unit.
- (5) Not more than 100 milligrams of opium per 100 milliliters or per 100 grams.

[Previous Section] [Next Section]

[Overview]

[Credits and Conditions] [Structure] [Your Comments]

- UNITED STATES CODE
  - TITLE 21 - FOOD AND DRUGS
    - CHAPTER 13 - DRUG ABUSE PREVENTION AND CONTROL
      - SUBCHAPTER I - CONTROL AND ENFORCEMENT
        - Part E - Administrative and Enforcement Provisions

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§ 889. Production control of controlled substances

- (a) Definitions
  As used in this section:
  - (1) The term "controlled substance" has the same meaning given such term in section 802(6) of this title.
  - (2) The term "Secretary" means the Secretary of Agriculture.
  - (3) The term "State" means each of the fifty States, the District of Columbia, the Commonwealth of Puerto Rico, Guam, the Virgin Islands of the United States, American Samoa, the Commonwealth of the Northern Mariana Islands, or the Trust Territory of the Pacific Islands.
- (b) Persons ineligible for Federal agricultural program benefits
  Notwithstanding any other provision of law, following December 23, 1985, any person who is convicted under Federal or State law of planting, cultivation, growing, producing, harvesting, or storing a controlled substance in any crop year shall be ineligible for -
  - (1) as to any commodity produced during that crop year, and the four succeeding crop years, by such person -
    - (A) any price support or payment made available under the Agricultural Act of 1949 (7 U.S.C. 1421 et seq.), the Commodity Credit Corporation Charter Act (15 U.S.C. 714 et seq.), or any other Act;
    - (B) a farm storage facility loan made under section 4(h) of the Commodity Credit Corporation Charter Act (15 U.S.C. 714b(h));
    - (C) crop insurance under the Federal Crop Insurance Act (7 U.S.C. 1501 et seq.);
    - (D) a disaster payment made under the Agricultural Act of 1949 (7 U.S.C. 1421 et seq.); or
    - (E) a loan made, insured or guaranteed under the Consolidated Farm and Rural Development Act (7 U.S.C. 1921 et seq.) or any other provision of law administered by the Farmers Home Administration; or
  - (2) a payment made under section 4 or 5 of the Commodity Credit Corporation Charter Act (15 U.S.C. 714b or 714c) for the storage of an agricultural commodity that is -
    - (A) produced during that crop year, or any of the four succeeding crop years, by such person; and
    - (B) acquired by the Commodity Credit Corporation.
- (c) Regulations
  Not later than 180 days after December 23, 1985, the Secretary shall issue such regulations as the Secretary determines are necessary to carry out this section, including regulations that -
  - (1) define the term "person";
  - (2) govern the determination of persons who shall be ineligible for program benefits under this section; and
  - (3) protect the interests of tenants and sharecroppers.

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DRUG ADDICTION -- WHO BENEFITS

by B. Stuart Hoarn

The reason that it's so difficult to come up with solutions to social problems is because those who are concerned about them too often concentrate all their attention and energies on those who are suffering. Nowhere has this been demonstrated more clearly than with the narcotics - opium, morphine, and heroine - in the "drug scene".

In seeking to eliminate social problems - especially this one - I think we're doomed to spin our wheels un-til we fearlessly take time out to learn all about who is benefiting, and exactly how they're benefiting, from the byproducts of our social ills. Because if too many are profiting - particularly if they are deriving lots of status and political and economic clout in the process - then all the efforts of the do-gooders among us will be as fruitful as straightening deck chairs on the Titanic.

First, they all must be identified and called to task. One is quick to ask: "Who can possibly gain anything from drug addiction besides pushers?" Answer: Lots of us folks. Big Boys At The Top The most obvious beneficiary of heroine addiction is, of course, international organized crime. The mark up on street heroine is as high as 225.000 percent, and des-pite the relatively sizeable overhead and operating expenses entailed in conducting business outside the law (including big payola to corrupt cops and police bureaucrats), the underworld reaps fantastically huge net returns on this, the most lucrative of its conglomerate interests. Law enforcement interception only stops five percent of the product reaching its consumers. That isn't much shrinkage. Lots of big retail stores lose more than 10 per-cent to employee thieves and shoplifters, many whom are addicts.

The actual heroine brokerage and distribution system has about eight levels. Almost without exception, law enforcement attention effects operators only at the bottom two or three levels, small fish, usually addicts themselves, who deal primarily to support their own habits. They take most of the risks and realize only a tiny fraction of the mark up.

The big boys at the top hardly ever have problems with lawmen, unless of course they fail to make promised payoffs. The big boys are international businessmen who have a lifestyle largely indistinguishable from the captains of our large business concerns including the business of governing. They reside in the same posh suburbs, have plush apartments in the same European capitals, circulate in the

same social sets, and send their kids to the same exclusive private schools.

The Instant Escape

Not to be forgotten in any list of beneficiaries are the users themselves. They buy a product they want and they pay a terrible price. But no one can deny that, at first, heroine provides a source of immediate gratifi-cation and welcome "fast, fast, fast relief" from a life without basic necessities in crowded ghettos; or from a comfortable but rootless suburban existence that lacksoine is that when it's of good pure quality (street stuff rarely is), it's less toxic to the body than most other drugs, including the over-the-counter ones. Dr. Vincent P. Dole, a specialist in human metabolism at Rockefeller University, with years of experience examining and testing long-ad-dicted heroine addicts says, "Cigarette smoking is unquestionably more damaging to the human body than heroine."

About the only real problem with heroine itself is that, like the other common sedatives, alcohol and barbiturates, heroine is addictive and too much can be fatal. When closely examined, nearly all other physiological, psychological, and sociological problems commonly attributed to heroine are actually traceable to consequences of the socio-economic conditions created by our narcotics prohibition laws.

John Rublowsky, author of The Stoned Age writes that in 1913, not a notorious year for crime, the country's per capita addiction rate "was considerably higher than today". But no one complained of a drug problem. Those who wanted drugs - almost any drug - simply purchased them at drugstores or by mail order at an affordable price. But then sale or possession of narcotics was made illegal, and the result was the tragic chaos we see today.

Ignorant Social Stigma

According to Rublowsky, perhaps the most deadly consequence came when the underworld moved into the newly created narcotics and gradually, "a daily dose for the typical addict that should cost no more than a few cents a day went up to $50 a day." Addicts of course turned to theft to support their habit.

I've thought that the Harris Narcotics Act of 1914 should have been subtitled,"How to Launch a Disastrous Crime Wave." As Dr. Thomas Szasz, a professor of psychiatry at Syracuse University has put it, "In the history of mankind, many more people have been injured or killed by laws than by drugs, [and] by politicians than by pushers.

We could launch a similar crime-and-chaos wave by out-lawing insulin. In no time, the underworld would take over the insulin concession, raise the prices, and our diabetics would get into shape to run, as some wit described the average 125 lb. junkie capable of doing the 100-yard dash in 4.3 seconds while carrying two TV sets and an airconditioner.

That's not as far fetched a parallel as it first seems.

It's not even particularly novel. After all, diabetics need insulin to keep from being sick, just as junkies must have heroine to stave off withdrawal sickness. Some protest that, "Junkies brought their disease of addiction on themselves." Well, many diabetics are responsible in large part for the development of their condition. Everybody knows that eating too many sweets and drinking too much alcohol can turn a latent diabetic, who would otherwise have no symptoms, into a full blown case. Strange how dia-betics used to carry the same kind of ignorant social stigma now reserved for alcoholics and those suffering from her-oine addiction. When will we ever learn compassion?

God's Own Medicine

In any case, the real question is that, if our narcotics laws have spawned a crime wave and caused so much suffering, why didn't we get rid of them a long time ago? Again, it's time to look for beneficiaries. In the late 1800's, narcotics use began to look like a serious contender against alcohol in the recreational drug scene. Racist attitudes towards a person of Chinese extraction kept all but non-conformists and down-and-outers away from opium dens. But laudanum [morphine-alcohol base] compounds were such as Lydia Pinkham's Potion and Dwyers Cherry Pectoral were common over-the-counter drugs known as "women's friends." Users and addicts, mostly women, could be found in all segments ofoldier's Disease."

During the post-Civil War period when the wonder drug [also called G.O.M. for ["God's Own Medicine"] was steadily winning new converts on its own, pathologists were producing much new evidence of the severe harm, including suspected brain damage [since confirmed], caused by alcohol, our number one drug then and now. Alcohol had its ardent detractors in the abolitionist movement, but more importantly, physicians treating alcoholics began to believe in, and see great benefits that could result if, failing abstinence, alcohol addicts could be switched over to the less toxic "morphia habit". Advantages to converting alco-holics were pointed out as late as 1928 by Dr. Lawrence Kolb, assistant surgeon gener-al of the United States Public Health Service. Needless to say, these developments could not have been well received among the nation's alcohol beverage producers: two threats to their livelihood at once, narcotics and fanatic abolitionists.

Outflanked by WCTU

The alcohol industry had very reason to join forces with the old guard pharmaceutical houses to pit their formidable lobbying against the social-recreational use of morphine and heroine. The es-tablished prescription pharmaceutical firms could not help but be upset because everybody and his brother was free to make and sell the best drug ever, morphine, in everything from mail-order catalogues to general stores. Tighter laws, involving federal licensing of manufacturing and distribution, would

virtually assure the old guard of a monopoly on the franchise for the wonder drug.

The result of all the lobbying by vested interests in the U.S. was the Harrison Narcotics act of 1914, and subsequent restrictive laws controlling the production, sale, distribution, possession, and use of opiatebased drugs. Morphine could no longer pose a threat to the most popular social accepted sedative, alcohol. And "the club", our old guard pharmaceutical firms, got their cherished monopoly.

The alcohol industry must have squandered too much of its war chest fighting off morphine, because the abolitionists, led by the Women's Christian Temperance Movement (WCTU), were able to outflank them and succeeded in bringing about prohibition of alcohol in 1920.

It's worthy of note that there haven't since been any significant populist antinarcotic movements similar to the alcohol abolitionists who temporarily triumphed over "Demon Rum." Narcotics use simply wasn't considered a significant problem until after the vested interests be-gan their "educational" cam-paigns. But for a while at least, the alcohol industry had to operate "outside the law" much the same as organized crime still operates the narcotic industry today.

Even during prohibition, alcohol had one good thing going for it: never was it illegal to use alcohol. Only manufacture-for-sale, sale, and public consumption were prohibited. People were free to use all they wanted, which helped to insure the eventual repeal of prohibition. Prohibition was a short-lived crime wave in so far as alcohol was concerned. When it was lifted, the Internal Revenue Service also became a big beneficiary. According to National Institute on Alcohol Abuse and Alcoholism (NIAAA) director Dr. Morris Chavetz, IRS collects more money in alcohol taxes these days than the federal government spends on public education. That's easy to believe when we real-ize that American consumers spend more than $3.1 million per hour on alcohol, 24 hours a day, for a total of $27.2 billion per year. [Canadians spend about $240,000 per hour, 24 hours a day, for a total of $2.1 billion per year (Statistics Canada, 1972)]

Battle Rages On

It appears that I've suggested laws can be bought and sold like any other commodity. Nothing could be closer to the truth. Most pieceshat the alcohol industry is busy waging massive anti-marijuana offensive. And the tobacco industry is just as busy lobbying for the right to manufacture and market marijuana cigarettes.

For now, it can safely be reported that the alcohol industry is ahead thanks to a fantastically successful move on the consumer front, of all places. The introduction of, and slick marketing campaign for, the new tutti-frutti flavored "pop" wines has made them the favorite of teenage

and pre-teen drinkers. Morris Chavetz says that, "The whole pop wine market [apple,strawberry and grape] is not the alcohol beverage choice of adults, but appeals to the teenage market. And [liquor stores] cannot keep enough in stock." He also re-cently announced that,"Every indicator and every statistic we have tells us that the switch is on - from a wide range of other drugs to the most devastating of all: alcohol." The supersweet pop wines are without a doubt a stroke of genius on the part of the alcohol industry, a move that may have set the tobacco industry's marijuana cause back for years. In fact the wines have been so successful with youngsters that now a new grape-flavored malt liquor is reported being test-marketed. The battle for the public's tastes and the minds of their elected representatives rages on.

Lobbying=Law-buying

This battle is one that costs big money. Therefore, it's not at all outlandish to view laws as free trade commodities and lawmakers as a saleable service available to the highest bidder, usually one vested or another. The narcotics prohibition laws were a product of intensive lobbying, and are kept with us by continuous lobbying. And lobbying is just another term for lawbuying. The two terms even sound the same.

Our next group of beneficiaries is the law enforcement industry. Not the rank and file who are out on the streets risking their necks to protect lives and property, but the bureaucrats who direct operations and act as public spokesmen - lobbyists - for the industry. Their business is like any other. Executive lawmen have a product which they must market. The product is a service of fighting crime.

Lawmen are like other humans. The ambitious get ahead. They want bigger homes, better cars, nicer furniture, college for their kids, and fatter incomes, just like anyone else who seeks top get ahead in our free enterprise system. In order for lawmen to have the same opportunities for advancement and affluence that are rewards for diligence in other enterprises, there must be similar growth and expansion at all times. The industry's services must become increasingly important and indispensable to consumers. In this case, the entire public.

As did alcohol prohibition, on a limited temporary basis, narcotics prohibition has provided a perfect vehicle for insuring the steady increase in demand for law enforcement services - demand that is necessary for any service industry to thrive. The Federal Bureau of Narcotics and Dangerous Drugs (BNDD) - Now joined by the Drug Enforcement Administration (DEA) - has grown to be one of the most important federal agencies.

Glamour-growth Industry

Similarly, the private protection industry has also

become a glamour-growth enterprise. Most property crimes are committed by addicts and users. Without them, security guard services, and electronic alarm and surveillance manufacturers, along with a veritable army of distributors and maintenance personnel, would be out of business.

The folks who populate the executive suites of the law enforcement industry, in both the public and the private sectors of the economy, advise a need for and promote their services relentlessly to keep up demand. Studies turned out by "scholarlyd into testimony given to Congressional committees conducting hearings on drug control legislation. Worse yet, the news releases and testimony are touted by the media with such repetitiveness that the public actually believes that heroin is the most dreadful substance on earth, endowed with fantastic destructive powers, including the ability to rot teeth.

Super-cops and Superflies

The description doesn't stop with news items, either. In fictional books, magazine stories, movies, and TV the never-ending battle between the glamorous "super-cops" and the sinister "superflies" makes for an inexhaustible supply of good-versus-evil plots with plenty of the key ingredient violence. Law enforcement agencies eagerly assist with the production ["Greatful acknowledgement is made to the men of the . . "] of this garbage because it provides them with hours and hours of free, prime-time ex-posure for their product.

Harry Anslinger, former BNDD commissioner, tended to alarm the public with crime statistics and fearful pronouncements about the alleged effects of the drug that he was set up in business to con-trol. Incidently, it's worthy of note that, all the while, Anslinger was arranging to supply morphine to a prominent congressman who had been addicted for years. Anslinger and his soulmates have built quite an empire for themselves. People who accuse bureaucrats of lacking business acumen should take a second look at "public servants" like Harry Anslinger. Because, in the same way fuel economy statistics sell compact cars, crime statistics, fueled mainly by the Harrison Narcotics Act, are selling a war which is, to a great extent, a war on those suffering from addiction.

Return to Legal Narcotics

The statistically-increasing size of the enemy in the war on crime is used to justify expansions of public departments, new facilities, and new equipment. Of course this means bigger salaries for administrators commensurate with managing larger departments. The private protection industry uses the same crime statistics in their advertising to sell more sophisticated surveillance and alarm devices and to expand the security guard business. All of this

healthful growth makes for the bigger and better houses, the fatter incomes, and so forth. All things the executives in organized crime and the top men in the alcohol industry and the pharmaceutical firms already have.

Next on our list of beneficiaries are the rehabilitation folks in the helping professions. These are the people who are admittedly the least happy with the conditions benefitting them. Even so, the drug crisis has been nothing short of a bonanza for expanding the social service industry. Huge bureaucracies charged with treating addicts have mushroomed at local, state, and federal levels. Not many addicts have quit using drugs, but never before has social work been such an important and attractive field for employment. There are plenty of lucrative administrative jobs, conventions to go to, cocktail parties, fund-raising benefits - everything necessary for the upward mobility, income growth, and social status that are features of any growth enterprise.

A common means of treatment is to addict addicts to methadone, a synthetic version of heroin, much more potent [it is administered orally, not intravenously, and a single dose can last up to several days] and much more legal. The distinguishing feature of these programs is inescapable: a return to legal narcotics.

An alarming number of addicts in methadone programs are also becoming alcoholics. And some rehabilitation indus-try publications are worrying in editorials that drug educa-tion and treatment workers are getting into alcohol in a big way, too. That's even worse news than we had last year when Frances Verrinder, former editor off marijuana. And it's being smoked by drug education and rehab workers because they're convinced that smoking it is infinitely safer than drinking alcohol. so much for rehabilitation industry and its foibles.

Medical Terrorism

Not to be forgotten on anybody's list of beneficiaries is the corrections industry. Property crimes and other illegal activities connected with heroin have filled our prisons to overflowing - an influx providing for immense growth and opportunity in the corrections field. Thousands of young people who might have otherwise sought careers involved with producing consumers goods are employed by prisons and probation departments. To make things worse, their charges are also diverted from the process of making and distri-buting goods and services. [It also costs a fortune to keep them on ice. Bureau of Prisons statistics indicate that maintaining a prisoner costs up to $16,000 per year in 1974]

A good case could be made for asserting that a big factor in our spiraling inflation is that we are paying too many ablebodied people to fill roles that don't produce the consumer goods and services we all want to have. And "soaring prices" and "inflation" are just terms that means

too many dollars are chasing after too few consumables. Inflationary jobs, of course, include defense related employment. But thousands upon thousands more depend upon our narcotics laws, and repel would mean that those human resources could be available for employment in productive sectors of the economy.

If they're not making consumables, what are the prisoners doing? corrections bureaucrats call it behavior modification, but the cons call it medical terrorism. What's happening to them is operant conditioning and aversion therapy on a mass scale.

Orwellian Social Planning

According to behaviorist psychologist James V. McConnell of the University of Michigan, the power to restructure the entire personality of prisoners is within society's grasp at last and the appropriate therapies are either already underway or in the planning stages at the prisons across the country. He says, "I believe that the day has come that we can combine sensory deprivation with drugs, hypnosis, and astute manipulation of reward and punishment to gain absolute control over an individual's behavior." He goes on to say, "We should reshape our society so that we all would be trained from birth to want to do what society wants us to do. We have the technologies now to do it. . . . No one owns his own personality. . . . You had no say about what kind of personality you ac-quired, and there's no reason to believe you should have the right to refuse to acquire a new personality if your old one is anti-social."

Wayne Sage, a contributing editor to Human Behavior magazine, reports the corrections industry has lots more in store. "In the backwoods of North Carolina, near the tiny village of Butner, the Federal Bureau of Prisons is constructing a mammoth 42-acre complex. . . . Butner will be the first in a series of three such facilities and, under the enormous construction program to follow, 66 new prisons are to be built, including 12 special youth facilities that will employ operant conditioning to remold juveniles. . . Target date for completion of the entire system is, ironically, 1984.

It's easy to see that the Orwellian social planners in the corrections industry and their behavior psychologist mentors in academe are having a field day with war-on-crime funds. They too benefit immensely from our present narcotics laws. It just may be that the narcotics laws, coupled with behavior modification in prisons, is the last, but most lethal weapon of sacred institution of cul-tural racism. Many ghetto drug treatment workers seem to think so. Johne thing is certain: As long as narcotics prohibition remains with us, the kind of social control that keeps most social drinkers from becoming alcoholics will never get a chance to operate in the heroin-using population. And as we're just starting to really learn with

alcohol, encouraging social control and teaching responsible use is the key to curbing abuse and preventing addiction.

Despite Everything - Inertia Proponents of cultural racism are the last to be added to the list of all-too-willing beneficiaries. That's quite a list, quite a lot of folks. In fact, so many of us are so busy making lots of headway with our own private interests as we build our new industries and expand old ones, that only a very few of us have had time to seek real solutions. These solutions lie in understanding that restrictive laws are severely limited in their ability to cope effectively with some problems, and that proper education and social control should be implemented to do jobs that restrictive laws can't.

In spite of continuing wars on crime, pious pronouncements, heavier penalties (more of the same bad medicine), Dramatic "scare tactic" education, and token efforts to assist suffers, inertia goes on blocking the only solutions which might actually eliminate the problems associated with heroin addiction - problems that quietly, but surely, produce by-products for vested interests who seem content with the status quo.

Some rays of hope are on the horizon, however. Countervailing forces in the economy are beginning to appear. Nonbeneficiary sectors in the business and industry are just beginning to count the cost of the status quo. The productivity losses stemming from alcoholism on-the-job have recently been estimated at some $25 billion annually (Canadian estimate is $250 million annually). Government Accounting Office data indicate that between four and eight percent of the total work force suffers from alcoholism: and, on the average, affected workers are losing 25 percent of their productivity each year. Every shiny new auto off Detroit's assembly lines has been put together, in part, by some heroin addicts and an awful lot more alcoholics.

Call for Change

For these reasons, there is an ever-increasing awareness that the joy in the council's of organized crime and the boardrooms of the alcohol industry is directly linked to the wailing and gnashing of teeth in the boardrooms of our manufacturers who are in a state of hopeless dismay over the productivity crisis. That same quandary is alarming agencies of government where there is a high degree of concern for the human resources of our nation.

More and more leaders in business, government and the professions are speaking out for paying the price for maintaining the unhealthy monolith founded by the Harrison Narcotics Act and other legislation that protects and benefits the vested interests of organized crime, war-on-crime chieftains, the alcohol beverage producers, and the pharmaceutical cartel. Morris Chavetz, NIAAA director, recently warned the Distilled Spirits Council of the United

States [DISCUS] that only responsible actions by the industry can delay such action as warning labels for alcohol beverage containers, severely restricting or limiting advertising, and ear-marking tax revenues for alcoholism treatment programs. He has challenged the liquor industry to work with NIAAA as "full and willing partners, rather than as reluctant allies or partial antagonists."

As enlightenment spreads, the call for change will grow stronger. The time is near, for already America's productivity woes and inflation are putting us at a severe disadvantage in the world economy. The day may be coming soon when we will see the National Association of Manufacturers (NAM), the "Big Three" automakers, the Congres for new restrictions on the promotion and advertising of alcohol.