dissent, on October 10, 1962, the Kefauver-Harris Drug Amendments to the Food, Drug, and Cosmetic Act of 1938 were passed by both houses of Congress. The purpose of the enactment was to ensure a greater degree of safety for approved drugs, and manufacturers were now required to prove a drug both safe and effective before it would be granted FDA approval for marketing.

Under the Food, Drug, and Cosmetic Act as amended, the sponsor of a new drug is required to file an investigational new drug application (IND) with the FDA before the drug may be clinically tested on human subjects. Only after carefully designed and structured human clinical trials, in which the drug is evaluated for safety and effectiveness, may the drug's sponsor file an NDA seeking approval for marketing. The FDA was given authority to issue good manufacturing practice (GMP) guidelines governing how drugs were to be manufactured, access to facilities for inspection, and jurisdiction over prescription drug advertising. The requirements for these and other submissions to the FDA are presented in Chapter 2.

Interestingly, WHO now considers thalidomide to be the standard treatment for the fever and painful skin lesions associated with erythema nodosum leprosum (ENL) in patients with leprosy and the FDA has approved its use for this purpose. Further, research into potential uses for thalidomide has determined that it is effective in the treatment of multiple myeloma, a blood and bone marrow cancer, and shows promise in certain inflammatory diseases, and in Kaposi sarcoma, a cancer of the blood vessel walls mostly found in people with HIV (10).

Comprehensive Drug Abuse Prevention and Control Act of 1970

The Comprehensive Drug Abuse Prevention and Control Act of 1970 (now referred to as the Controlled Substances Act [CSA]) served to consolidate and codify control authority over drugs of abuse into a single statute. Under its provisions, the Drug Abuse Control Amendments of 1965, the Harrison Narcotic Act of 1914, and other related laws governing stimulants, depressants, narcotics, and hallucinogens were repealed and replaced by regulatory framework now administered by the Drug Enforcement Administration (DEA) in the Department of Justice.

The Comprehensive Drug Abuse Prevention and Control Act of 1970 established five "schedules" for the classification and control of drug substances that are subject to abuse. These schedules provide for decreasing levels of control, from schedule I to schedule V. The drugs in the five schedules may be described as follows:

- Schedule I: Drugs with no accepted medical use, or other substances with a high potential for abuse. In this category are agents including heroin, lysergic acid diethylamide (LSD), mescaline, peyote, methaqualone, marijuana, and similar items. Any nonmedical substance that is being abused can be placed in this category.
- Schedule II: Drugs with accepted medical uses and a high potential for abuse that if abused may lead to severe psychologic or physical dependence. In this category are morphine, cocaine, methamphetamine, amobarbital, and other such drugs.
- Schedule III: Drugs with accepted medical uses and a potential for abuse less than those listed in schedules I and II that if abused may lead to moderate psychologic or physical dependence. In this category are specified quantities of codeine, hydrocodone, and similar agents.
- Schedule IV: Drugs with accepted medical uses and low potential for abuse relative to those in Schedule III that if abused may lead to limited physical dependence or psychologic dependence relative to drugs in schedule III. In this category are specified quantities of difenoxin, diazepam, oxazepam, and similar agents.
- Schedule V: Drugs with accepted medical uses and low potential for abuse relative to those in schedule IV that if abused may lead to limited physical dependence or psychologic dependence relative to drugs in schedule IV. Included in this category are specified quantities of dihydrocodeine, diphenoxylate, and similar agents.