# *Tech Lectures*®

## For the Pharmacy Technician

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# Lecture 16 - About Pharmacy Regulations

**LAW CE**

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**Federal Pharmacy Law & Technician Liability**

**Introduction**

**Goals & Objectives**

The Pharmacy Technician will have a basic understanding of the following:

1. Role of Pharmacist/Technician History
2. Governing Agencies
3. Select Federal Laws
4. Technician Liability
5. Terms used in this CE offering

Today, in most pharmacy settings, the role of the Pharmacy Technician is changing, as technicians become more actively involved in the distribution of drugs. Currently, over 50% of retail prescriptions and over 95% hospital medication orders are being filled by Pharmacy Technicians in the pharmacy setting. This includes the receiving and complete processing of a medication order, whether the order written for an outpatient prescription or an inpatient hospital order for an intravenous solution with additives. Although a registered Pharmacist must check all orders before they leave the pharmacy, the Pharmacy Technician must realize the potential for legal liability for their own actions also exists.

This CE offering will discuss a few federal laws*, which govern the distribution of drugs. Many of these laws and regulations are interrelated with several governmental agencies involved in their administration and enforcement. With the Pharmacy Technician being more responsible and more importantly accountable, a basic understanding of these laws is vital.

*Note: Only specific sections of these federal laws will be covered.

**History**

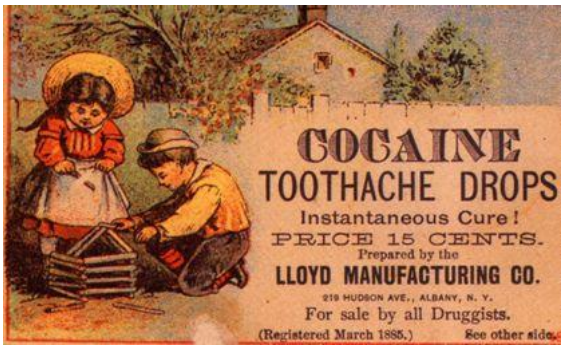
Opium in some form or a salt of morphine was the constituent of many cough/cold mixtures in the late 1800's and early 1900's. In some cases you would find more than one narcotic in the same recipe:

Sample Cough Syrup

*Rx Syrup of tar …….... fl. oz. 64*
*Syrup of wild cherry …….. .fl. oz. 45*
*Tincture Opium Camphorate … ..fl. oz. 8*
*Fluid extract of lobella ……... fl. dr. 6*
*Heroin……..…….….. gr 1/2*
*Fluid extract of Ipecac …….. . fl. dr. 4*

During the late 1800's and early 1900's, Pharmacists learned their trade "on-the-job" by practicing with a licensed Pharmacist and then taking an examination that incorporated what they had learned. The role of the Pharmacist was much different then, in the respect that the Pharmacist was more involved in being the source of drug products. The Pharmacist would compound drug products from chemicals and natural plant products according to prescriptions written by physicians or from family recipes handed down from generation to generation. The quality of the drug product was the responsibility of the Pharmacist. In

many cases, weighted drug products were actually dispensed as powders in carefully folded papers rather than tablet or capsule formulations. Liquid preparations often contained Narcotics to alleviate numerous symptoms.




Following World War II, the development and manufacturing of drug products slowly changed the role of the Pharmacist. Although they continued to be a source of drugs, the Pharmacist was compounding fewer drug products, as many already prepared for marketing by the manufacturer became available.

The role of the Pharmacist changed further as the process of research; development and manufacturing of new drugs appeared in the late 70's. The Pharmacist became more a source of drug information that required knowledge of the use(s) and Pharmacology of drugs (mechanisms of drug action).

The 1990's saw an even greater expansion of the pharmacist's role in the health care system. The Omnibus Budget Reconciliation Act of 1990 mandated that pharmacists perform perspective drug utilization reviews and counsel Medicaid patients when dispensing a prescription.

Today with the infiltration of new drugs, new drug regimens and new drug delivery systems, the Pharmacist is required to have knowledge of drug interactions and recognition of clinical aspects of drug therapy in patient care for specific disease states. The pharmacist of today not only dispenses drug products, but drug information in the form of counseling, as well.

With the changing roles of the Pharmacist, the roles of the Pharmacy Technician have also changed. Due to the shortage of manpower during World War II, the Pharmacy Technician played a key role in assisting the Pharmacist. But the roles were limited and strict guidelines allowed Technicians to perform only clerical duties. No longer is the Technician someone who just types labels and runs the cash register, "selling" the medication. Today Technicians have actively taken the role in the preparation and distribution of drug products and have even entered the clinical arena in assisting Pharmacists with data collection and quality control.

Today Federal and State laws help govern the manufacturing and distribution of drugs. Each law gives strict guidelines that must be followed to ensure patient safety. Adhering to federal and state regulations is crucial to preventing liability for the Pharmacist and the Pharmacy Technician; even innocent errors can lead to significant penalties.

**Governing Agencies**

In the United States, the following federal government agencies have a significant impact on health systems and drugs:

The Department of Justice (Drug Enforcement Administration),
Department of Health and Human Services
Food and Drug Administration
Health Care Financing Administration
Consumer Products Safety Commission.

At the state level, the government agencies that impact health care systems and drugs vary from state to state. The following is a list of state agencies that may be responsible for administering and enforcing laws impacting on health systems and drugs:

State Boards of Pharmacy
Licensing Boards
Departments of Agriculture
Departments of Health
Commerce Departments
Departments of Public Safety.

The more stringent law or regulation must be followed whether the federal law or regulation becomes more stringent than the comparable state law or regulation, or vice versa. In many cases the state law or regulation is more stringent than its federal counterpart.

**A Review of Pharmacy Laws**

**Federal Food Drug & Cosmetic Act**

The first significant piece of federal regulation dealing with drugs was signed by President Theodore Roosevelt and passed in 1906. It was known as the "Pure Food and Drug Act" and was prompted by the unsanitary practices in the food and drug industries during that period.

**Some major aspects of the new 1938 Act**

- Manufacturers had to submit evidence that the new drugs were safe prior to marketing
- All drugs had to have "adequate directions for use" and "adequate warnings" on their labels
- New drugs had to be tested clinically before marketing

The most significant provision of the Pure Food and Drug Act was that it defined and prohibited "adulteration" and "misbranded" foods, drinks and drugs which were involved in interstate commerce. [i]
In 1938, Congress passed the Federal Food Drug and Cosmetic Act (FD&C Act), which repealed the 1906 Act and added significant new requirements for manufacturers, distributors and health professionals indicating that a product is safe before it can be marketed.

The prompting of this new Act was mainly because of the "*Sulfanilamide Disaster*". In 1937, a drug company produced an antibiotic elixir containing a new wonder drug called sulfanilamide that was found to be effective treatment for diseases like strep throat and gonorrhea. That elixir was associated with 107 deaths in the United States, mostly in children. The cause of the deaths was an industrial solvent, "diethylene glycol", found in today's antifreeze, that was used to dissolve the antibiotic. It took 107 deaths to produce more meaningful supervision of prescription drugs.[ii]


In addition to the Sulfanilamide Disaster, there were numerous deaths and serious injuries caused by cosmetics that also gained the attention of Congress. Among them was a specific lash and brow dye that caused blindness. Because of this, the Federal Food Drug and Cosmetic act dealt for the first-time with regulation of drugs used as diagnostic agents, along with therapeutic devices and cosmetics.[iii]

Since its inception, the FD&C Act has had numerous amendments. Among them are the Insulin Amendment of 1941, the Penicillin Amendment of 1945 both of which required certification of safety and efficacy. Other Amendments included the Durham Humphrey Amendment of 1951, Kefauver-Harris Amendments of 1962, the Drug Abuse Control Amendments of 1965, and the Medical Device Amendments of 1976.

**The Kefauver-Harris Amendments of 1962**

As the Sulfanilamide Disaster of 1938 prompted the FD&C Act itself, another disaster later occurred prompting the attachment of this amendment to the FD&C Act. The drug Thalidomide was marketed in Europe as a tranquilizer and anti-nausea agent to thousands of pregnant women. In 1961 the drug was recognized as causing severe birth defects in children of mothers who had taken the drug. More than 10,000 babies were born with deformities, such as missing arms or legs, or limbs so stumped they were virtually useless. Although the drug Thalidomide was never approved by the FDA and

was still in the clinical testing phase, it was withdrawn from the market with much public fanfare. The amendment to the FD&C Act now required manufacturers to prove the efficacy or effectiveness and safety of new drugs before marketing them.

> "On July 16, 1998, FDA approved the use of thalidomide for the treatment of the debilitating and disfiguring lesions associated with erythema nodosum leprosum (ENL), a complication of Hansen's Disease, commonly known as leprosy. Because of thalidomide's potential for causing birth defects, FDA invoked unprecedented regulatory authority to tightly control the marketing of thalidomide in the United States. A System for Thalidomide Education and Prescribing Safety (S.T.E.P.S) oversight program has been initiated that includes limiting authorized prescribers and pharmacies, extensive patient education about the risks associated with thalidomide and a 100% patient registry. This oversight program is designed to help insure a zero tolerance policy for thalidomide exposure during pregnancy."[iv]

**The Durham Humphrey Amendment of 1951**

The attachment of this Amendment to the FD&C Act required that drugs that cannot be used safely without medical supervision must be labeled as such and dispensed only via a written/oral prescription from a licensed practitioner.

Drugs included would be known as "Legend Drugs" and must bear the Rx Legend on their label along with the statement*: "Caution Federal law prohibits dispensing without prescription*." The FDA Modernization Act of 1997 later replaced this and the statement was changed to "*Rx only*".

**The Harrison Narcotic Act**

In 1914, in an attempt to legally control the distribution of narcotics and restrict opium usage, the Harrison Narcotic Act was passed. The use of opiates/cocaine became a crime unless prescribed by a physician. The law specifically provided that manufacturers, importers, pharmacists, and physicians prescribing narcotics should be licensed to do so at a moderate fee. It also limited the amount of opiates that could be used in recipes or prescriptions. In a way this was a prohibition of opiates and much opposition took place, as supply would not meet demand.

Other attempts were made to place controls on abusive substances, including the 1965, **Drug Abuse Control Amendments** to the Federal Food, Drug and Cosmetic (FD&C) Act for stimulants, sedatives, and hypnotics. In 1970**, The Federal Controlled Substances Act** (CSA) was passed and repealed both the Harrison Narcotic Act and the Drug Abuse Control Amendments.

## The Poison Prevention Packaging Act

The United States Poison Prevention Packaging Act (PPPA) was passed in 1970 and is currently administered by the U.S. Consumer Product Safety Commission. The Act was decreed to prevent young children from accidentally ingesting hazardous substances ordinarily stored about the house. The law requires toxic, corrosive, or irritant substances to be packaged in such a way that it will be difficult for children less than 5 years to open them, yet not difficult for adults to open.[v]

The Act also requires special packaging for both prescription and non-prescription drugs. Prescription drugs intended for topical or other non-oral administration do not require child-resistant packaging.

> Since the safety closures (or caps) of child-resistant containers can wear down, regulations under the PPPA Act prohibit the re-use of child-resistant containers.

The Act exempts prescription drugs from child resistant packaging if either the prescriber or patient requests it or if the medication is on the list of drugs which are exempt; including Nitroglycerin and sublingual / chewable preparations of Isosorbide Dinitrate, both of which are used for angina.

## Federal Anti-Tampering Act

Enacted in 1982 mainly due to the tampering and contamination of Tylenol® capsules in the Chicago area that led to seven deaths, the Federal Anti-Tampering Act made it a federal offense to tamper with consumer products.[vi]

The Act gave enforcement authority to the FBI, the Department of Agriculture and the FDA. Tamper means "improper interference for the purpose of alteration and to make objectionable and/or unauthorized changes in the product."

Tamper-resistant packaging is required for certain over-the-counter (OTC) products, cosmetics and medical devices. The FDA requires that the labeling of tamper-resistant packaging bear a statement alerting consumers to the tamper resistant feature.

## OBRA 1990 Act

The Omnibus Budget Reconciliation Act (OBRA) of 1990 was adopted as a condition for Pharmacies to participate in the federally funded, but state administered Medicaid program. To receive Medicaid funding, Pharmacies were required to follow a new set of specific guidelines that included the counseling of Medicaid patients on the use of new prescription drug orders. This law in effect expanded the standards of Pharmacy practice by forcing Pharmacists to do patient counseling.

In effect, the pharmacist must make a reasonable effort to obtain, record, and maintain a patient medication record (PMR) on each patient. The pharmacist must examine the patient's medication record and conduct a perspective drug use review when filling or refilling a prescription. Following the drug use review, the pharmacist must counsel the patient or the patient's agent about the drug dispensed. Information should include, but not be limited to the following:[vii]

- the name and description of the medication
- dosage form, route of administration and duration of drug therapy
- special directions and precautions for preparation, administration and use by the patient
- common severe side or adverse effects or interactions and therapeutic contraindications that may be encountered
- techniques for self-monitoring drug therapy
- proper storage
- prescription refill information
- action to be taken in case of a missed dose

Another requirement of OBRA was the establishment of a Drug Utilization Review Board (DUR) to evaluate the clinical appropriateness of drug use, evaluation and intervention.

## The Federal Controlled Substances Act (CSA)

The Controlled Substances Act (CSA), Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970, is the legal foundation of the government's fight against the abuse of drugs and other substances. This law is a consolidation of numerous laws regulating the manufacture and distribution of narcotics, stimulants, depressants, hallucinogens, anabolic steroids, and chemicals used in the illicit production of controlled substances.

DEA Form 222 is used to order Schedule I and II Controlled Substances. The order forms come in triplicate form with the first copy going to the supplier, the second copy goes to the DEA and the third copy is retained by the pharmacy. An authorized individual can only sign this order form.

Among the requirements of CSA is the registration of all parties involved, specific labeling and packaging of products, records of controlled substances, inventory control, prescription requirements, quotas and security and classification of controlled drugs.

**CSA - Classification**

The CSA places all substances that are regulated under existing federal law into one of five schedules. This placement is based upon the substance's medicinal value, harmfulness, and potential for abuse or addiction. Schedule I is reserved for the most dangerous drugs that have no recognized medical use, while Schedule V is the classification used for the least dangerous of addictive drugs. The act also provides a mechanism for substances to be controlled, added to a schedule, decontrolled, removed from control, rescheduled, or transferred from one schedule to another.

**CSA – Classification of Drugs**

| | |
|---|---|
| Schedule I<br><br>**(CI)** | The drug or other substance has a high potential for abuse.<br><br>The drug or other substance has no currently accepted medical use in treatment in the United States. |
| Schedule II<br><br>**(CII)** | The drug or other substance has a high potential for abuse.<br><br>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.<br><br>Abuse of the drug or other substances may lead to severe psychological or physical dependence |
| Schedule III<br><br>**(CIII)** | The drug or other substance has a potential for abuse less than the drugs or other substances in schedules I and II. |
| Schedule IV<br><br>**(CIV)** | The drug or other substance has a low potential for abuse relative to the drugs or other substances in schedule III. |
| Schedule V<br><br>**(CV)** | The drug or other substance has a low potential for abuse relative to the drugs or other substances in schedule IV. |

Correct DEA Number?

The DEA number can be easily verified by using the following calculation method:

- Add the first, third and fifth numbers to get your first sum
- Add the second, fourth and sixth number then multiply by two to get your second sum
- Add your first sum with your second sum. The last digit of this sum will be the same as the last digit of the DEA Number.

Example: AH1234563

1) 1 + 3 + 5 = 9
2) 2 + 4 + 6 = 12 x 2 = 24
3) 9 + 24 = 33 ----------→ AH1234563

**Technician Liability**

With the roles of the Pharmacy Technician changing and increased responsibility required of Technicians, the question arises as to whether the Pharmacy Technician should be held accountable or legally liable for their work.

Both the American Society of Health System Pharmacists (ASHP) and the American Pharmaceutical Association (APhA) feel that the Pharmacist should be the one held accountable or legally liable for anything that leaves the Pharmacy setting.[ix] This stance is mainly due to the fact that there is yet a national standardization of training and education required of technicians and because technicians do not need to demonstrate competency in most states. Currently only a handful of states register technicians, a smaller number licenses them and even less, require national certification of its technicians.

This is not to say that legal liability does not occur in the case of a Pharmacy Technician. Civil Liability in which an individual causes injury or damage to another through negligence or intentional action can lead to criminal charges and result in punitive damages regardless if the individual is a Pharmacist or Pharmacy Technician.

Pharmacy Liability[viii]

A Pharmacist in South Dakota filled a prescription correctly but failed to dispense the drug in a child-resistant container. An eleven-month-old child opened the vial, ingested the medication and died. The jury awarded the girl's parents $205,000.

A community pharmacy in Indiana, dispensed Inderal in place of Lasix, a mix-up that proved fatal to the patient. A settlement was reached requiring the pharmacy to pay $50,000 in damages to the patient's estate.

A Pharmacist who provided a West Virginia patient with unauthorized refills of a prescription for oral contraceptives for 2 ½ years was sued when the 51-year old woman suffered a stroke. The patient was awarded $110,000 settlement.

Pharmacy Liability[x]

New York City police arrested a Pharmacy Technician for allegedly stealing $170,000 worth of AIDS drugs from a nationally well-recognized retail Pharmacy, where he had been employed for the previous six months. The tech, reportedly contended that he gave the drugs away to AIDS patients who could not afford the costly medications. However, the police reported that the Pharmacy Technician was driving a $50,000 car, had $8,000 in an attach'e case when he was picked up, and couldn't provide the names of any patients to whom he said he gave the drugs. The police were called in after a company inventory revealed the AIDS drug shortage.

A Pharmacy Technician can also be Criminally Liability in the stealing or diversion of drugs since this is a criminal act. In this scenario, the Pharmacist could also be charged with negligence in allowing the Pharmacy Technician to obtain drugs illegally.

With some states mandating registration, licensing or certification, the Pharmacy Technician can face licensure/certification liability if they act outside the scope of licensure or certification authority. In this scenario, the Pharmacy Technician can be reprimanded (which would include loss of licensure or certification), for acting without the supervision of a pharmacist, acting as a pharmacist by making judgmental decisions or counseling patients which is a violation of Federal law that could also lead to serious legal implications.

Also, lawsuits generally do not cover just one individual. Generally anyone associated with the filling of a prescription or medication order can be held accountable. This would include the Pharmacist, Pharmacy and in some cases, the organization or parent company. Pharmacy Technicians are often drawn into civil cases as a way of gathering information on the real targets of the lawsuit.

The National Association of Boards of Pharmacy (NABP) established a task force to look into the standardization of the Pharmacy Technician role nationally. This would include not only didactic or academic competencies but practical competencies as well.

Task Force to Investigate the Expanded Use of Technicians, May 1999

Are Pharmacy Technicians accountable or legally liable for their work? Yes, especially with states beginning to mandate registration, licensing and national certification. As the responsibilities of the Pharmacy Technician increases, so does the potential for legal liability.

Today over 400,000 Pharmacy Technicians have passed the national Pharmacy Technician Certification Exam given by the Pharmacy Technician Certification Board (PTCB). This exam is voluntary and does a great service in offering an exam to ensure Pharmacy Technician didactic or academic skills

**Conclusion**

Both civil and criminal liabilities are becoming aspects of the Pharmacy Technician profession today as Technicians continue to gain more responsibility and accountability in the work they do. A general understanding of both state and federal laws by the Pharmacy Technician is necessary to ensure not only patient safety, but to better understand the potential for civil or criminal liability.

Even though, the role of the Pharmacy Technician is still being "defined", it is still important for the Pharmacy Technician to realize their limitations. Any procedure involving professional discretion or judgment concerning compounding, dispensing, and drug usage remains the responsibility of the pharmacist.

**About the Author**

Joe Medina, CPhT, BS Pharmacy, former Program Director of a Pharmacy Technician Program at two community colleges in Colorado is a lifetime national advocate for the Pharmacy Technician Profession. Mr. Medina has helped produce several textbooks and co-authored *the "Pharmacy Technician Workbook & Certification Review*" through Morton Publishing. With fifteen years as a Pharmacy Technician and fifteen years as a Pharmacist, Mr. Medina understands the needs of the Pharmacy Technician and the important role they play in interacting with Pharmacists, Medical paraprofessionals and the community in the Pharmacy setting.

## Important Pharmacy Laws

| Date | Law | Description of Main Objectives |
|---|---|---|
| | | |
| 1906 | Food and Drug Act of 1906 | Prohibited Interstate Commerce in adulterated food, drinks and drugs |
| 1911 | Sherley Amendment | Prohibited false claims about a drugs therapeutic effects |
| 1914 | Harrison Narcotic Act | Controlled the distribution and usage of Narcotics |
| 1938 | Food Drug and Cosmetic Act (FDC) | Required new drugs to prove safety before marketing |
| 1950 | Alberty Food Products vs. US | The purpose a drug is being used must be indicated on its labeling |
| 1951 | Durham-Humphrey Amendment | *"Caution: Federal Law prohibits dispensing without a prescription"* to be on all prescription bottles |
| 1960 | Federal Hazardous Substances Act | Required that all Hazardous materials be handled cautiously and disposed of in a well-recognized container marked "*Hazardous Material"* |
| 1962 | Kefauver-Harris Amendments | Manufacturers must prove effectiveness and safety of drug before marketing |
| 1966 | Fair Packaging and Labeling Act | Requires all consumer products in interstate to be properly labeled |
| 1970 | Poison Prevention Packaging Act | Required the use of child proof packaging on prescription drugs |
| 1970 | Controlled Substances Act | Regulates the manufacture, distribution, and sale of certain drugs that have a potential for abuse. |
| 1976 | Medical Device Act | Amendment to the FD&C Act to provide reasonable assurance of the safety and efficacy of medical devices |
| 1982 | Federal Anti-Tampering Act | Makes it a federal offense to tamper with consumer products and gives enforcement authority to the FBI, the Department of Agriculture and the FDA |
| 1983 | Orphan Drug Act | Provides incentives to promote research, approval and marketing of drugs for rare diseases |
| 1984 | Drug Price Competition and Patent Term Restoration Act | Extended the "Abbreviated New Drug Application" (ANDA) process and extended the patent life for all drugs |
| 1987 | Prescription Drug Marketing Act | Amendment to the FD&C Act to reduce the potential health risks that may result from the diversion of prescription drugs from legitimate commercial channels |
| 1990 | Omnibus Budget Reconciliation Act (OBRA) | Required Pharmacist counsel Medicaid patients on their medications |
| 1997 | FDA Modernization Act | Changed the legend requirement to *"Rx only"* |

***Lecture 16 - Pharmacy Regulations Worksheet***

## *Multiple Choice*

1. Of the following Pharmacy Laws, which one directly deals with the use of childproof caps for prescription bottles?

    a. Food and Drug Act of 1906
    b. Food and Cosmetic Act (FD&C)
    c. Durham-Humphrey Amendment
    d. Poison Prevention Act

2. In the ordering of Schedule II controlled substances from a wholesaler, what form should be used?

    a. DEA Form 111
    b. DEA Form 214
    c. DEA Form 222
    d. FDA Form 214

3. Of the following Acts/Amendments, which one was the first attempt to legally control the distribution of narcotics and restrict opium usage?

    a. The Harrison Narcotic Act
    b. The Drug Abuse Control Amendments
    c. The Federal Controlled Substances Act (CSA)
    d. The Food and Drug Act of 1906

4. If the federal law and a comparable state law do not agree, which one should be used?

    a. the Federal law as it is the standard for all of state laws
    b. the state law as it pertains to the individual state requirements
    c. the law which is most stringent
    d. the law which is less stringent

5. The first significant piece of federal regulation dealing with drugs, signed by President Theodore Roosevelt, was the:

    a. Pure Food & Drug Act
    b. Federal Food Drug & Cosmetic Act
    c. The Harrison Narcotic Act of 1914
    d. The Controlled Substance Act

6. The Omnibus Budget Reconciliation Act (OBRA) of 1990 was adopted as a condition for Pharmacies to participate in the federally funded, but state administered Medicaid program. Of the following statements, which one is most correct?

    a. The Pharmacist must make a reasonable effort to obtain, record and maintain a patient medication record on each patient
    b. The Pharmacist must examine the patient's medication record and conduct perspective drug use review when filling or refilling a prescription
    c. The Pharmacist must counsel the patient or the patient's agent about the drug dispensed.
    d. All of the above are correct

7. Of the following Schedules of Drugs, which one involves drugs or other substances that do not currently have accepted medical use in treatment in the United States?

    a. Schedule I
    b. Schedule II
    c. Schedule III
    d. Schedule IV

8. Which one of the legal liabilities can a Pharmacy Technician be held accountable?

    a. civil liability
    b. criminal liability
    c. licensure/certification liability
    d. all of the above

9. Of the following Acts, which one first required the clinical testing of new drugs before marketing?

    a. FD&C Act
    b. CSA
    c. PPPA
    d. OBRA

10. Which Act/Amendment was prompted due to the "*Thalidomide Disaster*" which left thousands of infants born with deformities such as missing limbs?

    a. The Federal Drug & Cosmetic Act
    b. The Orphan Drug Act
    c. The Sherley Amendment
    d. Kefauver-Harris Amendments

**Submit your answers online at the following URL:**

https://form.jotform.com/241496682947170

[i] http://www.fda.gov/opacom/laws/fdrgact.htm
[ii] http://www.fda.gov/opacom/laws/wileyact.html
[iii] http://www.fda.gov/oc/opacom/fda101/sld017.html
[iv] http://www.fda.gov/cder/news/thalinfo/default.htm
[v] American Journal of Public Health, 1986
[vi] Statement on Signing the Federal Anti-Tampering Act, 1983
[vii] http://www.tdh.state.tx.us/hcf/vdp/tsbp.html
[viii] Drug Store News for the Pharmacist, July 1993
[ix] Hospital Pharmacist Report, September 1997
[x] Drug Topics, May 1998