Introduction

- Early colonial food laws were written to protect consumers from economic fraud.
- In the early 1900s, federal food laws focused on food safety and prevention of food adulteration.
- This chapter will discuss federal food laws related to economic, aesthetic, and food safety expectations.

Pure Food and Drug Act (1906)
Federal Meat Inspection Act (1906)

- 1906, Pres. Theodore Roosevelt signed both acts into law.
- Regulatory responsibilities were divided among 2 agencies within the USDA:
  - Bureau of Chemistry (later the FDA) enforced the PFDA.
  - Bureau of Animal Industry enforced FMIA.

Pure Food and Drug Act (1906)
Federal Meat Inspection Act (1906)

- PFDA made it unlawful to manufacture and distribute into interstate or foreign commerce food or drugs that were adulterated or misbranded.
- PFDA gave the Bureau of Chemistry the authority to inspect food products and to turn violators over to the justice system.
- Violators were brought to trial by the Secretary of Agriculture.
- If guilty, the violator was charged with a misdemeanor and fined up to 500 dollars, one year in prison, or both.
First produced with two key ingredients, cocaine and caffeine

Cocaine was derived from the coca leaf

Caffeine was derived from kola nut

Thus, the name Coca-Cola

Pure Food and Drug Act (1906)
Federal Meat Inspection Act (1906)

Deficiencies in the law made it hard to prosecute
- No legal standards for food were stated in the law making adulteration and misbranding difficult to prove
- No legal authority was granted to an agency for inspecting warehouses storing food and drugs
- No legal authority was granted to restrict interstate commerce of food containing a naturally-occurring poison
- No legal authority was granted over false or misleading statements made about a food

Pure Food and Drug Act (1906)
Federal Meat Inspection Act (1906)

• PFDA defined adulteration and misbranding as it relates to food and drugs
• Definition allowed FDA and USDA to include foods processed in unsanitary environments
• PFDA was only 6 pages long but it paved the way for more stringent federal regulations

• An adulterated food has one of the following
  - mixed and packaged with a substance that reduces or injuriously affects its quality or strength
  - substituted in whole or part or subtracted from in whole or part
  - mixed with a substance added to conceal inferior or damaged quality
Pure Food and Drug Act (1906) 
Federal Meat Inspection Act (1906)

• An adulterated food has one of the following (cont’d)
  - manufactured to contain poisonous or harmful ingredients which renders the food injurious to health
  - manufactured to contain filth, decomposed or decaying material from plants or animals
  - manufactured to contain diseased animals or animals dying before slaughter

In layman’s terms:
• An adulterated food or drug was one that
  - was unfit for human consumption
  - produced under false pretenses
  - contained ingredients that are unsafe
    o poisons
    o filth
    o decomposed/decaying or diseased material

• PFDA is sometimes referred to as the Wiley Act since Dr. Harvey Wiley devoted his career to raising public awareness of adulterated food

• FMIA required that Bureau of Animal Industry verify
  - meat-producing animals were not adulterated or misbranded
  - meat producing animals were slaughtered and processed under sanitary conditions
  - adulterated and misbranded were defined as in PFDA
Pure Food and Drug Act (1906)  
Federal Meat Inspection Act (1906)

- FMIA animal species included cattle, sheep, swine, goats, horses, mules or other equine
- Today species include additional livestock considered appropriate by the Secretary of Agriculture
- FMIA tasks that are outlined are carried out by Food Safety Inspection Service within the USDA
- FSIS created as the Food Safety and Quality Service in 1977, renamed FSIS in 1981

Pure Food and Drug Act (1906)  
Federal Meat Inspection Act (1906)

- FMIA was the direct result of Upton Sinclair's reporting on the Chicago's meat packing industry
- Well-known Socialist
- Quoted
  
  “I aimed a the heart of American society and struck their stomachs”

Pure Food and Drug Act (1906)  
Federal Meat Inspection Act (1906)

- Under FMIA, the Bureau of Animal Inspection had 4 main responsibilities
  1. Mandatory inspection of livestock for evidence of disease before slaughter
  2. Mandatory inspection of every livestock carcass after slaughter for disease
  3. Monitoring the slaughter and processing operation for cleanliness
  4. Enforcement of the food safety regulatory requirements in livestock slaughtering establishments

Pure Food and Drug Act (1906)  
Federal Meat Inspection Act (1906)

- FMIA has been amended many times to strengthen it
  - Poultry Products Inspection Act (1957)
  - Wholesome Meat Act (1967)
  - Wholesome Poultry Products Act (1968)
- Bureau of Chemistry reorganized to Food, Drug and Insecticide Administration (1927), which was renamed again in 1930 to Food and Drug Administration
### Amendments to Federal Meat Inspection Act (1906)

- **Poultry Products Inspection Act of 1957**
  - 1800s: 50% of US population earned a living by farming
  - Backyard flocks furnished families with eggs and meat for dinner
  - Early 1900s: poultry breed for plumage, increased egg and meat yield and entertainment

- **Wholesome Meat Act of 1967**
- **Wholesome Poultry Act of 1968**
  - extend federal standards to foreign establishments that are importing products into the US
  - extend federal standards to state-inspected establishments that are distributing meat and poultry intrastate commerce
  - Also called “Equal-to Acts” as the amendments require that state, federal, and foreign meat and poultry establishments have the same standards of inspection

### Amendments to Federal Meat Inspection Act (1906)

- **Poultry Products Inspection Act of 1957**
  - 1940s, larger flocks reared on farms and sold to consumers as “New York Dressed” carcasses
  - New York Dressed meant blood and feathers were missing
  - 1942, carcasses with intestines removed was approved for commercial use
  - 1949, chicken slaughterhouses emerged
  - 1950s, USDA realized the same standards for poultry as for meat were needed
  - USDA assigned responsibility for monitoring processing operations

### Food, Drug, and Cosmetic Act (1938)

- PFDA provided no standards for determining the purity of food nor what could or could not be in food
- PFDA only required that a statement on the food be truthful
- Food labels were not required to state content weight
- Many cases brought to court were thrown out for lack of proof of adulteration or misbranding
Food, Drug, and Cosmetic Act (1938)

- 1917, the Bureau of Chemistry reported that the PFDA lacked
  - legal standards for foods
  - assigned authority to inspect food and drug warehouses
  - restrictions on poisons in drugs
  - limitations on naturally-occurring adulterations
- PFDA was difficult to enforce

Food, Drug, and Cosmetic Act (1938)

- Congress blocked early attempts to rewrite PFDA
- 1930s, Great Depression occurred
  - created a market for cheap products and stretching food production
  - adulteration increased
  - misbranding increased

Food, Drug, and Cosmetic Act (1938)

- President Franklin Roosevelt, once elected, called for a revision of PFDA
  - took 5 years of debate for a revision
  - new law was FDCA
- FDCA is still considered the primary US law regulating food, drugs, beverages, cosmetics, and medical devices
- Complete law can be found in the US Code Title 21(Food and Drugs), Chapter 9, sections 301-399d

Food, Drug, and Cosmetic Act (1938)

- Most noteworthy attributes of FDCA
  - gave FDA authority over 4 broad consumer products: food, drugs, cosmetics, and medical devices
  - included comprehensive listing of definitions to clearly communicate the law
  - included standards of identity
  - required specific food labeling components
- More than 100 amendments to FDCA have been made just for new definitions as food technology has advanced
Food, Drug, and Cosmetic Act (1938)

• Definition for food was one of the most critical. FDCA defined it as...
  - articles used for food or drink for man or other animals
  - chewing gum
  - articles used for components of any other such articles

Food, Drug, and Cosmetic Act (1938)

• Legally, food is defined by its intended use
  - food that is spoiled or decomposed is still considered food
  - chewing gum is considered food unless it contains nicotine or a laxative then it is a drug

Food, Drug, and Cosmetic Act (1938)

• FDCA strengthens definitions of adulteration and misbranding
  “A food shall be deemed to be adulterated if ......
  - it contains any poisonous or harmful substances which may render it injurious to health
  - it contains an added poisonous or harmful substance which is unsafe
  - it contains any filth, putrid or decomposed material that is unfit for food

Food, Drug, and Cosmetic Act (1938)

• A food shall be deemed to be adulterated if ......
  - it is handled under insanitary conditions where it may become contaminated or where it may be rendered injurious to health
  - its container is composed of any poisonous or harmful substances which may make the food injurious to health
**Food, Drug, and Cosmetic Act (1938)**

- A food shall be deemed to be adulterated if ......
  - any valuable component of the food has been omitted or substituted, or if any damage or inferiority has been concealed, or if anything has been added to increase its bulk weight or reduce its quality/strength
  - it contains a color additive which is unsafe

- **FDCA makes provisions for unavoidable substances that are naturally occurring or are introduced during production, processing or handling**
- **FDCA requires safe tolerances are set**
- **Good Manufacturing Practices**
  - Defect Action Levels
    - covers unavoidable or natural contaminates of food that are not harmful

- **Defect Action Levels**
  - Established for substances such as
    - insects
    - insect parts
    - worm fragments
    - fly eggs
    - rodent dropping
    - mold
    - foreign matter
  - Informal standards set to warn of inadequate sanitation

- **Good Manufacturing Practices prohibits mixing of defective foods with uncontaminated foods to reduce the overall load**
- **FDA publishes online a defect action level handbook entitled**
  “Levels of natural or unavoidable defects in foods that present no health hazards for humans”
Amendments to the Food, Drug, and Cosmetic Act (1938)

- Most notable amendments altered the authority of the FDA or extended coverage of the law
- Amendments discussed here:
  - Miller Pesticide Amendment
  - Food Additive Amendment
  - Color Additive Amendment
  - Dietary Supplement Health Education Act
  - Public Health Security and Bioterrorism Preparedness Response Act
  - FDA Food Safety and Modernization Act
  - Patient Protection and Affordable Care Act

Amendments to the Food, Drug, and Cosmetic Act (1938)

- First 3 amendments were written after WWII
- Food production increased to feed troops
- People began to move off the farm into the city
- Many new ingredients and packaging materials that did not require preapproval by the FDA
Amendments to the Food, Drug, and Cosmetic Act (1938)

- Miller Pesticide Amendment, 1954
  - EPA not yet formed (1970)
  - pesticides regulated by the FDA
  - regulation began, 1910 – Federal Insecticide Act
  - Miller Act required safe tolerances for pesticides in food be set
  - Miller Act instructed FDA to "protect the public" but also to consider "the necessity for the production of adequate, wholesome and economical food supply"
  - Don’t be so strict that you keep manufacturers from making food

- Food Additive Amendment, 1958
  - Congress realized it needed proof that a food additive was poisonous to block it from being added to food
  - Congress also noted that food technology was providing food with longer shelf-life, increased flavor, and added nutrients
  - Congress was concerned that the legal system would hinder these advances
Amendments to the Food, Drug, and Cosmetic Act (1938)

• Food Additive Amendment, 1958
  - legally defined “food additive”
  - established that additives must be approved by the FDA before use in a food
  - burden of proof of safety of a food additive was placed on the manufacturer
  - definition includes two parts
    - items included in the definition
    - items excluded in the definition (exempt)

Amendments to the Food, Drug, and Cosmetic Act (1938)

• Food Additive Amendment, 1958
  - Food additive is defined as or includes any substance, “the intended use of which results or may be reasonably expected to result, directly or indirectly, either in their becoming a component of food or otherwise affecting the characteristics of food.”

Amendments to the Food, Drug, and Cosmetic Act (1938)

• Food Additive Amendment, 1958
  • Key words of the definition:
    - direct additives: an ingredient
    - indirect additives: contamination from food contact surfaces or packaging
    - component of the food: emulsifiers, thickeners
    - affecting the characteristic of the food such as irradiation, which changes color, fat oxidation, microbial load
Amendments to the Food, Drug, and Cosmetic Act (1938)

- **Food Additive Amendment, 1958**
  - **GRAS, Generally Recognized As Safe**
  - "reasonable certainty in the minds of competent scientists that the substance is not harmful"
  - Based on long history of use in food
  - Based on published scientific evidence
  - Such as Lactic Acid Bacteria used in dairy fermentation

- **Color Additive Amendment, 1960**
  - Color additive defined: "a dye pigment or substance that can impart color when added to food, drug, or the human body"
  - Same pre-market approval as for food additives
  - No GRAS or Prior-sanctioned substances
Amendments to the Food, Drug, and Cosmetic Act (1938)

• Color Additive Amendment, 1960
  - Color additive uses in food
    o increase consumer acceptance
    o correct for losses that occur during food production or processing
    o correct for color variations
  - Two classes:
    o Certified
    o Exempt from Certification

Amendments to the Food, Drug, and Cosmetic Act (1938)

• Color Additive Amendment, 1960
  - Certified Color Additives
    o man-made, synthetic
    o Seven certified for use in food
      FD&C Blue No.1   FD&C Red No.5
      FD&C Blue No.2   FD&C Yellow No.6
      FD&C Green No.3  FD&C Yellow No.7
      FD&C Red No.4
  - Exempt from Certification
    o pigments derived from natural sources
      minerals, plant extracts, animals
    o FDA does not require batch testing
    o FDA does not require safety standards
    o Not GRAS or prior-sanctioned
    o 25 color additives FDA approved
      beet powder, annatto extract, tumeric, vegetable juice, beta-carotene
  - Each batch is tested by FDA and manufacturer to ensure safety and consistency

Amendments to the Food, Drug, and Cosmetic Act (1938)

• Food Additive Amendment, 1958
  - Additives Exempt from Certification are difficult to use for commercial manufacturing of food
    o do not have precise chemical identity
    o lack uniformity of color
    o high levels needed to achieve desired color
    o typically fades quickly
Amendments to the Food, Drug, and Cosmetic Act (1938)

• Food Additive Amendment, 1958
  - Manufacturers petition FDA for approval of a new food or color additive
  - Petition must include
    1. Identify the food additive
    2. Proposed use of the food
    3. Technical effects of the additive in the food
    4. Method of analysis for the additive in the food
    5. Full report of all safety investigations of the additive (animal and toxicology studies)

• Delaney Clause, 1958
  - part of Food Additive Amendment
  - prevents the addition of any substance to food that induces cancer in humans or lab animals
  - applicable to pesticides, food and color additives
  - Zero tolerance policy: allowable level is zero for any additive or pesticide that induces cancer at any level of exposure

Amendments to the Food, Drug, and Cosmetic Act (1938)

• Food Additive Amendment, 1958
  - Petition must include
    6. Description of manufacturing control procedures used during production, including reproducibility of the additive composition and strength
    7. Samples of the additive and/or samples of the food containing the additive, if requested
    8. FDA does not issue an "approval" but instead "no objection at this time"
    9. FDA specifies type of food additive can be used in, max level of usage, and labeling requirements

• Delaney Clause, 1958
  - did not define cancer which leave the phrase "induce cancer" open to interpretation
  - some argue zero tolerance is scientifically impossible since methods of analytical analysis have improved
### Amendments to the Food, Drug, and Cosmetic Act (1938)

- **Delaney Clause, 1958**
  - Food Quality Protection Act, 1996
    - Removes Delaney Clause for pesticide residues on food
    - States instead - reasonable certainty to cause no harm from aggregate exposure
    - EPA sets tolerance level for pesticides on food
    - EPA determines if risk from pesticide is negligible
    - This law eliminates pesticides from the Food Additive Amendment

- **Dietary Supplement Health Education Act, 1994**
  - Prior to 1938 little was known about dietary supplements
  - 1976, Vitamin-Mineral Amendment defined for the first time “special dietary use”
  - Initially, FDA regulated supplements as drugs
  - Congress felt the average citizen could make their own decision on supplements
  - Senator Proxmire established the Proxmire Amendment, which prohibited FDA from placing maximum limits of potency on vitamins and minerals within a food
  - FDA began regulating them as food additives with the idea that some dietary supplements could be unsafe food additives.
Amendments to the Food, Drug, and Cosmetic Act (1938)

• Dietary Supplement Health Education Act (DSHEA), 1994
  - 1990, Nutrition Labeling and Education Act gave FDA authority over food labeling including dietary supplements
  - But did not enhance their authority over supplements more than that
  - Instead, DSHEA is the first amendment to reduce the FDA’s authority

• Dietary Supplement Health Education Act (DSHEA), 1994
  - Dietary supplements
    o are regulated as food but are exempt from key regulations regarding food
    o are less regulated than food or drugs
    o do not require premarket approval before use in foods
    o Excludes supplements that make a structure-function claim on their label from being classed as a drug

• Dietary Supplement Health Education Act (DSHEA), 1994
  - Key aspect of DSHEA: first time “dietary supplement” was legally defined
    - Includes:
      o intended use
      o components or ingredients
      o form presented
      o labeling instructions
Amendments to the Food, Drug, and Cosmetic Act (1938)

• Dietary Supplement Health Education Act (DSHEA), 1994
  Dietary supplement must meet all of the following requirements
  1. Intended to supplement the diet and contains one or more of the following
     vitamin mineral amino acid herb
     substance that increases dietary uptake
     concentrate, metabolite, extract or combination of the above

  2. Intended for ingestion by mouth
  3. Not meant to be conventional food or as a sole item of a meal or diet
  4. Includes an item approved as a new drug and was prior to approval marketed as a dietary supplement, unless a notice was issues finding the conditions of use unlawful

  5. Does not include a new drug certified as an antibiotic
  6. Does not include a new drug, antibiotic, or biological for which substantial clinical investigations have been instituted and made public and which was not before such approval marketed as a dietary supplement unless after notice it was found to be lawful

  More simply put
  - To be regulated as a dietary supplement, food for special dietary use must:
    o be intended to supplement the diet
    o have specific composition
    o be taken by mouth
    o be labeled as dietary supplement
    o not be intended to be conventional meal
Amendments to the Food, Drug, and Cosmetic Act (1938)

• Dietary Supplement Health Education Act (DSHEA), 1994
  - DSHEA describes the form in which the dietary supplement must be sold
  - Dietary supplements cannot be a new drug unless it was sold as a supplement before 1994

Amendments to the Food, Drug, and Cosmetic Act (1938)

• Dietary Supplement Health Education Act, 1994
  - Label of a dietary supplement must include
    1. Statement of identity
    2. Net quantity of contents
    3. Directions for use
    4. Other ingredients
    5. Supplemental facts
    6. Name and address of manufacturer or distributor
    7. If a structure-function statement is used, then the FDA disclaimer must appear

Amendments to the Food, Drug, and Cosmetic Act (1938)

• Dietary Supplement Health Education Act (DSHEA), 1994
  - FDA disclaimer when a structure-function statement is used
    “These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease”
Amendments to the Food, Drug, and Cosmetic Act (1938)

• Dietary Supplement Health Education Act (DSHEA), 1994
  - National Medicines Comprehensive Database currently has > 54,000 different dietary supplements listed
  - Dietary supplements are regulated as under PFDA
  - Consumer Reports published that >6,300 reports were submitted to FDA on serious adverse events associated with dietary supplements during the last 4.5 years

- 85% of adults use vitamins and minerals to supplement their diet
- Dietary supplement industry is worth 24 billion dollars annually
- Controversy over dietary supplements will not likely end soon
Amendments to the Food, Drug, and Cosmetic Act (1938)

- Public Health Security and Bioterrorism Preparedness Response Act, 2002
  - Passed in response to tragic events of September 11, 2001
  - Also called Bioterrorism Act 2002
  - Protect US food from intentional and unintentional contamination of food manufactured in domestic and foreign establishments

Amendments to the Food, Drug, and Cosmetic Act (1938)

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Amendments to the Food, Drug, and Cosmetic Act (1938)

- Public Health Security and Bioterrorism Preparedness Response Act, 2002
  - Center for Disease Control and Prevention developed a preparedness program to facilitate communication, direction and first-hour response following an act of bioterrorism
  - Consists of teams of specialists that categorize and monitor infectious agents and disease outbreaks

Amendments to the Food, Drug, and Cosmetic Act (1938)

- Public Health Security and Bioterrorism Preparedness Response Act, 2002
  - Act contains 4 major provisions of FDA authority
    1. Administrative detention authority
      - retain any food shipment that FDA believes may pose a threat to the US
      - use of “believe” enhanced their authority
      - 30-day detention limit for testing
      - imported food has 24 hour limit
      - manufacturer’s can appeal detention decision
Amendments to the Food, Drug, and Cosmetic Act (1938)

- Public Health Security and Bioterrorism Preparedness Response Act, 2002

2. Federal facilities registration
   - All domestic or foreign food manufacturers must register with FDA before they can distribute food within the US
   - Includes: listing of all facilities, names of company executives, all product brand names, national origin of all ingredients, annual production

3. Additional records
   - Source of all product inputs
   - Immediate destination of products
   - Tracing products in the system
   - FDA is allowed to review and copy the records

4. Prior notice of imported food shipment
   - Foreign establishments must give FDA prior notice of product shipment into the US
   - Must include: product name, quantity shipped, country of origin, production date
   - FDA can refuse entry if prior notice is not provided or inaccurately filed

Example
- 1970, postdoctoral student in parasitology named Eric Krantz intentionally fed his roommates *Ascaris* eggs
- This was a peace-offering meal after an argument over a few dollars in rent
- 7 guests became ill
- 2 guests had respiratory failure
Amendments to the Food, Drug, and Cosmetic Act (1938)

- Public Health Security and Bioterrorism Preparedness Response Act, 2002
  - Kranz was brought to trial for murder but was acquitted
  - Lack of evidence that he poisoned the food
  - Lawyer claimed the students could have become sick from the water system or from handling clothing

Example
- Rural Oregon, 1984
  - Rajneesh cult group argued with locals over land
  - Rajneesh decided to run for office to “win” the argument
  - To control the election outcome, cult members contaminated a salad bar with *Salmonella Typhimurium* making voters too sick to vote

Amendments to the Food, Drug, and Cosmetic Act (1938)

- FDA Food Safety Modernization Act, 2011
  - Pres. Obama signed it
  - Designed to shift FDA’s regulatory authority from a reactive stance after a product is manufactured to a proactive approach with process control points to prevent food safety issues
Amendments to the Food, Drug, and Cosmetic Act (1938)

- FDA Food Safety Modernization Act, 2011
  - Strengthened FDA’s authority in 5 areas
    1. Preventive controls
    2. Inspection and compliance
    3. Import food safety
    4. Response
    5. Partnerships

- FSMA requires all food manufacturers to implement a food safety plan with preventive controls for processing and handling hazards that could make the food unsafe

- Hazard is a biological, chemical, or physical contamination that could cause a food to be unsafe for human consumption

Amendments to the Food, Drug, and Cosmetic Act (1938)

- Patient Protection and Affordable Care Act, 2010
  Preventive controls
  - GAPs: recommended standards to improve safety and quality of produce
  - controls: growing, harvesting, sorting, packing, storing, hygiene, packaging, temperature, animals in the growing area, soil and water programs

Amendments to the Food, Drug, and Cosmetic Act (1938)

- FDA Food Safety Modernization Act, 2011
  - Consumption of fresh produce is viewed as a major concern
  - Specifically targets safe production and harvest of fruits and vegetables with science-based control of hazards – Good Agricultural Practice
Amendments to the Food, Drug, and Cosmetic Act (1938)

- Patient Protection and Affordable Care Act, 2010
  Inspection and compliance
  - mandatory FDA inspection frequency of food processing facilities
  - based on risk assessment
  - high risk foods: once every 3-years
  - low risk foods: once every 5-years
  - risk determined by the known risk for the food, facility's compliance history, rigor and effectiveness of their food safety plan

Amendments to the Food, Drug, and Cosmetic Act (1938)

- Patient Protection and Affordable Care Act, 2010
  Import food safety
  - Foreign food establishments must perform supplier verifications that ensure food safety
  - FDA can refuse an import if inspections are refused and risk-based certification is not performed
  - FDA expedites shipment review as incentive for shippers to take additional safety measures

Amendments to the Food, Drug, and Cosmetic Act (1938)

- Patient Protection and Affordable Care Act, 2010
  Response
  - FDA can force a product recall now
  - Prior to FSMA, recalls were voluntary
  - FDA can also suspend plant operation based on reasonable suspicion that a product is unsafe

Amendments to the Food, Drug, and Cosmetic Act (1938)

- Patient Protection and Affordable Care Act, 2010
  Partnerships
  - federal, state, local, tribal, territorial agencies work together to extend resources
  - funds for additional training allocated to ensure success of partnerships
  - example: now USDA and FDA share inspection authority at US shipping ports
  - one inspector inspect imported meat, fruits, and vegetables instead of duplicating inspections
Amendments to the Food, Drug, and Cosmetic Act (1938)

• Patient Protection and Affordable Care Act, 2010
  - later called Obamacare
  - Consists of 9 Titles
  - One title addresses food labeling of menus sold at chain restaurants, retail establishments, and vending machines
  - Enhanced nutritional information needed
    o due to an increasing rate of obesity
    o due to 33% of caloric intake is from food prepared outside of the home

Conclusion

• Our system of food laws is flawed but serves as a model for food legislation in many other countries
• FDCA has endured 75 years as it included an extensive list of definitions providing legal basis for interpretation
• 100+ amendments improve these definitions

Amendments to the Food, Drug, and Cosmetic Act (1938)

• Patient Protection and Affordable Care Act, 2010
  - All chain restaurants with 20 or more locations are required to list caloric content of menu items
  - Must also state additional nutritional information available upon request
  - Condiments, daily specials or temporary items served < 60 days annually are exempt
  - Those with less than 20 locations may volunteer to be regulated under Obamacare

Conclusion

• Some of the FDCA amendments altered the authority of FDA
  o Miller Pesticide Amendment
  o Food and Color Additives Amendments
  o DSHEA
  o Bioterrorism Act
  o FSMA
  o Obamacare Act
Conclusion

• DSHEA is historic as it is the first law to reduce the FDA authority
• FSMA is historic as it is the first law to mandate an inspection frequency for FDA
• Food laws are reflective of our society, culture and political climate