



Consumer Protection

Chapter 18

FDA Food and Drug Regulation

- FDCA

- Food, Drug, and Cosmetic Act of 1938 allows FDA to control false advertising of drugs, prescription drugs, expanded enforcement and inspection systems, and set safe levels of additives in foods

- See Drug Exporting Regulation

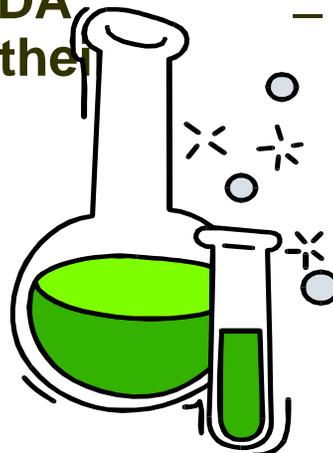
- Other nations adopt FDA regulations as part of their drug standards

- Food Quality Protection

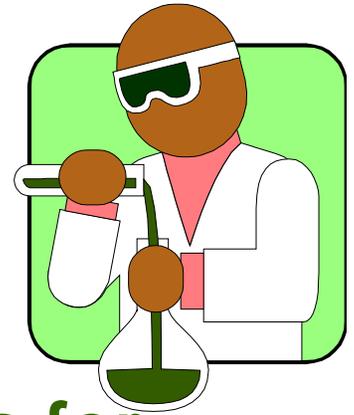
- Food Additives Amendment (Delaney Clause) added to FDCA in 1958 more authority (very strict) on additives
- amended by flexible Food Quality Protection Act: “reasonable certainty of no harm”

- Enforcement

- FDA can force existing products--food, cosmetics, medical devices--removed from the market, i.e. silicone breast implants



Nutrition Labeling and Education Act 1990



- **Required new regs:**
 - apply to more than 250,000 products
 - prevent misleading product claims
 - help consumers make informed decisions
- **Nutrients by serving size**
 - labels must show certain components in foods by realistic serving size
- **Standards for health claims**
 - words must have certain meanings
 - fresh--can't have been processed, frozen or preserved
 - low fat--3 or fewer grams of fat per 100 grams of food
 - low calorie--fewer than 40 cal per 100 grams

Tobin v. Astra Pharmaceutical



- Tobin, pregnant with twins, was placed on ritodrine to suppress contractions.
- She complained of side effects such as racing heart and swelling, but was told that it was normal. In mid-March she was admitted into the hospital with fluid in the lungs and congestive heart failure.
- She delivered healthy twins.
- Within a month, she needed a heart transplant.

She sued Astra, the distributor of ritodrine. Astra moved to have the case dismissed because the drug was approved by the FDA. The motion was denied and the drug company appealed.

- HELD: Appeals court affirmed.
- “We reject the argument that FDA approval preempts state product liability claims based on design defect.”

Federal Trade Commission (FTC)

- Helps enforce antitrust laws (Bureau of Competition)
- But also devotes resources to the Bureau of Consumer Protection
 - **protect against “unfair and deceptive acts or practices in or affecting commerce”**





Federal Trade Commission (FTC)

- **Complaint begins legal process**
- **Many complaints settled by consent decree - terms of settlement frequently include**
 - **prohibition of practices**
 - **redress for consumers**
 - **payment of civil penalties**
- **A few cases get administrative trials at FTC**
 - **may appeal to Commissioners for review**
 - **may next appeal to federal Court of Appeals**

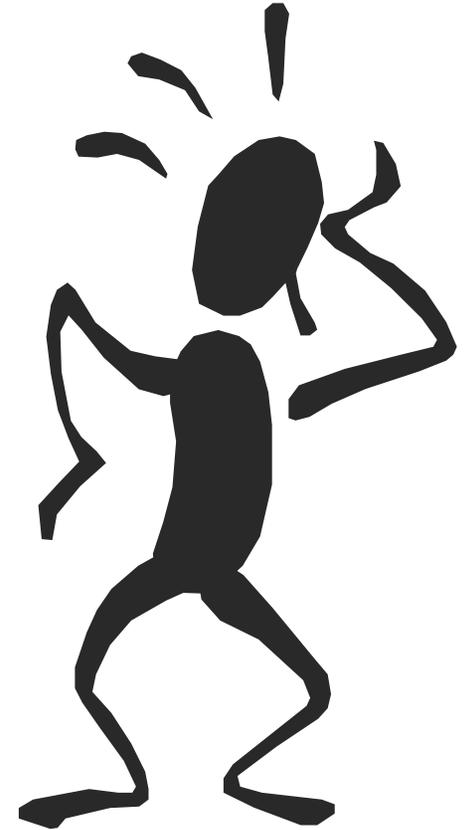
Unfair and Deceptive Acts and Practices

- **FTC has considerable leeway**
- **Deception:**
 - 1) misrepresentation or omission of information
 - 2) likely to mislead reasonable consumer
 - 3) deception is material
- **Clarifying the elements:**
 - 1) not *all* omissions are deceptive
 - 2) look at *entire content*
 - 3) reasonable consumer is *ordinary person*
 - ads for very young or the ill have tougher standard
 - 4) must be likely to affect consumer's product choice
 - 5) no proof of injury to consumer is needed

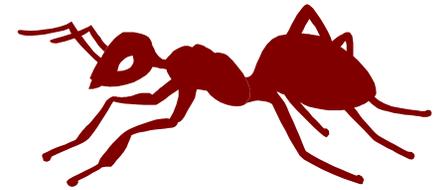


Unfairness

- **Usually tagged onto deceptive charge**
 - 1) **causes substantial harm to consumers**
 - 2) **consumers cannot reasonably avoid injury**
 - 3) **injury is harmful in its net effect**



Orkin Exterminating v. FTC



- In '66 Orkin said that if customers continued to pay a set annual fee their homes would be retreated, if termites reappeared.
- By '75 Orkin realized the fee was too low and gave notice to 200,000 customers that the fee would be increased by the greater of \$25 or 40%.
- The FTC found the price increase to be unfair, and ordered Orkin to roll prices back to their original level.
- Orkin appealed.
- The FTC concluded that it was an “unfair practice” to breach 200,000 contracts.
- Orkin argued that they were not attempting to be deceptive, but the court found that there was an extraordinary level of consumer injury and that deception is not a required component of unfairness.
- **HELD: The court affirmed the FTC decision.**

Regulating Advertising Claims



- Advertising substantiation program
- Must have reasonable basis for claims
- FTC considers following in what is reasonable basis
 - product
 - type of claim
 - consequences of false claim; benefits of truthful claim
 - cost of developing substantiation
 - amount of substantiation experts believe is reasonable
- **Note regarding telemarketers**
 - Subject to the Telephone Consumer Protection Act and Telemarketing and Consumer Fraud and Abuse Prevention Act
 - The result is the FTC's Telemarketing Sales Rule
 - Consumers can sue telemarketers for damages if they violate consumers' instructions to be removed from call lists.

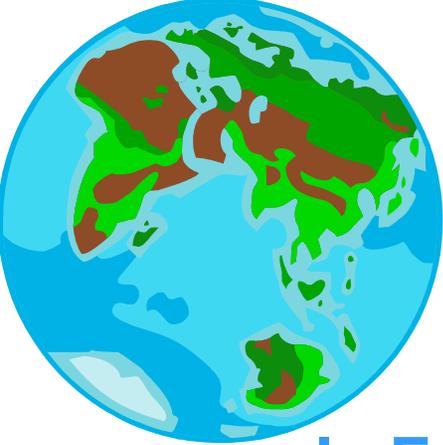
Listerine Mouth Wash case

- Recent KFC investigation

False Advertising and the Lanham Act

- Private parties can bring actions under the Lanham Act
- Similar to FTC cases, but plaintiffs can get double damages





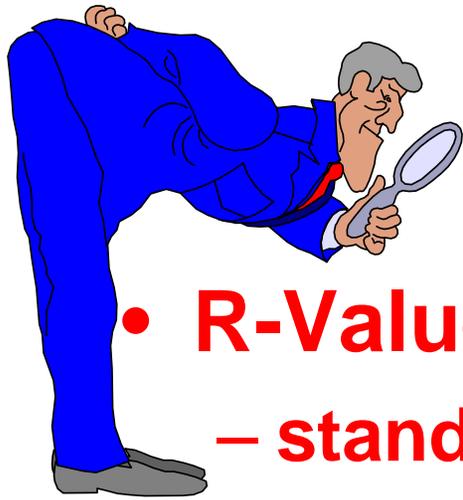
“Foreign Advertising Regulation”

- In Europe ad regulations are tightest in northern Europe and loosest in the Mediterranean countries
- **Britain: Standard is that an ad is illegal if it misrepresents a product**
- **U.S.: Ad is illegal if it simply misleads**
- **Japan: Beer ads promote “extra strong” alcohol content -- illegal in the U.S. under Bureau of Alcohol, Tobacco & Firearms rules**



“Regulating Cyberspace Advertising”

- **FTC prosecutes dozens of on-line scams and false advertising.**
- **Fortuna Alliance collected over \$6 million from “investors” in a pyramid scheme.**
- **A company had to pay \$195,000 to consumers re: “self-improvement” products**
- **FTC pushed Congress to pass the Children’s On-line Privacy Protection Act that protects on-line users under 13.**



Trade Regulation Rules

- **R-Value rule**
 - **standardize measures of home insulation**
- Mail-order rule
 - reasonable basis for expecting to ship products in time they say or offer refund
 - i.e. “allow 5 weeks for shipping” or must ship within 30 days
- **Used car rule**
 - **dealers must give clear information on who pays for repairs after sale**



Magnuson-Moss Warranty Act

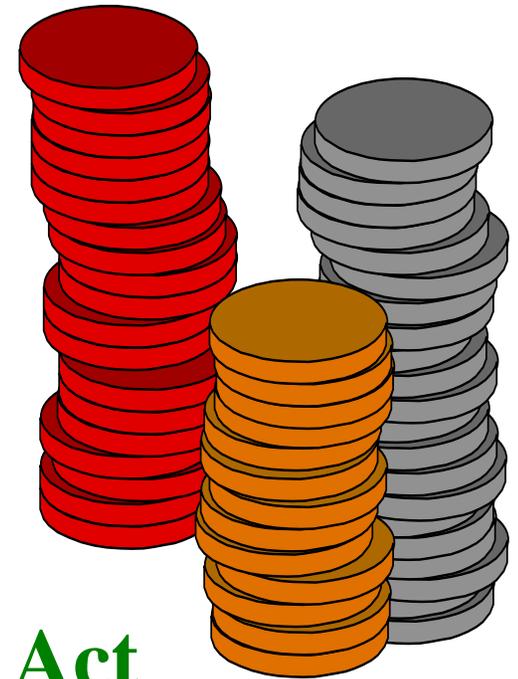
FTC sets guidelines for consumer product warranties

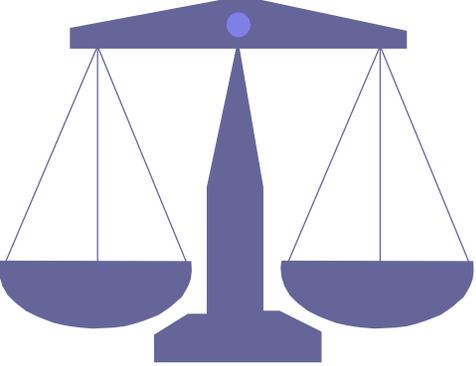
- **Requires written warranties to include:**
 - what parts, problems it covers
 - time period of coverage
 - what will or won't be done to correct problem
 - how to get service
 - state law impact on warranty

- **Full warranty:**
 - anyone who owns product during service period
 - free of charge
 - replace or refund at consumer's option
 - no need to send warranty registration card
 - implied warranties are not limited
- **Anything short of these is limited warranty**

Consumer Credit Protection Act (CCPA) Major Elements

- **Truth-in-Lending Act**
 - Consumer Leasing Act
 - Fair Credit Billing Act
- **Restrictions on Garnishments**
- **Fair Credit Reporting Act**
- **Equal Credit Opportunity Act**
- **Fair Debt Collection Practices Act**
- **Electronic Funds Transfer Act**





Consumer Credit Protection

Requirements on Creditors

- **Disclose all relevant terms**
- **Provide procedures for correcting inaccurate bill and charges**
- **Provide accurate information in consumer reports**
- **Not use race or sex in determining creditworthiness**
- **Abusive debt collection techniques prohibited**



Truth-in-Lending Act (TILA)

- Encourage consumers to shop around for credit
- Standardize loan forms and terms to help consumers understand finance charges
- Must disclose cost of credit in dollars and interest rate
- If loan has these things, they must be listed:
 - service, activity, carrying and transaction charges
 - loan fees and points
 - charges for credit life and credit accident and health insurance
 - fees for credit reports in non-real estate
- Have civil and criminal penalties

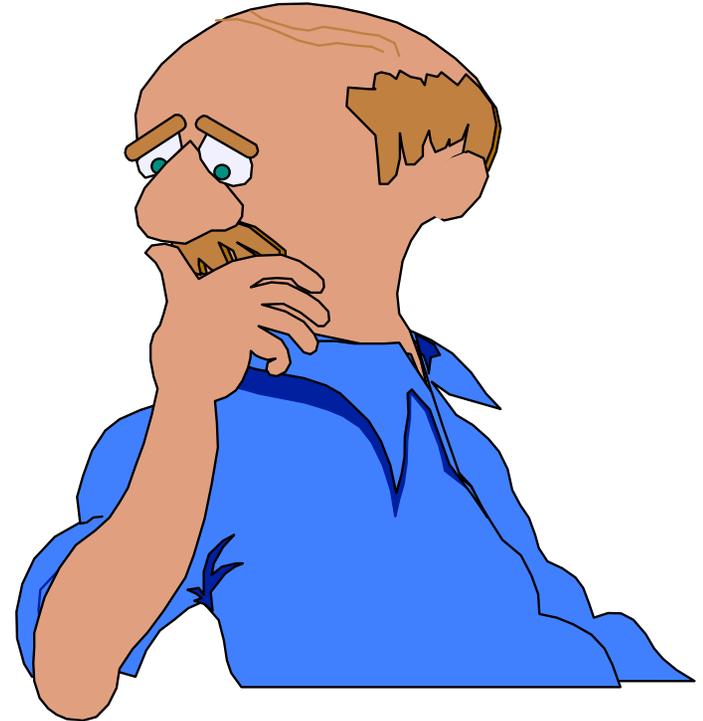
Consumer Leasing Act



- Does for leases what TILA does for consumer credit
 - Applies to personal transactions, not for business use
 - Lease must be longer than 4 months and less than \$25,000
 - See Exhibit 18.2 Credit Sale Disclosure Form
- **Must disclose:**
 - number, amount and period of payments and total payments
 - express warranties
 - ID party responsible for maintaining the property
 - does consumer have option to buy and at what terms
 - penalties for terminating lease early

Fair Credit Billing Act

- Protect consumers from inaccurate charges
- FCBA provides:
 - procedure to dispute billing errors
 - prohibits mailing of unsolicited credit cards
 - procedures to report lost/stolen credit cards
- Can also sue for civil penalties



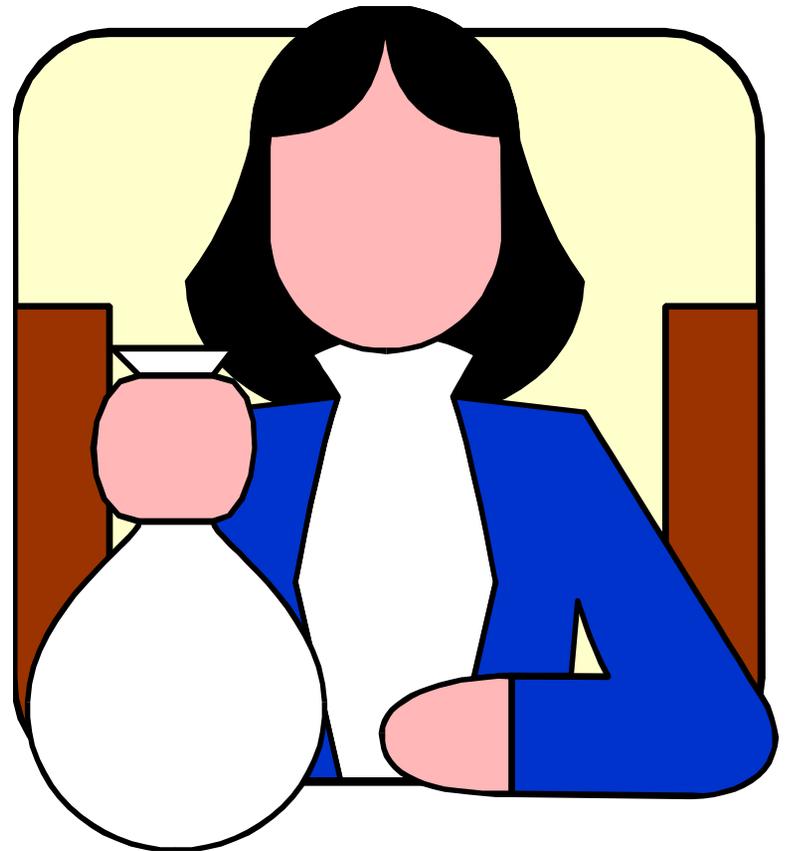
Fair Credit Reporting Act



- Regulates credit bureaus
- Consumers can see credit reports that result in credit being denied
- Credit bureaus must:
 - respond to consumer complaints within 30 days
 - tell consumers who have asked for their credit history
 - provide toll free service number
 - get permission before giving report to employer or that contains medical info

Equal Credit Opportunity Act (ECOA's Prohibited Bases)

- Prohibits discrimination against applicants for credit on basis of race, sex, color, religion, national origin, marital status, receipt of public benefits, good-faith exercise of rights under CCPA or age



ECOA Notification Requirements

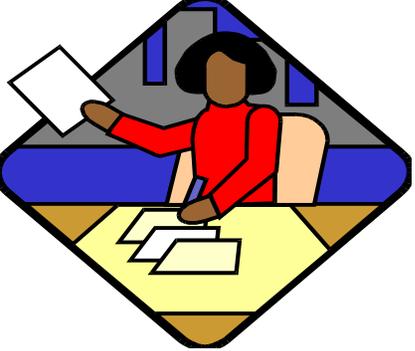


- **Credit denied or less-favorable, creditor must provide written:**
 - basic provisions of ECOA
 - name and address of agency regulating compliance by creditor
 - statement of specific reasons for action taken or disclosure of right to get a statement of reasons

Fair Debt Collection Practices Act

- Eliminate unfair, deceptive, and abusive collection techniques by debt collection agencies
- Restrictions Imposed
 - Does not apply to creditors collecting own debt
 - prohibits threats, obscene language, publication of a list of delinquent consumers, harassing phone calls





Gammon v. GC Services

- **GC, a debt collector, sent Gammon a letter that stated that it supplied the U.S. with systems to collect taxes.**
- **Gammon sued, claiming GC violated the FDCPA that holds illegal the false representation that the debt collector is affiliated with the U.S.**
- **District court dismissed, stating that GC's statement could not be read to mean that it was linked to any gov't. Gammon appealed.**
- **HELD: Gammon had a claim under FDCPA.**
- **The appeals court used “unsophisticated consumer” standard, and determined that Gammon could have interpreted the statement to imply that GC was affiliated with the government.**
- **Case remanded for further proceedings.**

Info debt collector must send

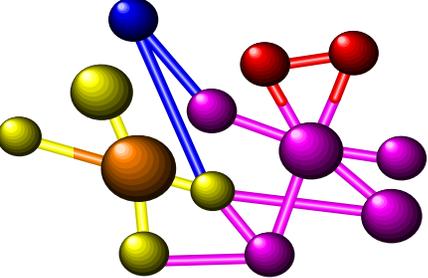
- Amount of debt
- Name of creditor
- Unless consumer disputes validity of debt within 30 days, assume debt is valid
- Must show proof of debt if disputed



Electronic Fund Transfer Act

- Limits liability from stolen ATM card if consumer reports loss of card
 - No more than \$50 if financial institution is notified within 2 days
 - Maximum liability is \$500 if consumer notifies financial institution within 60 days
- Financial institutions liable to consumers for damages from failure to make electronic transfers of funds
- Consumers have 60 days to report errors; financial institutions must investigate and resolve within 45 days





“Can Consumer ‘Protection’ Go Overboard?”

- Patient is going blind - wet macular degeneration.
- Sight in left eye is lost.
- Needs procedure at Eye Institute that uses angiogenesis inhibitor Thalidomide to stop growth of unwanted blood vessels.
- FDA rules say
 - Left eye is too bad to qualify
 - Right eye is too good
- Cancer and Alzheimer’s patients wait while FDA “dithers over drugs already deemed safe but whose effectiveness has not yet reached the 100% rate it insists on.” Should people have more choice to try drugs before final approval, which may take years?

U.S. v. Park



- Park was CEO of Acme Markets, a grocery store chain. He was charged with violating the FDCA, because food in warehouses was contaminated by rats.
- Park was convicted in district court; appeals court overturned the conviction holding that Park was not personally responsible. The government appealed to the Supreme Court.
- **HELD**: Court of Appeals reversed.
- The Supreme Court stated that the act punishes, “negligence where the law requires care, or inaction where it imposes a duty.”