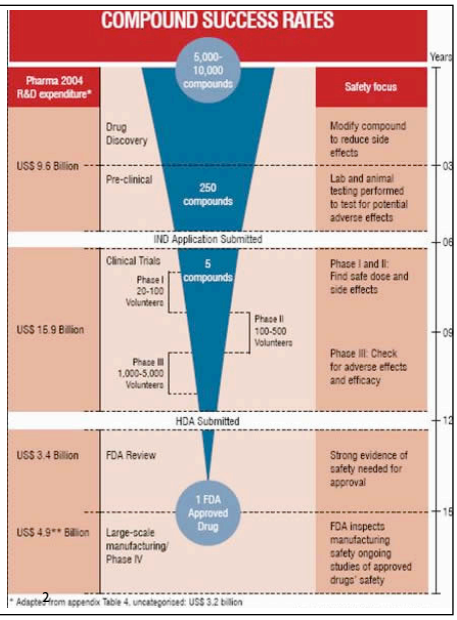
Ethical Issues around the costs of prescription drugs.

US275 Scientific Ethics
John R. Hoffman
Arcadia University

Drug Development Challenges

- only a small proportion of interesting chemicals
  - are approved as a new medication
  - time-consuming and costly process



http://www.pharmafocusasia.com/strategy/drug_development_challenges.htm

Patents provide limited protection for the drug manufacturer.

- issued by patent and trademark office
- patent protection
  - prevents other companies from manufacturing same product.
  - 20 years from date of invention
  - often filed before clinical trials
  - effective protection normally 7 - 12 years

"Innovator" drugs are the first to be available.

- Branded drugs
  - produced by the developer
  - protected by patent
- recover investment costs of drug development
  - drug discovery
  - clinical trials to prove safe and effective
  - estimated at $800 million for a new drug.

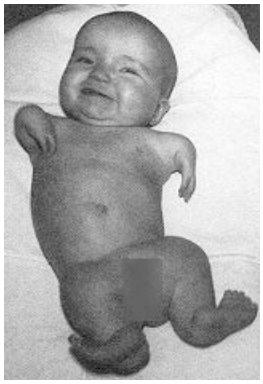
FDA grants exclusive marketing rights to manufacturer upon approval of a new drug.

Exclusivity lengths

- Orphan Drug (ODE) - 7 years
- New Chemical (NCE)- 5 years
- "Other" Exclusivity - 3 years for a "change" if criteria are met
- Pediatric Exclusivity (PED) - 6 months added to existing Patents/Exclusivity
- Patent Challenge – (PC) – 180 days (this exclusivity is for ANDAs only)

New uses of old drugs

- many drugs have multiple uses
  - new uses require
  - new clinical trials to show that the drug is effective for treatment of a new disease.
- Thalidomide
  - FDA denied approval for use as sedative
    - causes severe birth defects (1957 - 1961)
  - now used to treat multiple myeloma (form of cancer)



Generic firms challenge patents to be able to market prescription drugs.

- if successful in challenge
  - get exclusive copycat rights for six months

Generic drugs

- US Food and Drug Administration (FDA) considers a generic drug to be
  - *"identical, or bioequivalent, to a brand name drug in dosage form, safety, strength, route of administration, quality, performance characteristics and intended use."*

Generic drugs are much cheaper than branded drugs.

- Manufacturer only has to document that the biological activity is the same as the name brand drug
  - does not have to show original research and testing
  - submit abbreviated new drug application (ANDA)
- Generics save retail pharmacy users $8 - 10 billion per year

http://www.tva.gov/insidetva/sep08/generics.htm

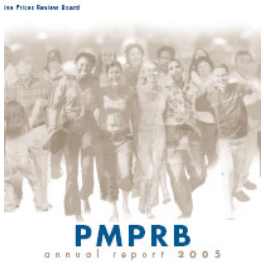
Generic drugs are not identical to brand drugs.

- cheaper
- bioequivalent
  - active ingredient the same
  - other ingredients different
- not all drugs available as generic
  - if patent hasn't expired

Canadian government has established the "Patented Medicine Prices Review Board"

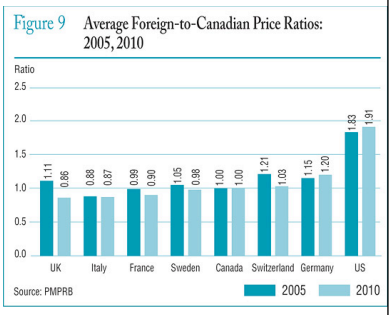
ensure patented drug prices are not excessive

- existing drugs cannot increase price by more than the rate of inflation
- most new drugs cannot cost more than similar drugs for the same illness
- new class of drug cannot cost more than the median price for the drug in other countries.



Drug prices in Canada are cheaper than in the United States.

- Government price control
  - cap on wholesale cost
- Government Health Care plan
  - buy drugs in bulk at a discount
- Lower liability
  - Court awards and damages against health care providers and drug companies much lower than in U.S.



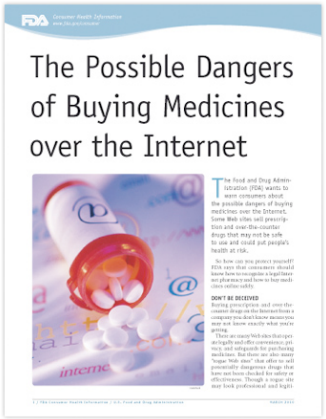
Patented Medicine Prices Review Board
Annual Report 2010

The United States is the only industrialized country with no price controls on patented medicines.

- Drug companies
  - the presence of price controls limits innovation and development of new drugs.
- Patient advocates
  - government research provides much of the basic science information needed for drug development.

Purchasing drugs outside of the country.

- No FDA oversight
  - questions of quality assurance
  - counterfeit potential
  - untested substances not available in U.S.
    - safety unknown
    - possible interactions with other drugs



FDA Consumer Health Information

The Possible Dangers of Buying Medicines over the Internet

The Food and Drug Administration (FDA) wants to warn consumers about the possible dangers of buying medicines over the Internet. Some Web sites sell prescription and over-the-counter drugs that may not be safe to use and could put people's health at risk.

So how can you protect yourself? FDA says that consumers should know how to recognize a legitimate pharmacy and how to buy medicines online safely.

DON'T BE DECEIVED

Accelerated Approval

- surrogate endpoints rather than traditional measures of effectiveness
- used for serious, life-threatening illnesses without satisfactory treatments
- example: most HIV drugs
  - however, continued study post-marketing research
  - FDA can withdraw approval

FDA Office of Orphan Products Development

- provides incentives for companies to develop products for rare diseases
  - affect fewer than 200,000 people in U.S.
  - or unlikely to recover costs of developing a new drug treatment
  - 350 drugs since 1983,
    - only 10 from 1973 - 1983

Assignment

Drug costs?

Watch the ABC news video. Vital Cancer Drug Shortage at: http://abcnews.go.com/WNT/video/vital-cancer-drug-shortage-leukemia-cytarabine-chemo-therapy-treatment-13378686

In your discussion group:
Pharmaceutical companies have to balance the goals of producing safe and effective medications while continuing to stay in business by generating a profit. However, the costs of certain vital medications may limit their availability low-patients, production rates limits the supply of medication in circulation, and other medications may not be available across the globe. At a time when illegal drugs can be obtained relatively easily, what can be done to ensure ready access to needed medications?

Readings

Follow the pill: Understanding the U.S. Commercial Pharmaceutical Supply Chain. Henry J. Kaiser Family Foundation. http://www.kff.org/rxdrugs/upload/follow-the-pill-understanding-the-u-s-commercial-pharmaceutical-supply-chain-report.pdf

Obama Tries to Speed Response to Shortages in Vital Medicines. Harris, G. (10/31/11). New York Times. http://www.nytimes.com/2011/10/31/health/policy/medicine-shortages-addressed-in-obama-executive-order.html

Supply of a Cancer Drug May Run Out Within Weeks. Harris, G. (02/11/12) New York Times. http://www.nytimes.com/2012/02/11/health/policy/supply-of-methotrexate-a-cancer-drug-may-run-out-soon.html

Averroes, Medieval Spanish-Arab philosopher and physician in *Triunfo de Santo Tomás.* Andrea Bonaiuto, 14th century

Any Questions?

Email me at:
hoffmanj@arcadia.edu

http://www.vippitbullkennels.com/images/animated-question-mark.gif