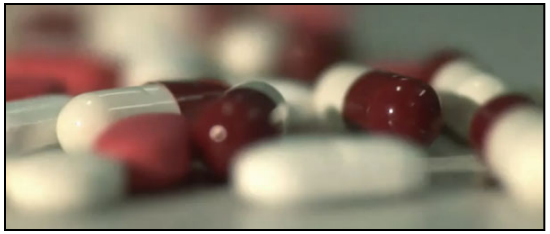
PRESENTATION



Drugs and Medical Devices
Regulatory & Industry Overview

Presented to:

Vanderbilt University

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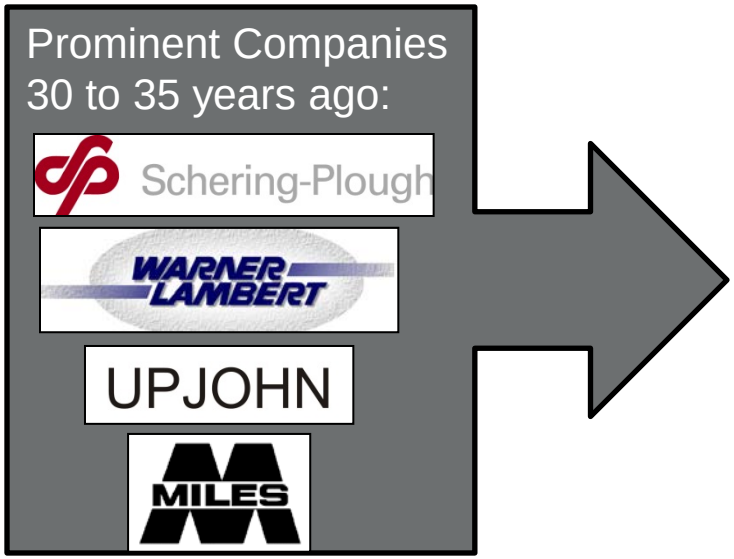
U.S. Pharmaceutical Industry Overview

Industry Overview



- Over last 4 decades the U.S. industry has undergone substantial consolidation
- Profile of the industry has changed, but certain characteristics remain

Prescription Drug Segment – *Research Based Companies*

Industry Overview

- Expense of innovative research and difficulties of obtaining FDA approval for new chemical entities have made the research driven segment of the industry smaller
- Intellectual Property, centered on the NDA approval process and reimbursement by health insurance or government, is key
- Price of newly approved drugs must provide attractive return on investment before generic competition enters the picture
- Many research-based companies maintain separate business units in related fields so they can maintain revenue and earnings stability, such as:
  - medical devices
  - over-the-counter drugs
  - dietary supplements
  - foods to maintain revenue and earnings stability

Prescription Drug Segment – *Development Based Companies*

Industry Overview

- Important part of the prescription segment is made of companies who make no pretense that they are doing innovative research in medicine:
  - Focus on drugs that are already FDA approved where the patent has either expired or will soon expire
  - Work to establish the need for the product respecting physicians is largely already done
  - Much of the work to establish reimbursement is also done
  - Emphasis is on economical, efficient production in areas that are commercially attractive

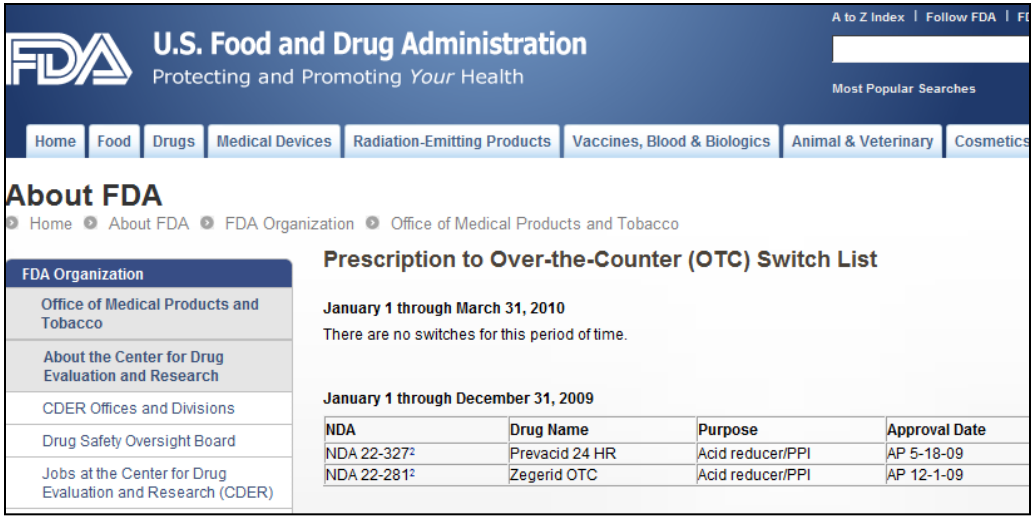
Over-the-Counter Segment

- Run with a completely different business model because over-the-counter drugs are not eligible for either insurance or governmental reimbursement
- Critical component is still intellectual property, but is it normally trademarks rather than patents
- Drivers of OTC business:
  - print
  - radio
  - television
  - social media

- Market is divided between branded and generic products
  - Generic
    - Accounts for 20 to 45% of branded volume
    - Distribution channels and methods of sale are completely different
      - Most large companies run the OTC operation as separate business unit

Over-the-Counter Segment (Cont'd)

- Area of growth
  - "Switch" (from prescription to OTC status) as strategy for maintaining profitability once patent protection expires
    - "Switched" drugs are regulated as "New" drugs and frequently require additional studies (especially label comprehension) to justify the switch



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FDA Organization

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- CDER Offices and Divisions
- Drug Safety Oversight Board
- Jobs at the Center for Drug Evaluation and Research (CDER)

Prescription to Over-the-Counter (OTC) Switch List

January 1 through March 31, 2010

There are no switches for this period of time.

January 1 through December 31, 2009

NDA	Drug Name	Purpose	Approval Date
NDA 22-327[2]	Prevacid 24 HR	Acid reducer/PPI	AP 5-18-09
NDA 22-281[2]	Zegerid OTC	Acid reducer/PPI	AP 12-1-09

FDA Drug Approval Process - *"New Drugs"*

Regulatory

(Applies to All Prescription Drugs and Some Over-the-Counter)
Approval by FDA Needed Prior to Marketing or Shipment

- Requires preclinical and clinical studies
- Must meet the "Substantial Evidence" standard
- FDA individually reviews and pre-approves label & advertisements
- Extensive annual reporting including label changes, etc.
- The most expensive and time consuming drug approval process
- Manufacturing establishment must be registered and inspected by FDA whether located in the US or abroad

FDA Drug Approval Process - *"New Drugs"*

Regulatory

(Applies to All Prescription Drugs and Some Over-the-Counter)
Approval by FDA Needed Prior to Marketing or Shipment

- Facility must meet GMP's
- Inspections on a 2-3 year cycle (if no issues)
- Distribution of NDA prescription drugs is largely limited to pharmacy wholesalers, pharmacies (including pharmacy chains and mass merchandisers with pharmacists on staff)
- Not a "legal document" prepared by lawyers but a medical/scientific document prepared by medical and technical staff
- Qualification for Reimbursement is separate from Regulatory Approval

FDA Drug Approval Process - *"New Drugs"* (cont'd)

Regulatory

Subsequent Abbreviated NDA ("ANDA") process for "New Drugs"

- Must refer to an original NDA, but must await patent expiration
- Relies on the underlying NDA, proof relates to equivalence of the ANDA drug to the NDA drug
- FDA reviews and pre-approves label & ads
- Annual Reporting to FDA
- Much less expensive and time consuming than the NDA process

FDA Drug Approval Process - *"New Drugs"* (cont'd)

Regulatory

Subsequent Abbreviated NDA ("ANDA") process for "New Drugs"

- Manufacturing establishment must be registered and inspected by FDA whether located in the US or abroad and meet GMP's
- Inspections on a 2-3 year cycle (if no issues)
- Distribution of NDA prescription drugs is largely limited to pharmacies (including chain drugs and mass merchandisers with pharmacists on staff)
- Not a "legal document" prepared by lawyers but a medical/scientific document prepared by medical and technical staff

FDA Drug Approval Process – "Monograph Drugs" (Applies to most over-the-counter drugs)

Regulatory

Not eligible for Medicare/Medicaid Reimbursement

No Product Approval by FDA Needed Prior to Marketing or Shipment

- Do not require preclinical or clinical studies
- Are not "New Drugs" because they meet the standard of "General Recognition of Safety & Effectiveness" – a higher standard than "Substantial Evidence" because consensus of qualified experts must be supported by peer reviewed published literature
- FDA retains theoretical jurisdiction over advertising but in practice defers to the Federal Trade Commission
- Manufacturers and distributors must be registered with FDA but annual reporting requirements are much less stringent
- Distribution of Monograph Drugs is usually not restricted to pharmacies; other retail establishments are able to sell monograph drugs more wholesalers therefore distribute monograph drugs

FDA Drug Approval Process – *"Monograph Drugs"* (Applies to most over-the-counter drugs)

Regulatory

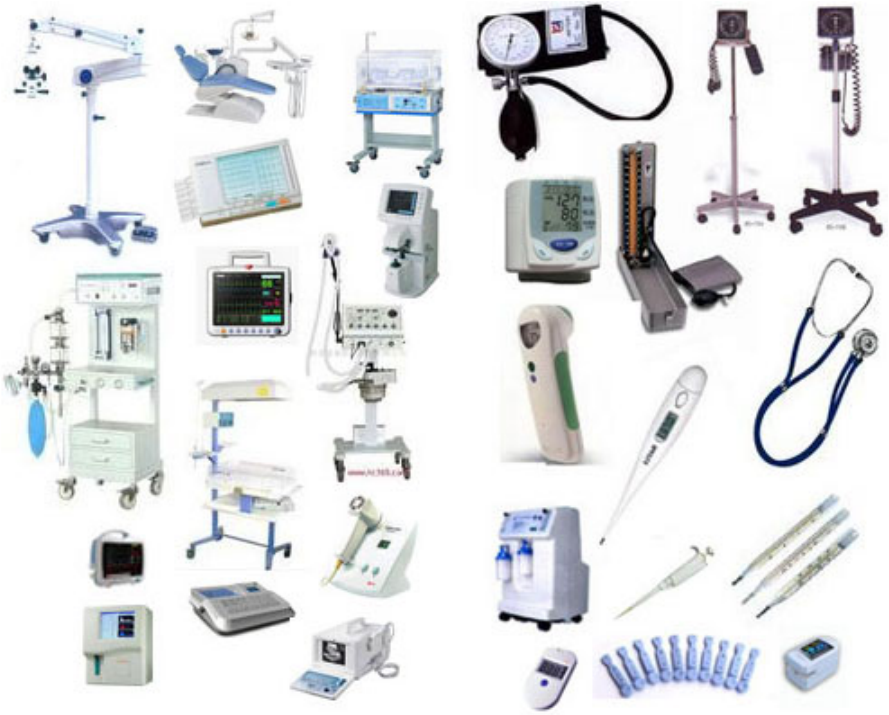
Not eligible for Medicare/Medicaid Reimbursement

No Product Approval by FDA Needed Prior to Marketing or Shipment

- Generally not eligible for reimbursement by government or insurance coverage
- Monograph drugs are sold by print, television or radio advertising of trademarked products OR by store brands competing with and comparing themselves to trademarked products
- Manufacturing establishment must be registered and inspected by FDA whether located in the US or abroad and meet GMP's
- Inspections on a 2-3 year cycle (if no issues)
- Ingredients, directions for use, warnings must meet the requirements of published FDA regulations (monographs) appearing at 21 CFR 330 and following
- Compliance with the official monograph is self-executing involving regulatory and legal judgments, but not medical

Medical Devices

- Two Distribution Classes:
  - Prescription or
  - Over-the-Counter
- Three Levels of Regulatory Complexity



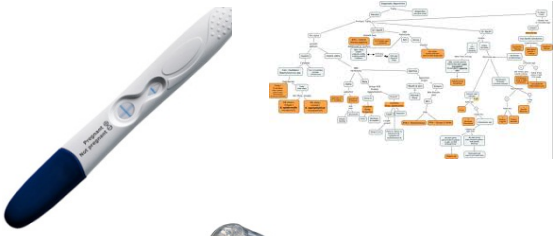
Three Pathways to Market

Class I

- Devices are not subject to FDA Premarket Approval or Notice
  - Examples: Tongue Depressors, Gauze Pads, Scalpel

Class II

- Devices require premarket notification (and FDA agreement) under §510(k) of the FDC Act
- Review of labeling, claims to establish "Substantial Equivalence" to an already approved device
  - Examples: OTC Pregnancy Tests, Diagnostic Algorithms



Class III

- Devices require formal Premarket Approval
- Generally requires clinical support, possibly under IND controls
  - Examples: Pacemakers, Implantable devices
- Accessories to Devices are regulated as Devices
  - Example: Contact lens wetting solution is not a drug, it is a device

Baker Donelson's Role

- Strategic Regulatory & Commercial Guidance
- Identification, Protection and Optimization of Patent IP
- In/Out Licensing and Technology Transfer
- Corporate Organization Including Joint Ventures
- Development of Non-Patent Intellectual Property – Trademarks, 510(k)'s, PMA's
- Litigation
- Risk Assessment and Due Diligence Investigations
- Country of Origen, Tariff, Import/Export Restrictions and Requirements