**Case Study on Nov 16th, 2007**

**Developing a Drug**

* Large US companies spend 14% of their sales around $30 to$50 Million Dollars annually on R&D
* 21st Century - 10 to 15 years to bring a new medicine in market and cost approx. $802 Million
* 1 : 5000 to 10000 tested compounds became an approved drug
* 3 in 10 drugs produced revenues which exceeded R & D Costs
* Pharmaceutical Research Programs concentrated on therapeutic diseases or seek to exploit the science behind newly discovered diseases
* Fast Growing therapeutic categories such as diabetics, Alzheimer’s memory and anti-aging attracted the most research money
* 1983 – ***Orphan Drug Act*** to help pharmaceutical companies to concentrate on diseases affecting few people (for disease affected fewer than 200,000)
  + 2006, over 280 drugs had received marketing approval under the act
* ***10/90 Act*** – 10% of pharmaceutical R & D was aimed a diseases that affected 90% of the world population

**The Process**

* Pharmaceutical companies build vast libraries of chemical compounds and they are tested against the 58000 diseases.. The company which tests more is good
* Drug development has become more molecular biology based.
* Computer modelling enabled scientists to go at a molecular level and run simulations
* Drug Development
  + Discovery
  + Preclinical Trials
  + Clinical Trials (3 phases)
* Development of drop
  + 8.8 years in 1960s
  + 13.6 years in 1990s
  + 10.9 years in 2000s
* Once Drugs are approved, there are still investigation on side affects
* CRO’s (Contract Research Organizations) - Performed functions from initial product development and clinical trial implementation to preparation of applications for regulatory approvals (Some works are outsources to CRO’s by pharmaceutical companies)
* Me-too Drugs : the drugs which could compete with block buster drugs with out infringing its patent. Only slight change in chemical composition and construction.

**Burgeoning Biotech**

* Biotechnology Industry – 1976
* By 2005 - 1444 Biotech firms in the US (found by researchers from pharma companies)
* $52.7 billions in sales – by 2015
* 2 big companies
  + Amgen (revenues over $12 billion)
  + Genentech (brought 53% of the cash generated by all biotech firms)
* Biotech companies spent the same amount of money to develop a drug
* Pharmaceutical and Biotechnological companies partnerships, deals and joint ventures (pharma companies paying amount to them)

**Growing Generics**

* Initial patents were for 17 to 20 years. Reduced to 11 to 12 years now.
* Generic drugs become competitors with less costs
* ***Hatchman-Waxan Act :*** 1984 – to protect Patents , US Government released
  + Companies needs to show the chemical and biological equivalence to the original drug
* Used to take 3 years for generics to come, but after 2005, it was out by months
* Brand drug Vs Generic - $101.71 to $ 29.82
* International competition – Tested and manufactured in developed companies

**Manufacturing Drugs**

* Chemical Engineers came up with a way to do mass production which could not be sustained by small companies
* FDA were monitoring the manufacturing process to the drug expiration
* 10% of the cost of the drug was manufacturing
* Outsourcing was done to other countries. China and India were leaders in basic manufacturing
* 120,000 chemical Engineers graduated every year in India

**Pharmaceutical Consumption**

* UK – 56% of the US Price
* Japan – 76% of the US Price
* UK had National Health Service (NHS) which was strict and lot of drugs were rejected which were sold in US
* US spent $26 Billion on R & D whereas $ 21 Billion was spent by UK
* 1997 to 2000 – US had twice the drug launches than Europe
* ***Developing Countries***
  + Pricing and access to drugs were of concern to developing countries bcoz of poverty
  + 40% of world population was out of reach to most drugs
  + Only 17% of the people were receiving drugs (One for HIV) in Africa
  + Government had less health care spending
  + Brazil allowed the manufacture of Patent drugs whereas this was violated
  + Pharmaceutical firms responded by pointing at programs to give drugs at cheaper rates or free
  + Many pharma companies made drugs to developing world and sold it at a cost
* Pharma Companies - differential strategies for different countries. Grey market developed because of this where the drugs were bought cheaply and sold at a rate to other companies

**US Market**

* Spent $1.7 Trillion on Health care and around $5700 per person
* US – patients need a prescription for a drug to be disbursed
* 2005 –
  + 51.5% of drugs were dispensed at chains such as Walgreens,
  + 21.7% - independent pharmacies and the rest
  + 26.8% - food stores, long term care facilities and mail order

**Rise of Managed Care (MCO)**

* Rising Health care costs gave way to Managed Care Organization (MCO) (20th century)
* MCO contacted employers to offer medical care for employees
* 1988 to 2002 – fee for service coverage declined from 73% to 5%
* MCO grew from 27% to 95%
* Insurance grew – 70.4% were covered by Govt or Pvt Insurance
* MCO’s contacted PBM’s for large dispense of drugs
* 1990’s – Drug companies integrated, forwarded and purchased major PBM’s
* 1993 – Merck acquired Medco Containment services - $6 billion
* 2003 – Merck had Medco - $2 billion
* 2006 – CVS acquire caremark - $21 billion
* PBM’s and MCO’s developed “disease management programs”

**Access & Pricing**

* 14.2% - no health Insurance
* 1997 – 13.6% ; 2005 – 16.8% - received Insurance from Govt (> 65 years)
* 2004 - Part D – for elderly and disabled people
* Cost for Part D increased ($16.2 Trillion compared to $13.4 trillion for Social Security)

**Selling & Marketing Drugs**

* Less time with Doctors for reps
* 1997 – media advertisements
* DTC (Direct to Customer) advertisement - $4.2 billion
* 2005 – guiding principles for DTC

**Merck & Co**

* Merck - Excellence in Research (Science Led company)
* Doctors recommendation – “Gold Standard” of pharmaceutical research
* 2001 - Top 2 drugs in 5 therapeutic categories

**Research**

* FDA Approval rate of 70% compared to 50% industry standards
* Hire top Scientiests - credential
* 2001 - Peter Kim – Top academic researcher
* 2006 – 6 major labs across NA and Japan, smaller laps in UK, France, Spain, Italy and Japan
* Focus on developing block buster drugs (drugs which have more than $1 Billion profits)
* Entered new files –
  + 1986 – Diabetics
  + 1991 – Bone Disease
  + 2004 – Cancer
* 2005
  + $23 billion in annual sales
  + 62000 employees in 120 countries
  + 31 factories world wide
  + Revenues from 200 countries outside US
* Differential pricing for different companies

Drawbacks

* 2003 - Potential block buster drug failed clinical trials
* 2004 - Company withdrew arthritis drug , Vioxx
* Stocks fell by 60% in 2000

**Mergers**

* Mergers could take place to
  + take advantage of economies of scale
  + address revenue shortfall which might fall after patent expirations
  + gaps in drug development pipelines
* 20% & 30% of sales from externally licenses drugs
* 1999 – 10 outside alliances
* Mergers were to complement the R & D effort (as per Kim)

**Marketing**

* Did not believe in Marketing initially since the products were good
* 2004 – thoughts changed (molecule was the product, now label is the product)
* Zocor – blockbuster drug
  + 1996 Pfizer introduced Lipitor
  + Due focused marketing approach, sales went up for Lipitor to $12.2 Billion compared to $4.4 billion of Zocor
* Under Gilmartin, they started to concentrate on marketing
* ***Mirroring*** strategy reduced. Number of reps visiting the doctors on the same drug was reduced
  + More emphasis on the drug value, cost effectiveness and efficacy was discussed
* Each Therapeutic category, an increased focus by business strategy teams
* Operational Excellence was stressed to reduce costs

**Current Challenges & Response**

* Litigation Liability for drug Vioxx
  + 1999 to 2004 – the above drug was sold, then with drawn in Sept 2004
  + Annual sales was $2.4 billion when it was withdrawn
  + More than 18 months of usage of drug – increased risk of cardio vascular incidents in patients
  + 2006 – 14,200 lawsuits for 30,000 patients
  + Liability of $4 to $ 10 Billion which can increase to $25 billion
  + Merck decided to fight cases as it wanted to prove the reasons for heart attach problem can be different
* Expiration of number of patent drugs
* Companies ability to replace the block buster drugs
* General Restructuring plan
  + Close 5 manufacturing plants
  + Reconfigure Operations to speedup production
  + Lay off 7000 employees
  + **2006** – focus on nine priority disease areas

**Pfizer Inc.:**

* 2005 – Largest pharmaceutical company with
  + sales of $51 billion
  + 106,000 employees
  + 10% share of worlds prescriptions
  + 14th largest firm in 1990 – grown through mergers
    - 15 were leaders in therapeutic markets
    - More than 8 were block buster drugs including Lipitor
* Spent $7 billion on R & D
  + 47% higher than the closest competitor
  + Employed 12,000 researchers

**Research**

* Pfizer had the worst pipeline relative to its size in the global industry
* Sales – recently launched drugs were not good
* Forced to delay anticipated drugs
* Declining R & D productivity
* No block buster drug was developed in the lab since 1998
* 2006 - had 9 major labs through US, UK, Japan and as well as satellite labs around the world

**Marketing**

* Best and effective marketing and largest sales force in the Industry with 9000 reps
  + Each rep costed $1,70,000 per year including car, computer and benefits
* Advertising budget of $3.5 Billion in 2005
* Different reps might visit the doctor for the same Pfizer drug
* Good Recognition of reps (Top Down)
* Partner of choice for Biotech firms in marketing
* Bundle drugs in negotiations with PBMs

**Mergers**

* Warner Lambert – acquired the company who asked for help in marketing (Lipitor the block buster drug)
* Cost reduction of $ 270 million after merger with Warner Lambert and American Home Products
* Pharmacia – sell Cox 2 inhibitors to treat arthritis (Merger in 2003)
* Top in Japan and Europe, 4th in US
* After pharmacia , closed 3 major centers

**Current Challenges & Response**

* Patent challenges in Lipitor and Celebrex
* Pfizer Reps had improperly promoted drug uses that the FDA did not approve
* Some drugs were withdrawn (Bextra - $1.3 Million in revenue, Celebrex with 2004 sales of $3.3 billion)
* Lost Patent protection for one of the top selling drugs Zoloft in 2006
* 2005 announced cost cutting initiative
  + Plan closings
  + Administrative cut backs
  + Streamlining sales force
* 2006 – Sold consumer health care business to Johnson and Johnson (had revenue of $3.9 billion) – was sold for $16.6 billion
* $17.7 Billion of its excess cash on future acquisitions
* $17 billion to buy back stock