



Pharmaceutical Policy and Politics Clerkship

UMass Medical School/Center for Health
Policy and Research (CHPR)

Introduction

- National spending on prescription drugs was \$154 billion in 2001 and is expected to reach \$366 billion in 2010. While prescription drugs only represent around 10% of total health expenditures, their rising costs are having a profound effect on Medicaid programs, private insurance premiums, hospital budgets, and those paying out-of-pocket.
- Increased prescription drug expenditures can be attributed to increases in utilization and rising drug prices. Senior citizens, in particular, have rallied legislators to address the high cost of their medications. Such efforts led Congress to pass the 2003 Medicare Modernization Act, establishing a drug benefit as part of Medicare. Legislators and interest groups have also proposed importing prescription drugs from Canada, where prices are as much as 40% cheaper than in the U.S. Others believe that the only way to keep prescription drug prices in check is for there to be price controls in place.
- The most significant challenge to making prescription drugs more affordable is the pharmaceutical companies themselves. These companies claim that price controls would prevent them from recouping money spent on drug development and from raising enough money for future R&D. However, many people argue that pharmaceutical companies can afford to lower prices since they spend more than \$19 billion dollars a year on marketing and less than half this amount on R&D.

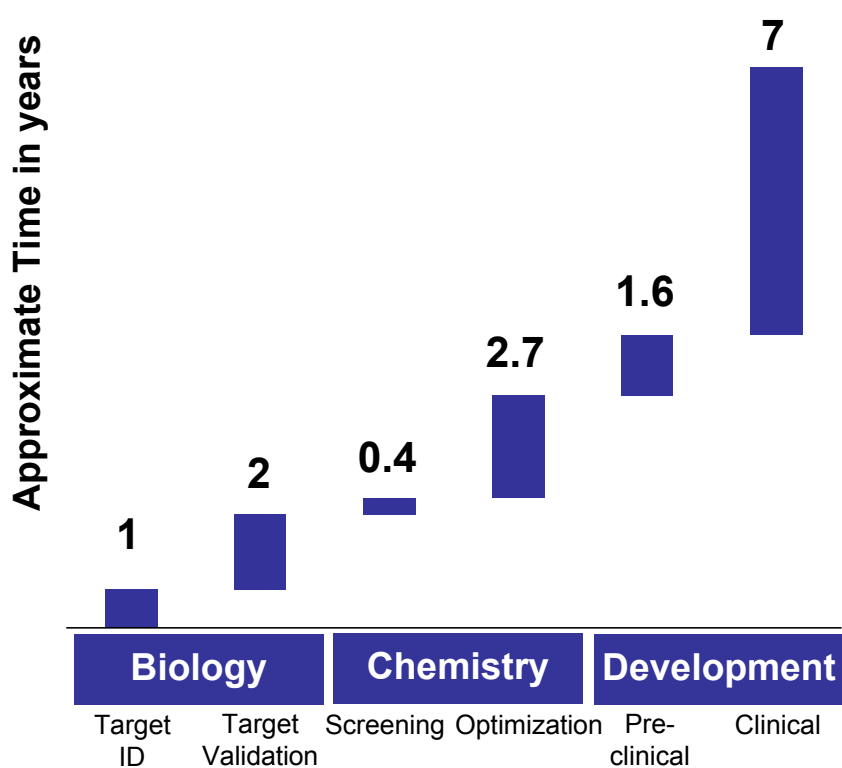
Why Are Drug Prices So High?

- The estimated cost of bringing a drug to market is approximately \$880 million
- In 2000, the top ten companies spent an average of 14% of sales on R & D and 36% on marketing/advertising
- Price discrimination: pharmaceutical companies sell drugs at variable rates (uninsured purchasers pay the most)
- Patent extensions by introducing newer versions of same drug
- Sometimes new drugs are priced according to a certain therapeutic value, i.e. a cost comparable to a surgery that the drug replaced
- Currently, in the United States, there are no price controls because the government has little or no bargaining power
- In all other modernized countries, systems are in place so that the government has considerable bargaining power with pharmaceutical companies
- In 1999, the United States accounted for 41.3% of the world pharmaceutical market

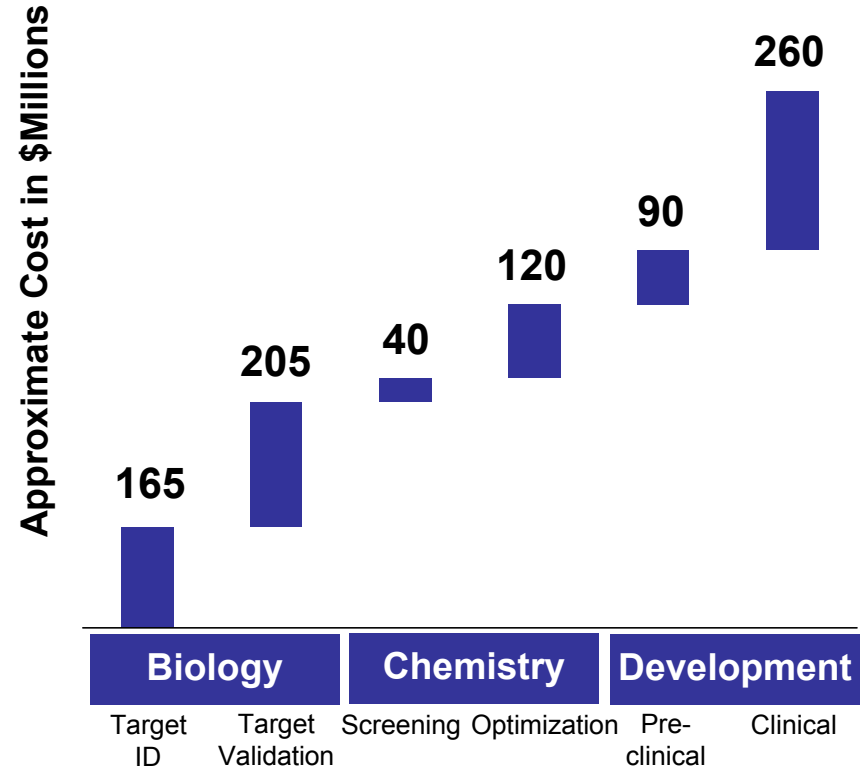
Source: The Boston Consulting Group, 2001 as cited in Tutty, 2004

Drug Research and Development is Expensive and Time-Consuming

Time: 14.7 years total



Cost: \$880 million total



Note: Cost of drug includes failures. Target identification includes initial experiments that companies may have outsourced to academic research institutions. Source: A Revolution in R&D: How Genomics and Genetics are Transforming the Biopharmaceutical Industry, The Boston Consulting Group, November 2001

How Patients Are Affected

- Uninsured
 - Increased price means decreased access
- Free care
 - Increased price leads to significantly diminished revenue for community clinics because free care pharmacies are only reimbursed 25% of the cost of the drug
- Medicaid
 - Increased price results in decreased number of patients enrolled due to fixed budget
- Medicare
 - Out of pocket expenses for seniors increase
- Private Insurance Companies
 - Pharmacy costs rose 14-16% in 2003
 - Increased costs result in higher premiums for businesses enrolled in program, eventually passing costs onto patients



Addressing Rising Rx Drug Prices

- Drug Re-Importation
- Litigation Against Drug Companies
- 2003 Medicare Modernization Act
- National Healthcare
- Physician Responsibility
- Price Controls
- Improving Access to Healthcare



Drug Re-Importation from Canada

- Canada's government sets price controls on American-made drugs
- Due to unregulated drug market in US and single-payer system in Canada, these price controls can be implemented
- Re-importation has already been approved at the city, county, and state level
- Examples: Springfield, MA; Montgomery County, MD; New Hampshire
- Patients mail or fax hard copies of their prescriptions and information forms to the Canadian companies, and are mailed their drugs

Drug Re-Importation Continued

■ Advantage

- Since Canada pays approximately 60% as much as the US does for drugs, this is a good alternative to paying full price

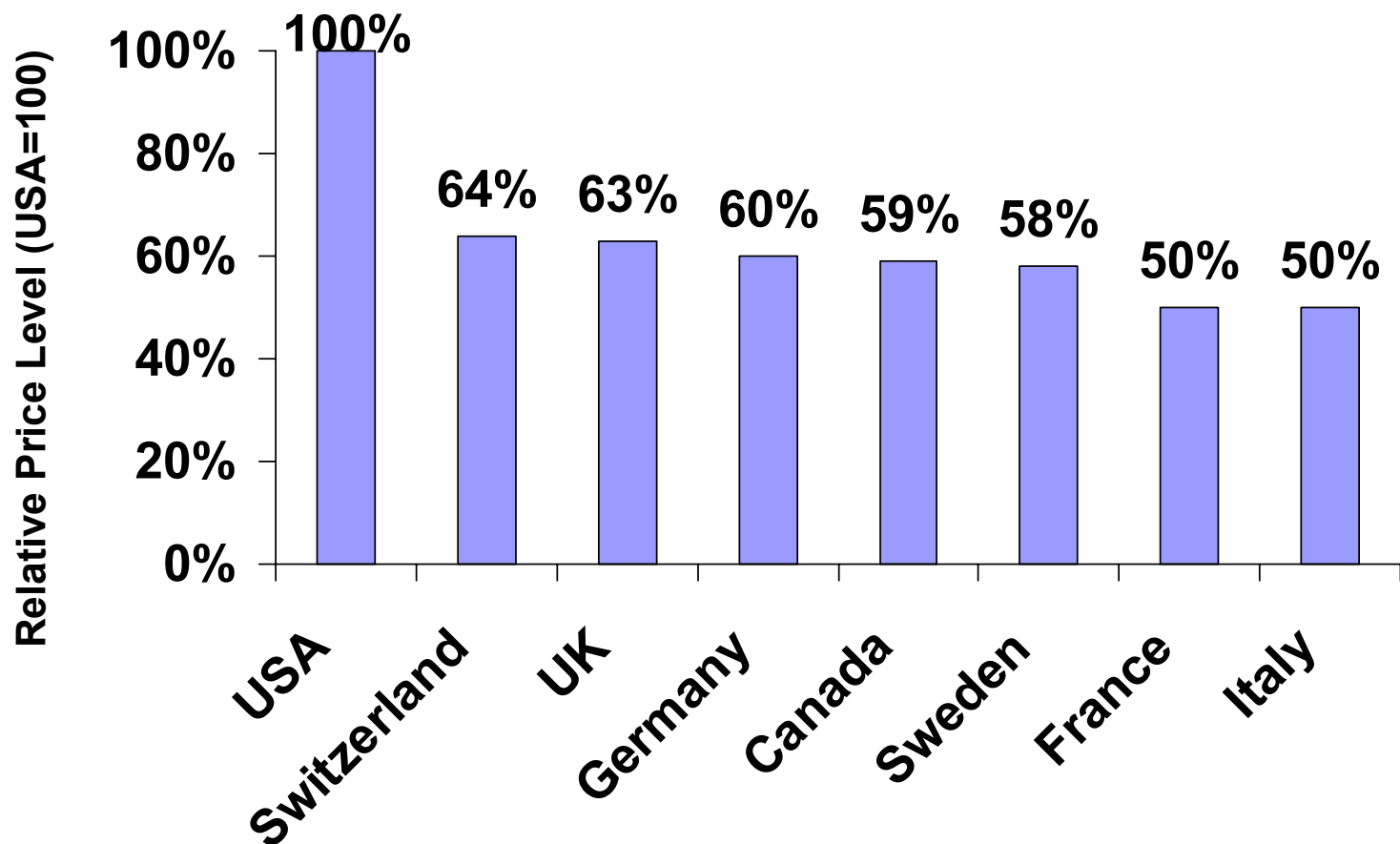
■ Disadvantages

- Canadian version of the FDA is not as stringent as US FDA
- Counterfeit drugs, bogus websites, scams
- Liability issues
- Volume: Canada could never buy enough drugs to support the amount of needed in the US

■ Conclusions

- Importation could work as a temporary patch for keeping costs down but will not be the final answer
- Candidates focusing on the issue because it is a “wedge issue”: easy to understand and makes for nice sound bytes

Average Foreign-to-American Price Ratios: All Patented Drug Products in 2001



Note: Percentages reflect relative price levels of drugs sold by manufacturers to wholesalers, hospitals, and pharmacies

Source: Patented Medicines Prices Review Board, "2001 Annual Report," Province of Ontario, Canada, 2002 (www.pmprb-cepmb.gc.ca)

Litigation Against Drug Companies

- Organizations like Prescription Access Litigation (PAL) Project file suits against drug companies for price gouging and manipulation, payoffs of generic companies, and patent fraud
 - Hope is that litigation will alter drug company behavior and practices

 - Advantages
 - Early success with lawsuits: 2 cases settled in 2 months against Bristol-Myers Squibb (\$42 million) and GlaxoSmithKline (\$75 million)
 - Much of settlement monies go to consumers
 - Disadvantages
 - Drug company behavior difficult to change
 - Settlements are relatively small compared to profits
 - Companies often deny any wrongdoing even after settlements
 - Conclusions
 - Organizations like PAL are necessary as watchdogs for drug company behavior
 - Only so much that can be done-settlements can be a drop in the bucket and companies are stubborn in regards to ethics changes
- Source: Prescription Access Litigation Project

Medicare Modernization Act (MMA)

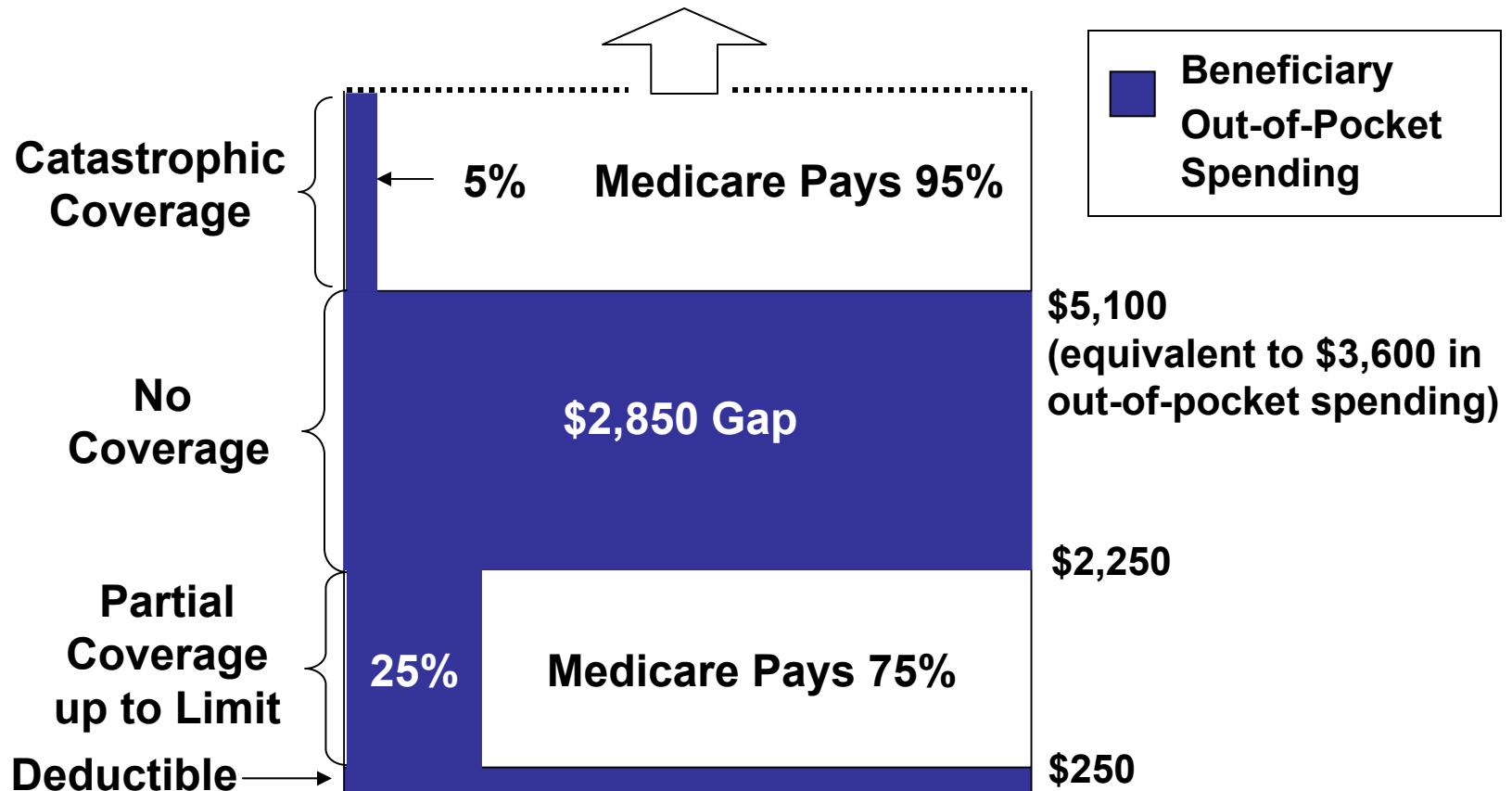
- Medicare will provide prescription drug benefit to beneficiaries through a new fourth component: Medicare Part D

- Coverage depends on income and assets
 - Standard Benefit
 - Income >150% Federal Poverty Level (FPL): coverage gap (“donut hole”) exists
 - Partial Subsidy
 - Income between 135% and 150% of FPL: no coverage gap
 - Full Subsidy
 - Income below 135% FPL: no coverage gap

MMA Continued

- Encourages privatization
 - \$89 billion in subsidies and tax benefits to encourage employers to cover retirees
 - \$14.1 billion over 10 years to private plans
- Restricts eligibility for low-income patients
 - Asset test required for beneficiaries to receive partial or full subsidies
- No mechanism for pharmaceutical cost control
 - Government unable to negotiate prices with drug companies
 - No change in current law for re-importation
- Large coverage gap in Standard benefit
 - Beneficiaries receive no assistance between \$2,200 and \$5,000 in pharmaceutical drugs

Medicare Beneficiaries' Out-of-Pocket Drug Spending in 2006



**New Medicare Rx Benefit
+ ~\$420 in annual premiums**

Note: Benefit levels are indexed to growth in per capita expenditures for covered Part D drugs. As a result, the Part D deductible is projected to increase from \$250 in 2006 to \$445 in 2013; the catastrophic threshold is projected to increase from \$5,100 in 2006 to \$9,066 in 2013.

Taken from KaiserEDU.org

National Healthcare

■ Problem

- 45 million Americans are without health insurance
- Two thirds of the uninsured are employed workers and their families
- Seniors covered by Medicare struggle with rising out of pocket costs, in particular for prescription drugs
- Medical bills are responsible for nearly half of all personal bankruptcies (79% of families filing for bankruptcy have health insurance)
- The administrative costs associated with the present system would be enough to cover all the uninsured

■ Solution

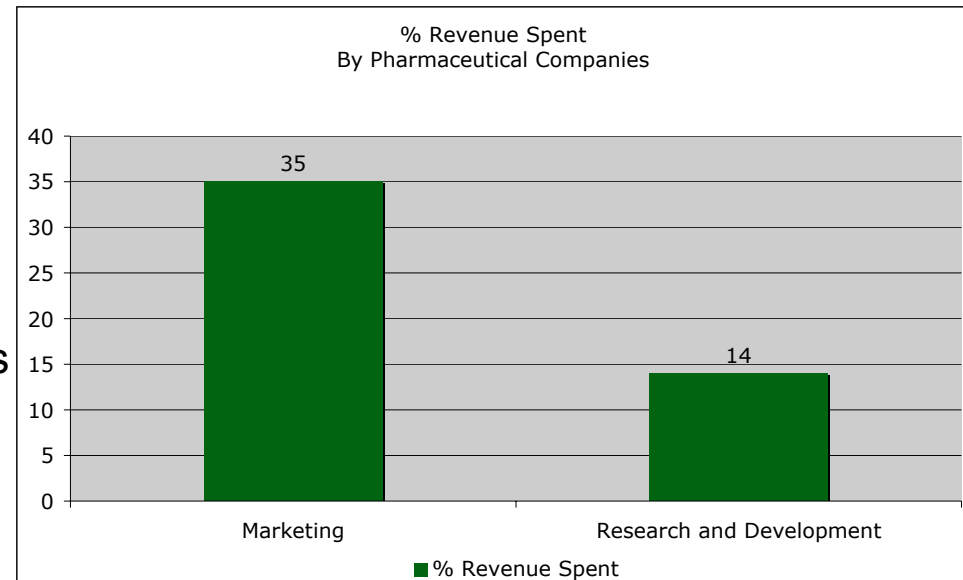
- Universal health care coverage, which means that all Americans would have insurance
- Care would be portable, accessible, and comprehensive. Most notably, there would be **no** out of pocket payments
- This system would be government financed and delivered mostly under private control
- This would mean the end of for-profit health care providers

Physician Responsibility

- Concept: Physicians are ultimately responsible for drug utilization.
 - Regulate the Utilization of Drugs:
 - Prescribe only what is necessary
 - Utilize generic drugs when possible
 - Educate the patient about generics v. brand name
 - Know the cost of what one's prescribing
 - Try alternative therapies (e.g. over-the-counter)
 - Educate Yourself:
 - Critically read/review medical literature
 - Listen to drug reps with a skeptical ear and ask questions
 - Utilize unbiased sources, e.g. *Medical Letter* & Epocrates
 - Adopt an Ethical Standpoint:
 - Weigh PhRMA's Ad benefits against ethical responsibility
- Cons- More time consuming and greater liability.

Price Controls on Pharmaceuticals

- Currently, U.S. Government does not regulate prices of pharmaceuticals
- Other advanced countries negotiate with U.S. drug companies for fair prices
- As a result, we pay more for our own drugs than do other nations
- Drug companies were the most profitable of all Fortune 500 companies last year, yet they justify high drug costs by suggesting they need to recoup for R&D.
- However, drug companies spend far more on marketing (35%), and shareholder profit than they do on actual R&D (14%)
- Implementing price controls in the US would lower the rising costs of health insurance, while limiting the political power of pharmaceutical companies



Improving Access to Healthcare

- Plan proposed by Health Care For All
(Non-profit organization devoted to bringing social justice values to the healthcare system)
 - Cover the uninsured
 - Affordable coverage for everyone
 - Fairness: employers must cover or contribute
 - Lower costs
 - Assist individuals and small businesses
 - Fair payments to doctors and hospitals
 - Improve quality
 - Public health commitment to health quality

Conclusions

- Pharmaceutical companies too powerful
 - Favored strongly by MMA
 - Shapes health policy through large monetary contributions
 - Drug prices too high and completely unregulated
- Physician's role is critical
 - Social responsibility
 - Education
 - Regulate prescription utilization

Resources

- **Health Care For All**
www.hcfama.org
- **Prescription Access Litigation**
www.prescriptionaccesslitigation.org
- **Executive Office of Health and Human Services**
www.mass.gov/portal/index.jsp?pageID=eohhs2homepage&L=1&L0=Home&sid=Eeohhs2
- **Center For Health Policy and Research**
www.umassmed.edu/healthpolicy
- **Physicians For a National Health Program**
www.pnhp.org/

Acknowledgements

- Jay Himmelstein, MD, MPH
- Michael Tutty

- Fran Anthes
- Thutrang Chang
- David Clive, MD
- David Seaver
- John McDonough, Dr.PH
- Brian Rosman
- Renee Hodin
- Marcia Hammas
- Stephen Mulloney
- Robert Nocon

- Dennis Lyons
- Katrina Iserman
- Dolores Mitchell
- David Himmelstein, MD
- Eileen McAnney
- Helen Flaherty
- Paul Jeffrey
- Ron Steingard, MD
- Charlie Alagero
- Andrea Grande
- Amelia Dungan
- John O'Brien
- Tim Cummins

Pharmaceutical Policy Clerkship 2004

