



Patents & Access to Medicines in Developing Countries: An Economic Perspective

Dr. Kristina M. Lybecker

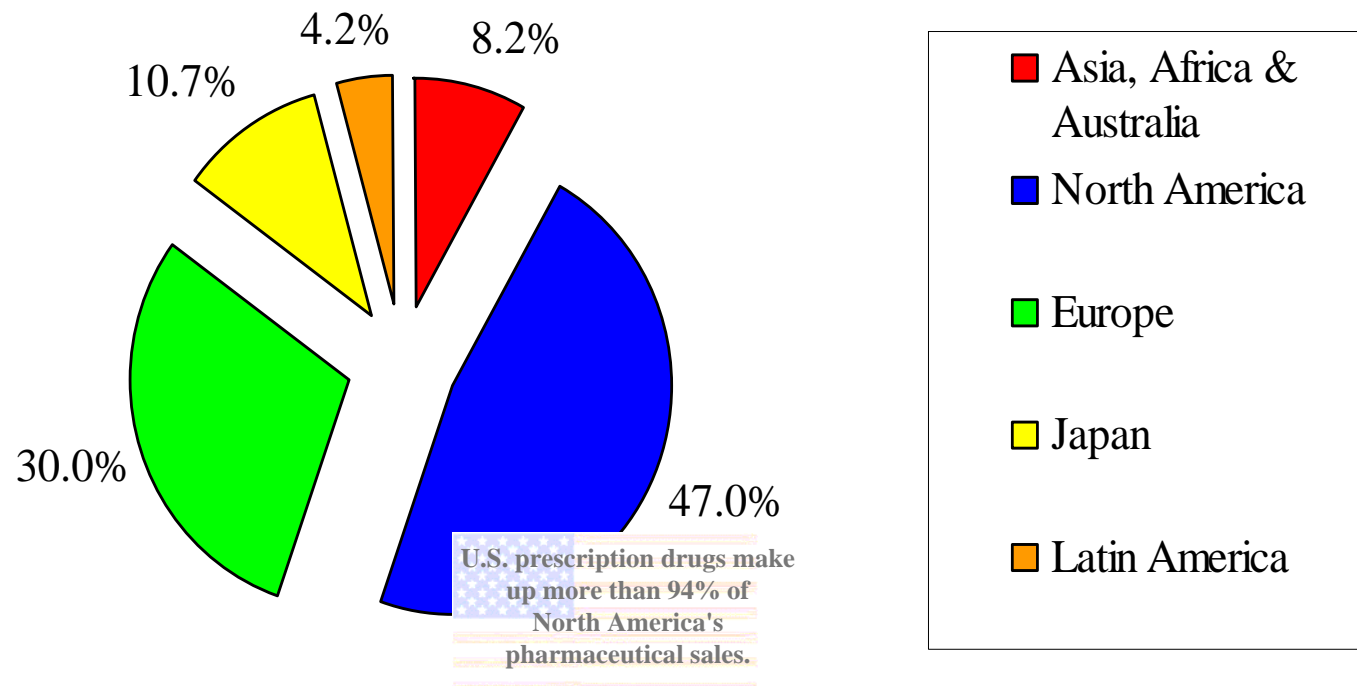
Department of Economics & Business
Colorado College
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The Market for Drugs: \$565.9 billion

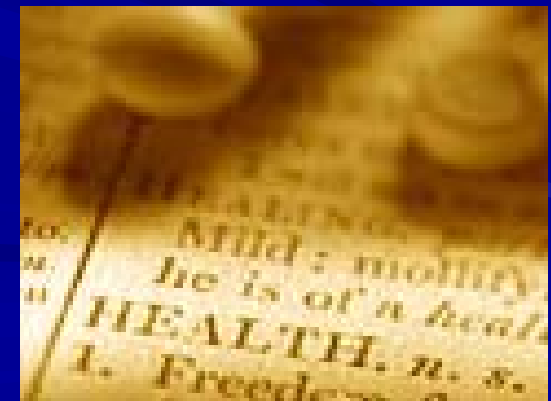
Pharmaceutical Sales by Region 2005

(US billions)



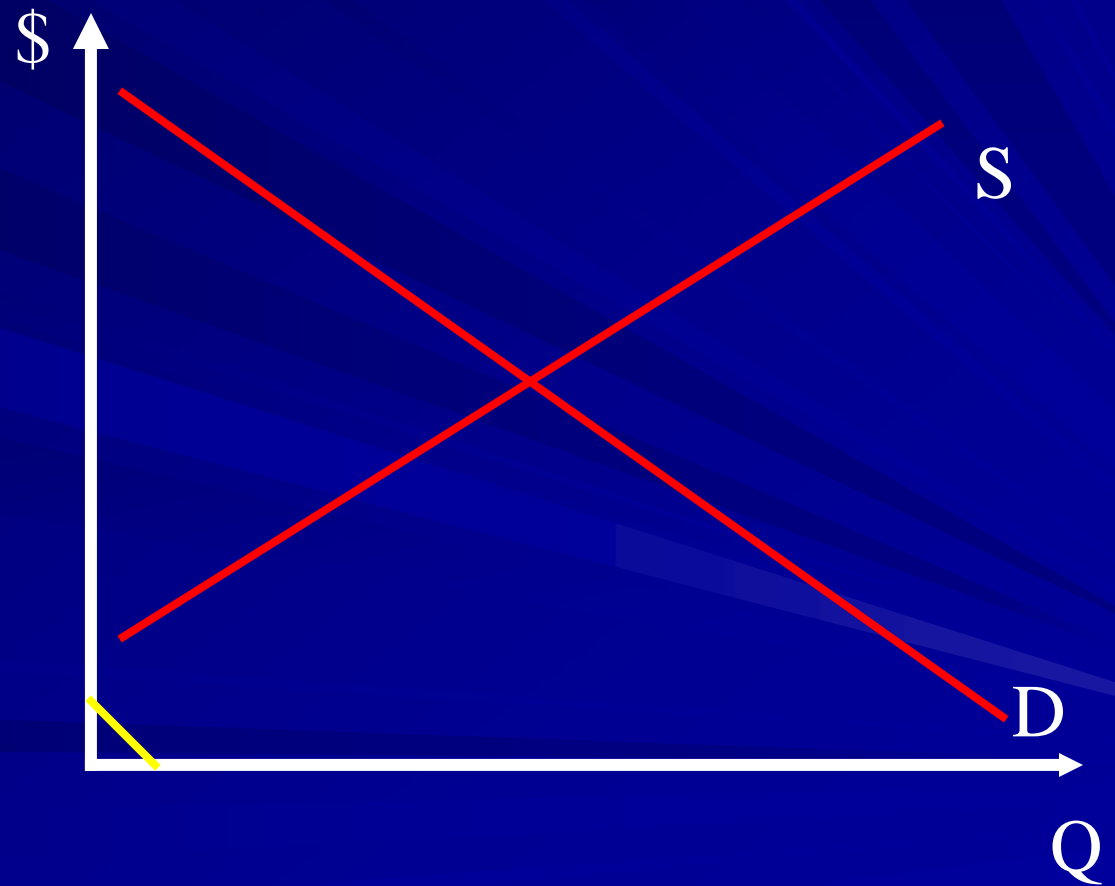
The Role of Patents : Bone of Contention

- **Two Perspectives**
- **Patents are...**
 - **Essential to protecting and preserving innovation on a global scale**
 - **A principle barrier for many consumers in developing countries to affordable medicines**



The Market for Drugs

- Unique Supply and Demand Characteristics



The Heart of the Industry: Innovation

patents are again seen as “unambiguously the least effective of the appropriability mechanisms”

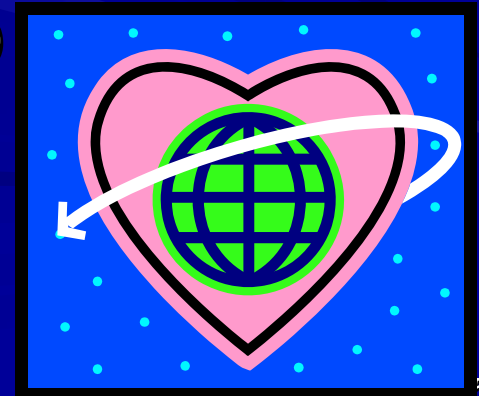
the drug industry regards them as strictly more effective than alternative mechanisms

Propensity to patent...

99% of product innovations (rank 1st)

43% of process innovations (rank 4th)

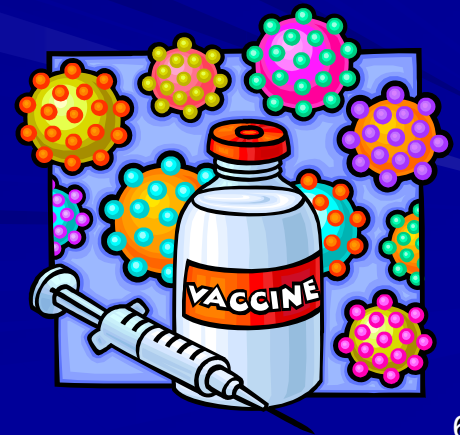
Levin, Klevorick, Nelson and Winter (1987), Taylor and Silberston (1973), Scherer (1997), Mansfield (1986), Mansfield, Schwartz and Wagner (1981), Tocker (1988), Mossinghoff (1998), Peretz (1983), Mossinghoff (1987), Santoro (1995), Smith (1990a, 1990b), Mossinghoff and Bombelles (1996), PhRMA (1997), and Bombelles (1999).....



Innovation: Difficult & Expensive

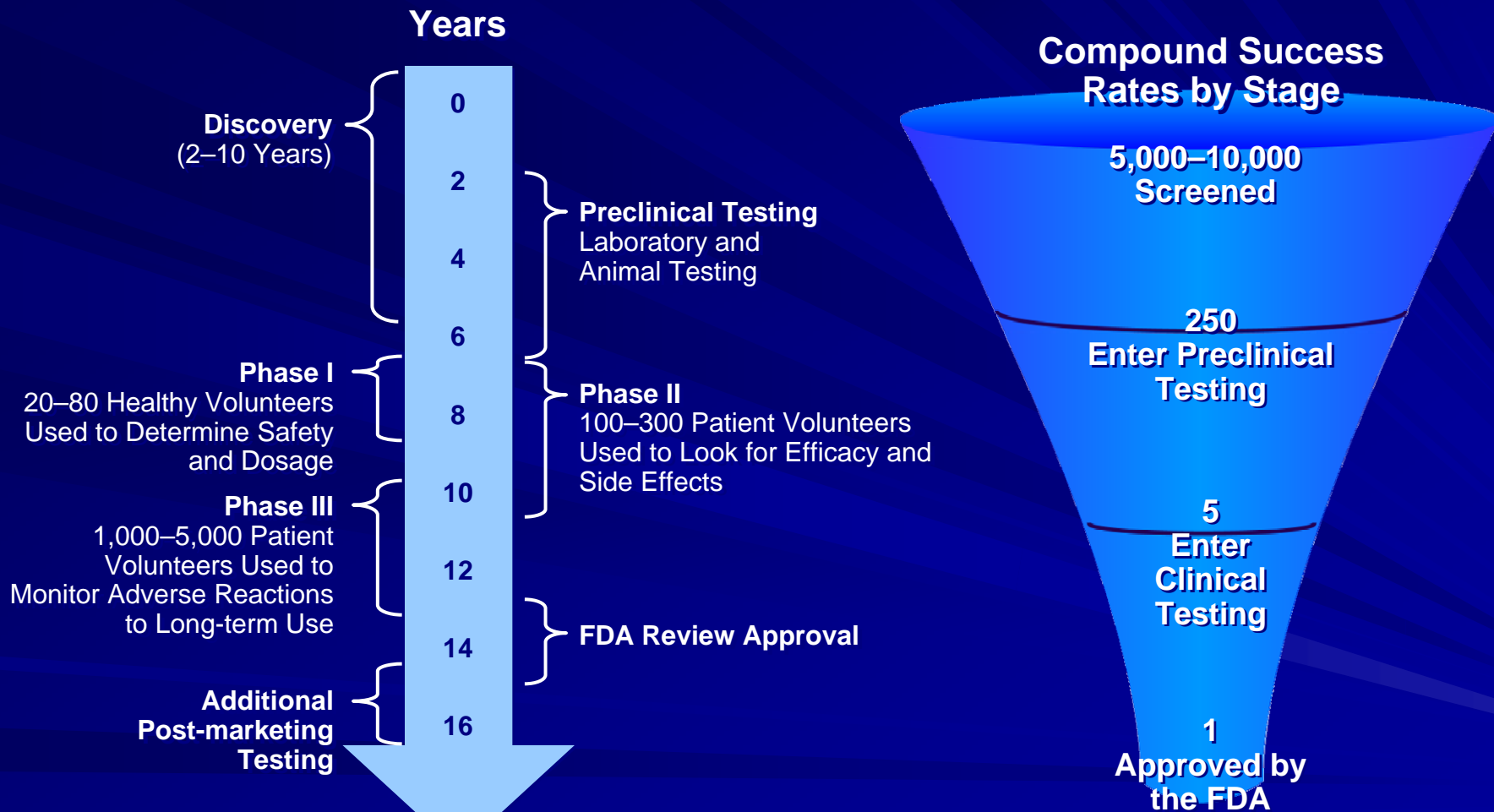
Imitation: Easy & Cheap

- Patents: disproportionately important
- High fixed costs of drug development
 - \$868 million (FTC): controversial!
- (Relatively) Low cost of production
- Incentive for Innovation: tradeoff



New Product Development

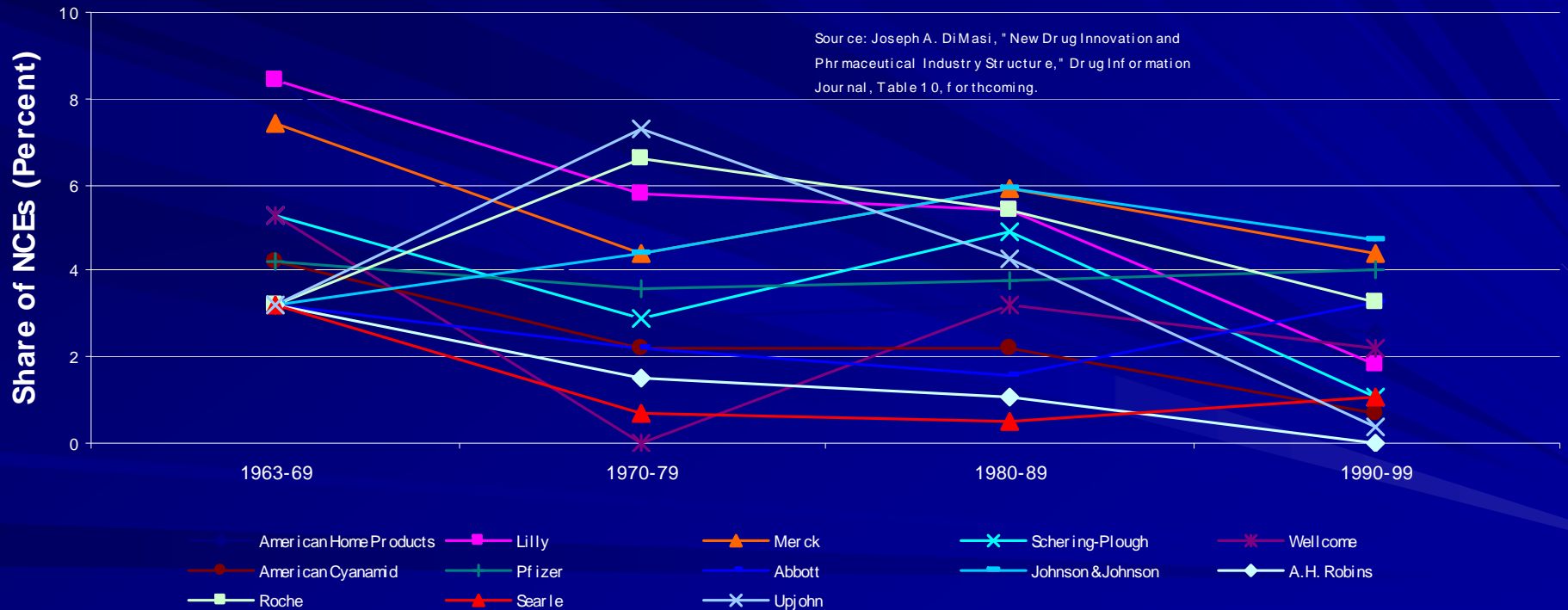
Risky and Expensive



**Net Cost: \$868 million
invested over 15 years**

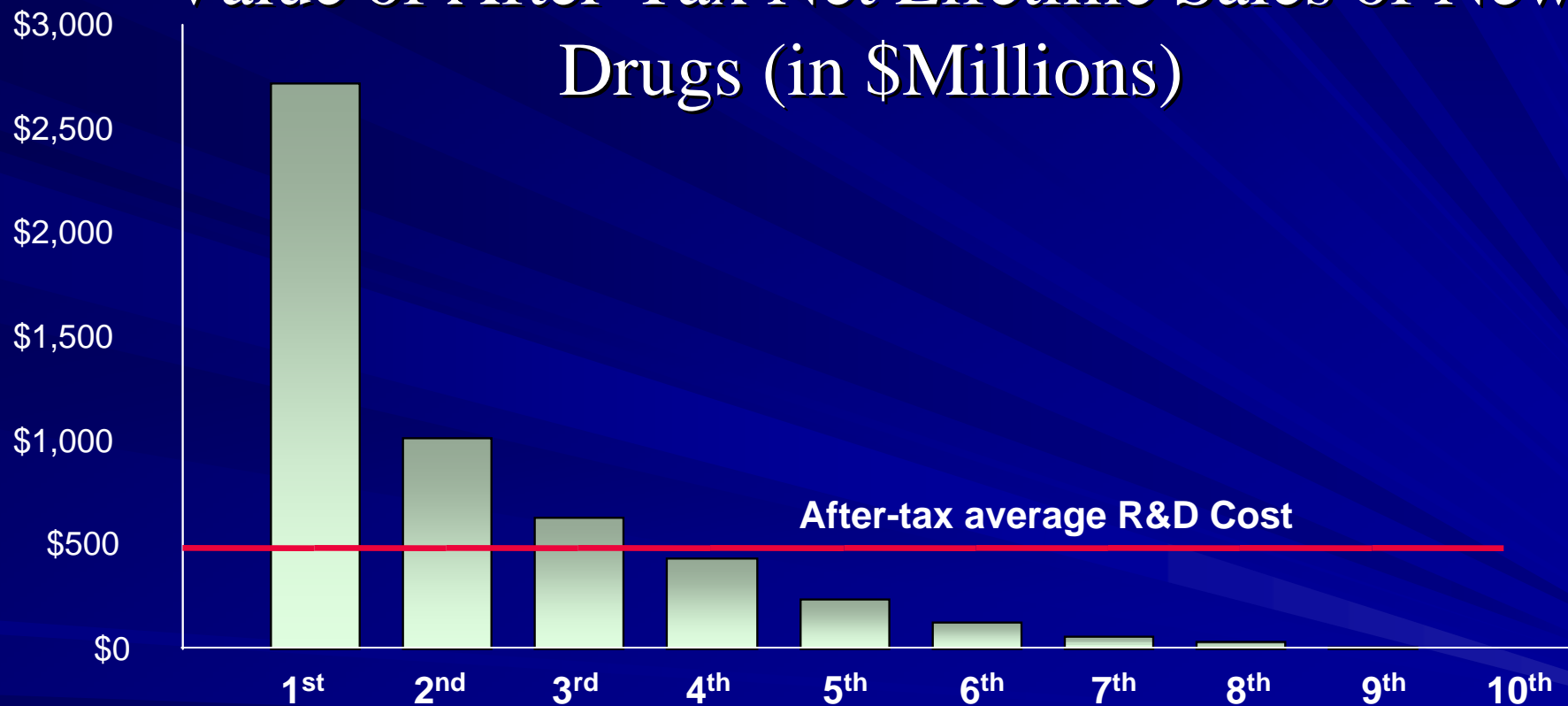
Source: Tufts Center for the Study of Drug Development
Thanks to Robert Helms

Share of NCEs by Leading Companies, 1963-1999



Most Products that Get to Market Never Make Enough to Recoup R&D Investment

Value of After-Tax Net Lifetime Sales of New Drugs (in \$Millions)



New Products Grouped in Tenths According to Financial Success

Drug Discovery: Difficult, Costly, Unpredictable

- Patents are **SUPER** important... or are they?
- Recent Study (Attaran, 2004)
 - Not on-patent
 - Not in-effect



Findings

Attaran, Health Affairs, May/June 2004

- **WHO's Essential Medicines List**
 - 319 medicines
 - 17 patentable (1.4%)
 - 65 nations, 4 billion people
 - When patentable, patents exist only 31% of the time



Link between Patents & Prices: Ramsey Pricing

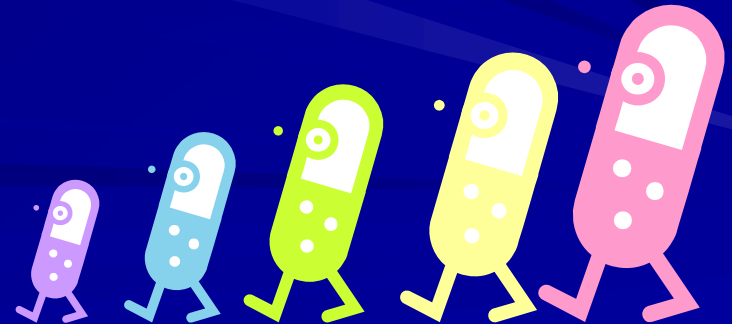
- Tremendous fixed GLOBAL cost: \$868 million
- Price Discrimination to ENHANCE Access
 - Economic Theory points to Ramsey Pricing
 - Different Prices based on Price Sensitivity
 - Maximize consumer welfare while recovering costs
- Unfortunately
 - Even MC too costly for many



**Not Patents.
Not Prices.
...then what?**

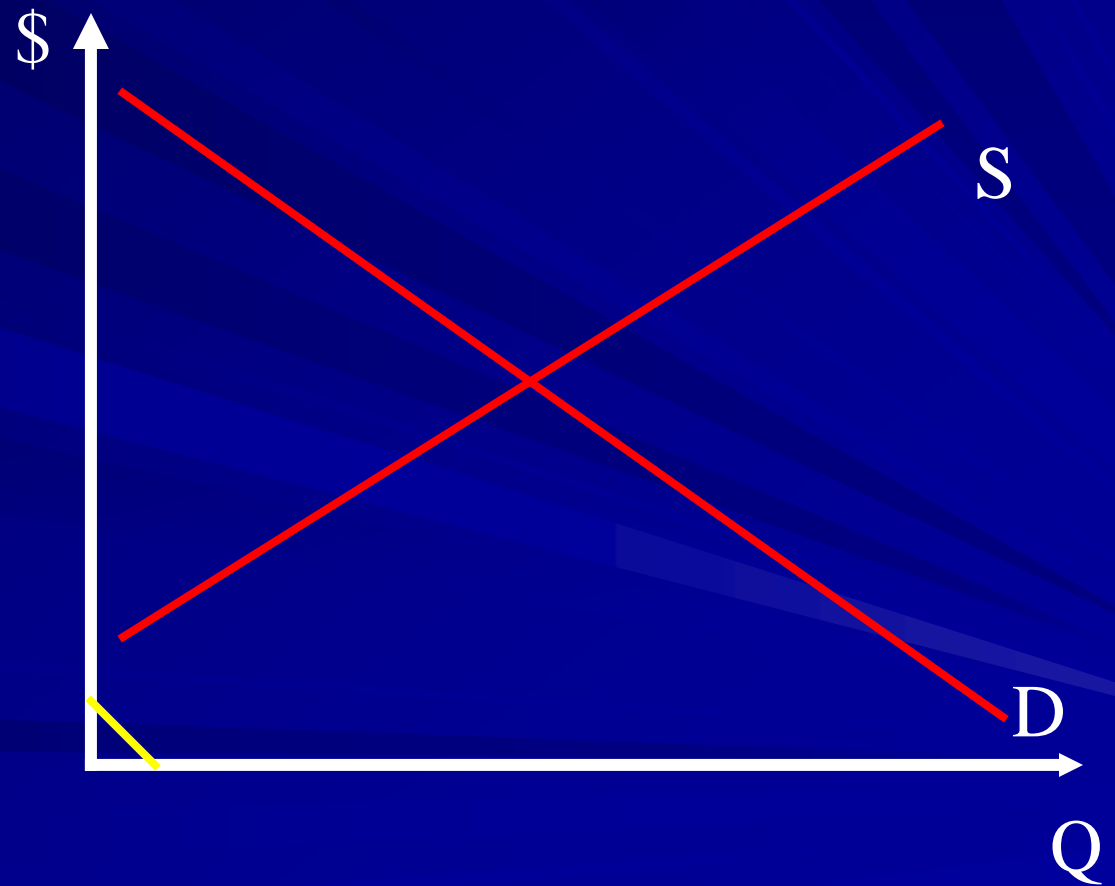
Looking for the Demand Side

- **For Sales and For Research**
 - **Pharmaceutical Firms need a Market**
- **Barriers to Access**
 - **if not Patents...**
 - **if not Prices...**
 - **Then what?**
 - **Poverty**
 - **Pirates**



The Market for Drugs

- Supply and Demand



The Market for Drugs

- Supply and Demand

- A closer look...



The Demand-side: Patients

- Quantity Demanded

the quantity consumers are willing and able to purchase over a specified period of time.



“The poor have no consumer power, so the market has failed them. I’m tired of the logic that says: ‘He who can’t pay dies.’”

Dr. James Orbinski
President, Medecins sans Frontieres 2000



Poverty

- **Half the world's population: less than \$2/day**
- **One third of developing country residents**
 - **No Access**
- **Africa: annual drug spending \$2/person**
 - **Even at cost, the price is too high**



Additional Factors

- **Poverty**
- **Lack of Market Incentives**
- **Lack of Insurance**
- **Insufficient Infrastructure**
- **Lack of Complementary Resources**
- **Counterfeiting**
- **Inadequate Education**



Drugs in the Healthcare Budget

- “The proportion of health spending for drugs can be much higher in developing countries. In the Cote d’Ivoire and Pakistan, up to 90 percent of household health expenditures are for pharmaceuticals” (Broun 1994)
- In most developing countries “...less than 10% of the population has health insurance and 60% to 90% of drug costs are paid for directly by patients and their families” (WHO 1997)

“Counterfeit medicines are a greater public health threat than AIDS or malaria.”

- African Health Official¹



¹Statement of African health officials, as quoted by Harvey Bale, President of the International Federation of Pharmaceutical Manufacturers Associations (IFPMA) (Bale 2003).

Counterfeiting


Financial Impact

Counterfeits
\$50 billion/yr



=

Annual GDP



Benin	Liberia
Burkina Faso	Guinea-Bissau
Burundi	Malawi
Cape Verde	Mauritania
Central African Rep.	San Tome & Principe
Chad	Niger
Comoros	Rwanda
Rep. of Congo	Sierra Leone
Eritrea	Seychelles
Guinea	Swaziland
Equatorial Guinea	Togo
Lesotho	Zambia

Pharmaceutical counterfeiting is “...as lucrative as pushing heroin, ...about as hard as photocopying,... (and) low on law enforcement’s agenda”.

Stipp, 1996



Moving Beyond the Market

Government Intervention

- **What's A Developing Nation to do...**
 - **Price Controls**
 - **Compulsory Licenses**
 - **Domestic Generic Production**
 - **Parallel Imports**
- **Risk:**
 - **Single Global Price**
 - **Reduced Innovation**
 - **Launch Delays**



Wanted: R&D for the Poor

- **Truly Neglected Diseases**
 - Chagas Disease
 - Dengue Fever
 - Human African Trypanosomiasis



Responding to Price Controls

- Reduce R&D investment
- Concentrate on Drugs for Larger markets
Drop small market projects (Vaccines)
- Increase Short-run Projects (relative to long-run)
- Reduce the Risk Profile of Projects
- Concentrate on “elective” or “vanity” products
- Neglected diseases: off R&D agenda



Compulsory Licensing

- **Generic Production before Patent Expiry**
- **Forcibly Overriding IP Rights**
 - If and when...
 - “National Emergency”
 - Great bargaining tool
 - Credible threat
 - Good Manufacturing Practices upheld?



Parallel Trade: Manifestation of Free Trade...right?

- Standard Free Trade Arguments do not apply
 - Comparative Advantage
- Lower Prices: not due to Lower Cost Production
- Lower Prices: result from Government Regulation
 - Mandated Price Controls
 - Not A Process of Negotiation



Parallel Importation: Driven by Arbitrage

- “Parallel imports are legitimately produced goods imported legally into a country without the authorization of a trademark, copyright, or patent holder. The essential purpose of such trade is arbitrage between countries with different prices.”

Ganslandt & Maskus, 2001, p.1

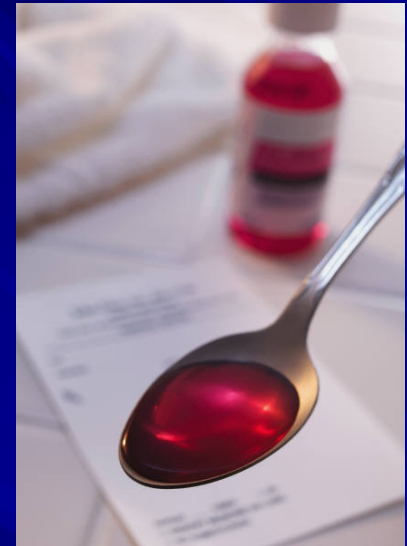
Parallel Trade Consequences: Absent Price Discrimination

- **Middlemen Celebrate**



Parallel Trade Consequences: Absent Price Discrimination

- **Middlemen Celebrate – yahoo!**
- **Global Price Convergence**
 - **Evidence in the European Union**
- **Launch Delays**
- **Supply restrictions**
- **Damaging to Industry**
 - **Decline of European Pharmaceutical Industry**
 - **Relocation of Firm Headquarters**



Solutions & Interventions

- **Market Failure, Ineffective Gov't Intervention...**
- **Creative Thinking!**
 - **Preserve Incentives to Innovate**
 - **Address the Costs (FC, MC)**
- **Overcoming other Obstacles**
 - **Public-Private Partnerships**
 - **Advance Purchase Commitments**



Creative Thinking

by Economists

- **M. Kremer**
 - Creating Markets for Vaccines through Auctions
- **J. Lanjouw**
 - Foreign Filing License – competition in poorest nations
- **Ridley, Grabowski & Moe**
 - Reward Neglected Disease R&D with Expedited Review
- **A. Hollis**
 - Price as a reflection of medical advance & novelty
- **Lybecker & Freeman**
 - Direct Tax Credit for Marginal Cost Pricing



Innovation:

Parameters to keep in mind

Encouraging	Inhibiting
Price: Market Pricing	Price: Price Controls
Differential Pricing	Parallel Trade
Secure IP Rights	Counterfeiting & Infringement
WTO: Narrow Interpret'n	WTO: Domestic Production
Strong Patent Protection	Compulsory Licensing

Concluding Remarks

- **The Numbers**
 - **\$1 billion**
 - **12 years**
 - **3 diseases**
 - **1/2 the global population**
 - **\$2/day**
 - **pennies...**



Ultimately...



Thank you

