CAFTA: Boon to Innovation, or Obstacle for Women?

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Research Question

How does **CAFTA (Central American Free Trade Agreement)** affect access to affordable life-saving drugs for women and families in Guatemala?

Why Is This Important?

- CAFTA
  - Establishes strong Intellectual Property rules
  - Promises “innovation”
- Guatemala
  - Major producer of generic drugs for Central America
  - History of U.S. intervention
- Women in Guatemala
  - Exclusion, discrimination by gender

Why Is This Important for the U.S.?

- Drugs affected by new rules are more commonly used in U.S. than in Guatemala
- What are implications for affordable medicines in the U.S.?

Barriers to Treatment

- Multiple factors influence disease prevention and treatment
- Trade agreements affect each one
- Wealth – level, equitable distribution
- Health care systems
- Access to medicines

CONTEXT

Political Crisis for Pharma

- Public outcry about high prices
  - U.S. pays highest prices in the world
  - Reimportation proposals
- Quality control:
  - COX-2 inhibitors (painkillers)
  - Psych drugs
- Crisis in Innovation
  - Fewer new drugs in research pipeline

Most Profitable Industry in World: Justified by R&D?

- 15% Research and Development
- 19% Profits
- 37% Marketing and Administration

Pharma Political Strategy: Trade Agreements

A. Protect high prices in US market
   - Block reimportation ("parallel importation")

B. Seek higher prices in other developed countries
   - Pharma: price controls harm quality, access, innovation

C. Maintain Intellectual Property structure in regional trade agreements with low/middle-income countries
   - "TRIPS-Plus" trade rules extend patents
   - Restrict production and sale of generics
   - Market to small number of wealthy individuals

Patents and High Prices

- Patents: Monopoly rights to originator for a given period of time
  - 20 years in total
  - Effectively about 14 years
- Can sell product without competition
- Keeps prices high

Role of Patents

- Key incentive to innovation
- Fairly compensates investments in R&D

  OR
- Props up exorbitant pharma profits in absence of competition, or actual innovation
- Perpetuate monopoly as long as possible by extending patent terms, lengths.

Generic Drugs

- Use different process to come up with a product “bioequivalent” to the brand-name drug
- Less expensive due to competition
- 50% of US prescriptions

TRADE AGREEMENTS

TRIPS

- Trade-Related Aspects of Intellectual Property Rights
- WTO Agreement
- All WTO members must give **patent holders** rights as stated in TRIPS
- 20 year product and process patents
- Phased in
  - Covered all high income countries as of 1996
  - Middle/Low income as of 2005
  - Least Developed Countries: 2015

"TRIPS"

- Can't **produce** generics domestically while patent in effect
- Claim: Can't **export** generics to low & middle income countries

Doha Declaration, 2001

- Countries can protect public health
- Compulsory licensing allowed
  - Can authorize generic production of patented drugs
- TRIPS Health Solution, 2003: Grants limited right to import/export generics for least developed countries that can't produce

"TRIPS-Plus" Rules

- Debate: Is TRIPS Floor or Ceiling?
- Can bilateral and regional agreements give patent holders ***greater*** monopoly rights than they enjoy under TRIPS?
- **US: Yes,** through bilateral/regional FTAs
  - Target low- and middle-income countries that can produce, and can export
  - CAFTA (Guatemala)
  - Thailand, Korea, Malaysia FTAs
- **India, China, Brazil, South Africa**: **No,** use WTO

"TRIPS-Plus" Lengthens Patents, Undermines Doha

- Data Exclusivity
  - Can't use originator's clinical trial data to establish safety and effectiveness of drugs for 5 years, even if no patent in place
- "Evergreening" rules extend patents
- Requiring licensing authorities to verify complex patents
- Barriers to generic competition, compulsory licenses
- Include plants and animals as patentable

Propping up US Drug Prices: Australia Free Trade Agreement

- "Parallel importation" = reimportation
- FTA could block reimporting lower priced drugs into US
- Could affect popular US drug price programs for VA, Medicaid, Medicare

Marketing Right

- Granted by FDA (in U.S.) or drug authority in each country
- Company must prove through clinical trials on humans that patented substances add up to a product that is safe and effective
- Usually takes 3-5 years after patent granted

License

- Brand-name companies or governments can license companies to produce and market an approved drug (while patent is in effect)
- From company: voluntary license
- From government: compulsory license
- Royalties paid to originator company

GUATEMALA

Conditions

Population

- 13 million
- $4,410 GDP
- Gini 48%
- UN Index of Power by Gender .47
- 51% poor <$2/day
- $256 per person on health care a year, 5.7% GDP
- Life expectancy 73/66
- Infant mortality 22/1000
- Maternal mortality 149/100,000

Leading Causes of Morbidity and Mortality for Women

Morbidity

- Respiratory Infection
- Anemia
- Pneumonia
- Acute diarhhea
- UTI

Mortality

- Pneumonia
- Diabetes
- MI
- Malnutrition
- Cervical Cancer

CAFTA and IP

- CAFTA grants greater monopoly rights to brand name pharmaceutical companies
- This continues a trend that dates back to at least 1999
- CAFTA intellectual property rules could make medicines more expensive and less available for women and families in Guatemala

Market Context

- Generic Drug Industry in Guatemala
- Government programs for affordable 1st line meds
- TNC campaigns to discredit generics
- “Open contract” bidding system: many drugs unavailable
- Multi-year efforts 1999-2007 to change Guate laws
- Increasingly expensive to register drugs

Rationale for Patents in Poor Countries

1. Patents are critical to funding innovation.
2. Drug companies will be motivated to market more drugs by the presence of patent protection.
3. Patent rules are irrelevant to problems in drug supply in low income countries, where few drugs are patented in any case, and where people experience poor access to medicines for other reasons.

Evidence: Funding Innovation Where?

- Not in poor countries: Used as marketing bases
- Transfer funds to brand name co.s in rich countries

Evidence: Patents Don't Increase Access

- Income level of country most decisive factor in drug co. choices to launch
- Patents and price controls moderate factor
- Moderate price controls not a significant delay; essential drug list does delay but not deny
  - Patents don't affect launch of blockbusters
- Low-income:
  - Local firms willing to enter with low patent protection
  - Lower prices, access, may justify delays

J Lanjouw. Patents, Price Controls & Access to New Drugs: How Policy Affects Global Market Entry, NBER 11321, May 2005

Evidence:
Patents Do Matter. But…

- The range of IP rules and measures discourage generics
- TRIPS-Plus rules extend patent rights in obscure ways

Data Protection in Guatemala

TRIPS (WTO)	Protects data against unfair commercial use
Guate 1999	DE, exceptions for access
Guate 2000	15 years DE
Guate 2003	5 years DE
Guate 2004	DE repealed
Guate 2005	5 years DE
CAFTA 2006	5 years DE

What Drugs Are “Protected?”

IP Rules Restrict Drug Choice for HIV/AIDS - China

- Original 1st line: d4T+ddI+NVP
- Toxic combination (2003 WHO Guidelines)
- Outcomes:
  - High incidence of side effects
  - High drop-out rates
  - Poor adherence
  - Feared high rates of resistance
- WHO recommends: d4T+3TC+NVP
- GSK patent on 3TC barrier to ARV rollout

- Suerie Moon, MSF, China

Segmenting Markets

- New drugs introduced under IP rules targeted to wealthy
- Fewer sides effects
- Less resistance
- High prices
- Strain on government funds

Guatemala and Protection

- 3 patented drugs: Plavix
- DE 15 years: Kaletra
- DE 5 years: Crestor
- Patented molecules: 100s of esoteric new substances

Ongoing Research

- Effect of new CAFTA rules on generic drugs now on the market
- Prices, availability of medicines

Policy Choices 2008

- Continue trade policy that benefits Pharma TNCs
- Adopt trade policies that protect and improve public health

Protect Global Health

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