

INTELLECTUAL PROPERTY AND THE ECONOMICS OF INTERNATIONAL HEALTH

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OVERVIEW OF LECTURE

1. The Drug Gap
2. Market and Government Failures
3. Country Examples
4. Take-Aways

THE LIMITED ACCESS TO DRUGS IN DEVELOPING COUNTRIES

**Market or Government Failure or
Both?**

THE DRUG GAP

THE PARADOX OF SCIENTIFIC AND TECHNOLOGICAL ADVANCES

- § Benatar, Daar and Singer (2003) in their call for global health ethics note that “(d)espite spectacular progress in science and technology during the twentieth century, as we enter the twenty-first the world is more inequitable than it was 50 years ago”

THE DRUG GAP

“At the beginning of the 21st Century, one-third of the world’s population still lacks access to the essential drugs it needs for good health. In the poorest parts of Africa and Asia, over 50% of the population do not have access to the most vital drugs”

- Gro Harlem Brundtland, Former Director-General, WHO, 2000

FINANCIAL CONCERNS

- § 50 to 90 percent of drugs in developing countries are paid for out-of-pocket
- § Payment is possible only if people can afford it
- § 1.3 billion people live on less than one dollar a day

Source: WHO and World Bank

DRUG GAP

- § In 38 countries public drug expenditure is < US\$2/capita
- § Commission on Macroeconomics and Health, sponsored by the WHO, found in 2002 that health care spending in the poorest countries is about \$57 billion short of the minimum needed for good basic care
- § 10 to 20% of sampled drugs fail quality control tests in many developing countries
- § In Uganda, availability of essential medicines varies two-fold among public health facilities and five-fold among warehouses

Source: WHO

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DRUG GAP

- § In a study on the quality screening of antimalarial products in some African countries only 58%, in all the countries, had acceptable content of chloroquine
- § More than 75% of the samples of sulfadoxine/pyrimethamine tablets had unacceptable dissolution properties
- § Thirty-eight countries spend less than two dollars per person per year on medicines, while many of these countries have large numbers of people living with HIV/AIDS
- § Overall health expenditure may be as little as ten - twelve dollars per person

Source: WHO

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MARKET FAILURES

LIMITED INCENTIVES FOR NEW DRUG DEVELOPMENT FOR DISEASES RELEVANT FOR DEVELOPING COUNTRIES

- § Developing countries represent a relatively small proportion of the global pharmaceutical market, providing limited market incentives for the development of new drugs specific to disease of those countries (including many tropical diseases)

PHARMACEUTICAL MARKET COVERAGE

A represents Global Diseases,

such as cancer, cardiovascular diseases, mental illness and neurological disorders, which constitute the major focus of the R&D-based pharmaceutical industry. Although affecting developed and developing countries, most people in developing countries who have needs for drugs to treat these diseases cannot afford them, and are thus not covered by the pharmaceutical market.

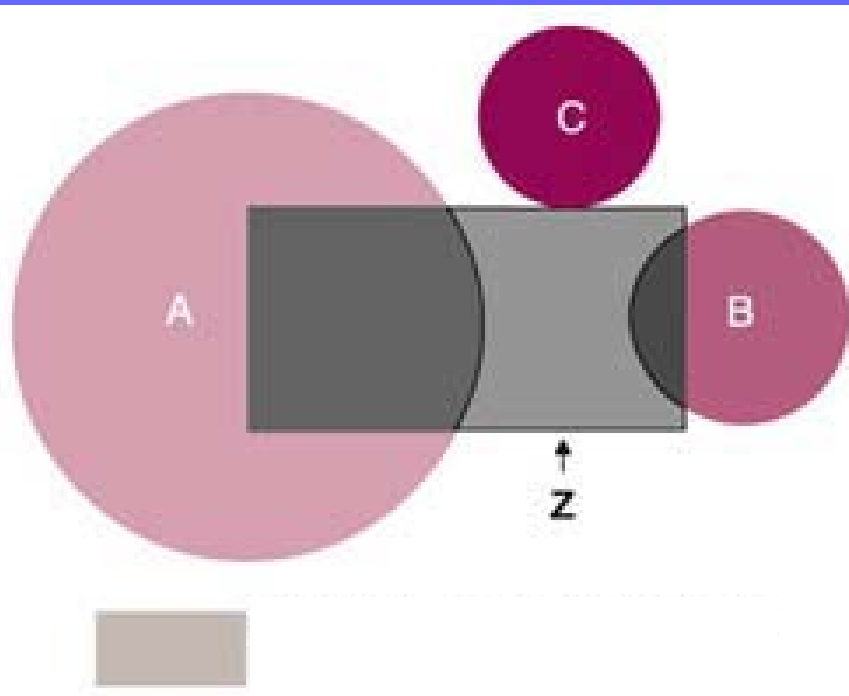
B represents Neglected Diseases,

such as malaria and tuberculosis (TB), for which the R&D-based pharmaceutical industry has only marginal interest. Although also affecting people in wealthy countries, for example TB patients or people who get malaria while traveling, these illnesses primarily affect people in developing countries.

C represents the Most Neglected Diseases,

such as sleeping sickness, Chagas disease and leishmaniasis, which exclusively affect people in developing countries. Because most of these patients are too poor to pay for any kind of treatment, they represent virtually no market and for the most part fall outside the scope of the drug industry's R&D efforts, and thus outside the pharmaceutical market.

Z represents the part of the pharmaceutical market for products addressing conditions other than those which are purely medical (such as cellulite, baldness, wrinkles, dieting, stress and jet-lag), which nonetheless represent a highly profitable market segment in wealthy countries.



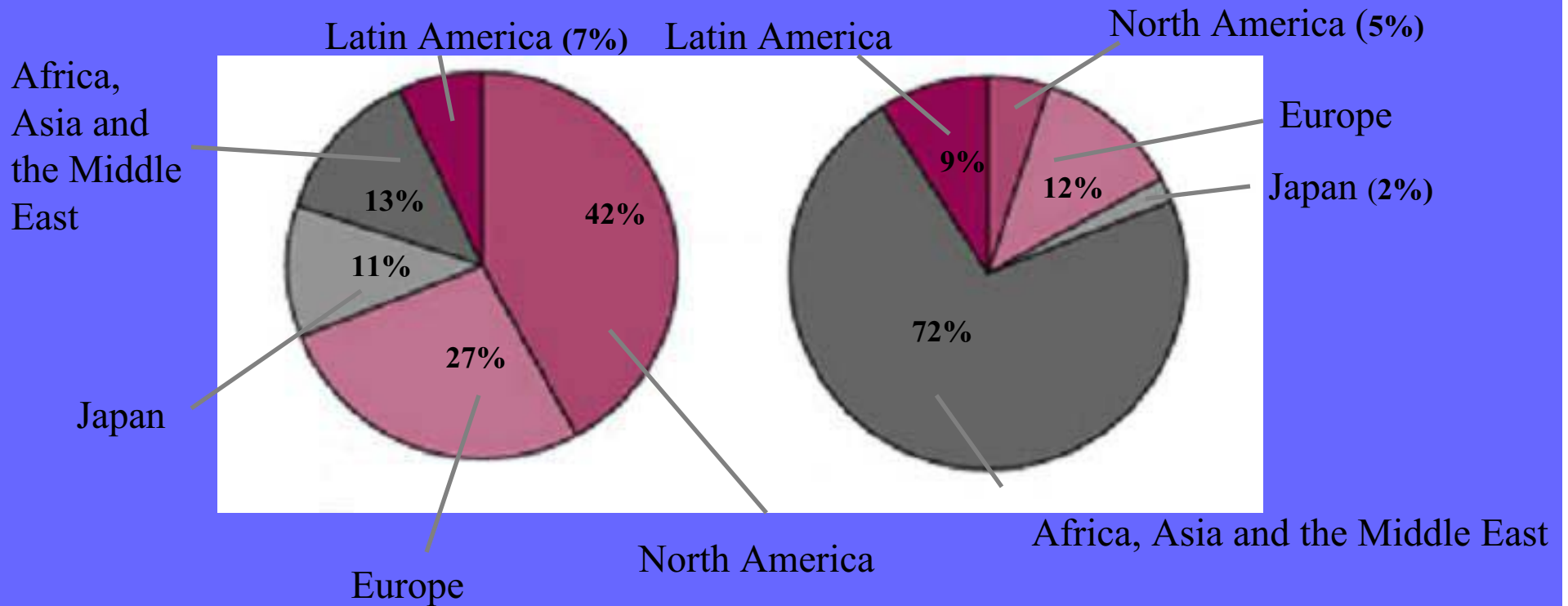
Source: Fatal Imbalance: The Crisis in Research and Development for Drugs for Neglected Diseases

PERCENTAGE OF WORLD DRUG MARKET COMPARED TO WORLD POPULATION

World Drug Market

World Population

(US\$406 billion in 2002) (Six Billion people in mid-2001)



Source: Fatal Imbalance: The Crisis in Research and Development for Drugs for Neglected Diseases

GOVERNMENT FAILURES

SOME INDICATORS

Country progress indicators WHO	1999 Status		2003 Target
	No./No. reporting	%	
Countries with public drug expenditure per capita of less than US\$ 2.00	(39/94)	41 %	35%
Countries with generic substitution allowed in private pharmacies	(83/134)	61 %	75%
Countries with public health insurance covering drug costs	(71/111)	64 %	70%

PHARMACEUTICALS REPRESENT SIGNIFICANT GOVERNMENT EXPENDITURE

- § Pharmaceuticals represent a significant proportion of government and private out-of-pocket expenditures in many developing countries, and provide a motivation for health sector reform

Source: Govindaraj, Reich and Cohen (2000)
World Bank Pharmaceutical Discussion Paper

GOVERNMENT EXPENDITURE (CONTINUED)

- § WHO reports that after human resources, pharmaceuticals are typically the highest expenditure in the health budgets of developing countries
- § Drugs can account from anywhere from 50 to 90 percent of non-personnel costs
- § Pharmaceuticals represent about one-third to two-thirds of total public and private health expenditure in developing countries (WHO/DAP, 1996)

INEFFICIENT USE OF RESOURCES

- š The inefficient use of pharmaceutical resources in many developing countries substantially reduces access to essential drugs and potential health benefits
- š Sometimes it is difficult to discern the difference between inefficiency and corruption

PHARMACEUTICAL SECTOR IS VULNERABLE TO CORRUPTION

The World Bank defines corruption as:

“...behaviour on the part of officials in the public and private sectors, in which they improperly and unlawfully enrich themselves and/or those close to them, or induce others to do so, by misusing the position in which they are placed.”

POTENTIAL IMPACT OF CORRUPTION

- š High levels of corruption have been found to correlate with lower levels of investment and lower growth rates
- š The most competitive countries have the least corruption
- š There is a clear relationship between good governance and positive development outcomes

REASONS WHY PHARMA SECTOR IS VULNERABLE TO CORRUPTION

- § There is a high degree of government intervention through its regulation
- § Wide information asymmetries between the patient and the physician and between the government and the health care provider
- § There are often poorly defined and documented processes which comprise the system
- § Limited institutional checks and balances in many countries
- § The size of the market and economic interests
- § The difficulty of determining what is corruption and what is inefficiency
- § Inappropriate incentive structures

IMPACT OF CORRUPTION ON THE HEALTH SYSTEM

- § The availability of essential drugs at a reasonable price can significantly reduce morbidity and mortality rates
- § The waste of resources as a result of corruption can reduce the capacity of the government to provide public health services
- § The greater dependency of the poor on the public health system implies that the poor are the most affected by corruption, which exacerbates existing inequalities in the public health system
- § A lack of transparency in the pharmaceutical system can reduce the credibility of public institutions in a country

INADEQUATE REGULATORY CAPACITY

- § Governments in developing countries commonly lack adequate institutional capacity to regulate pharmaceutical activities effectively
- § WHO reports that less than one in three regulatory agencies in developing countries are sound

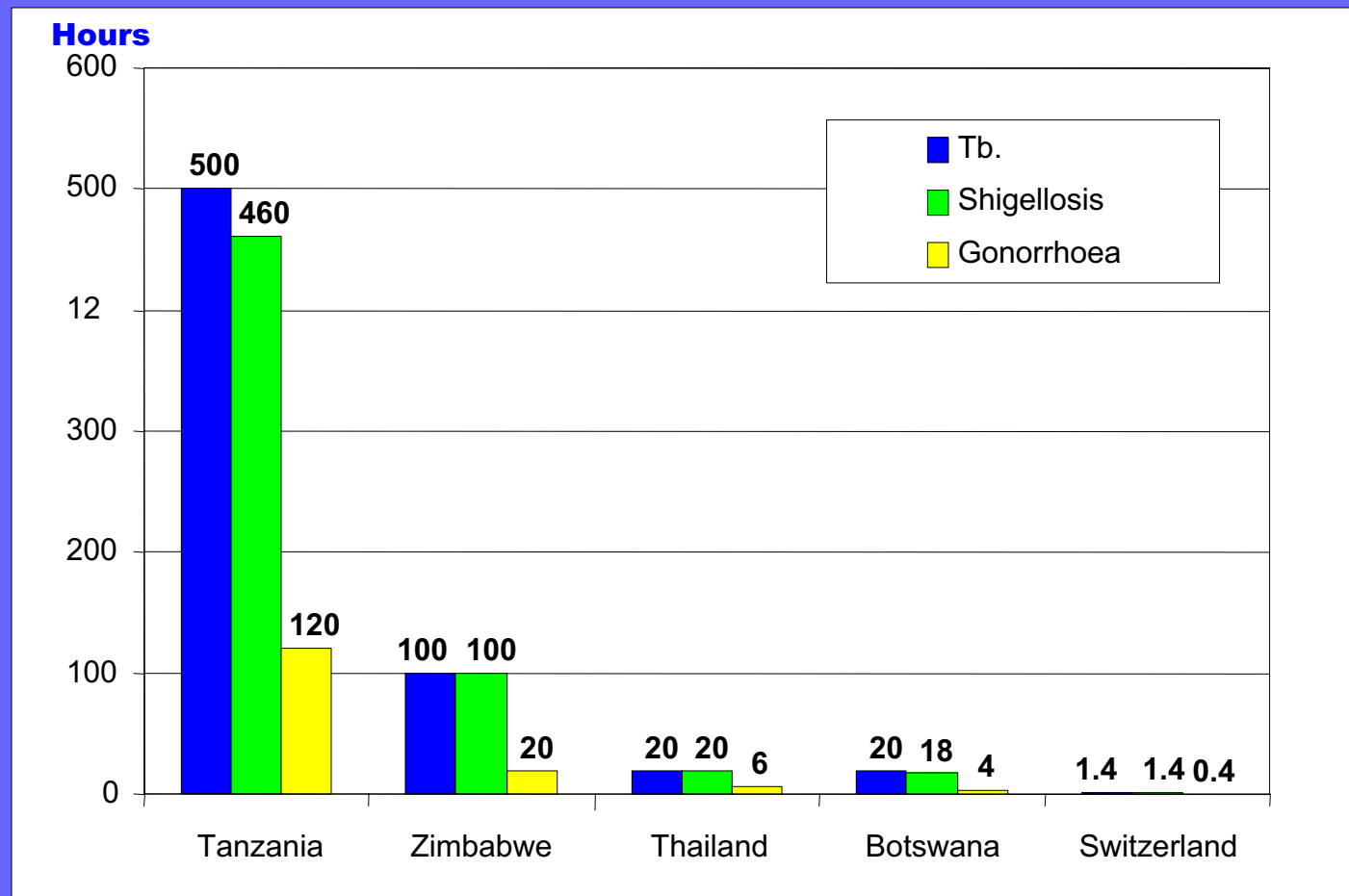
PUBLIC HEALTH EXPENDITURES

	<i>Total Public Health Expenditures</i>		<i>Total Public Drug Expenditures</i>	
	As % GNP	per Capita (\$US)	as % Health Budget	per Capita (\$US)
Bulgaria	3.80%	44.76	18.40%	8.24
Chad	0.60%	1.06	4.50%	0.05
Colombia	1.60%	20.03	18.00%	3.61
Guinea	0.40%	1.73	15.80%	0.27
India	3.20%	1.93	6.80%	0.13
Mali	0.40%	0.74	18.80%	0.14
Philippines	0.50%	4.53	13.30%	0.6
Sri Lanka	1.50%	8.58	15.60%	1.34
Thailand	2.00%	33.65	5.60%	1.89
Viet Nam	1.10%	2.32	20.00%	0.46
Zimbabwe	2.80%	12.43	36.10%	4.49

COUNTRY EXAMPLES

CHALLENGES

Number of working hours to pay for full treatment courses (average worldwide price)

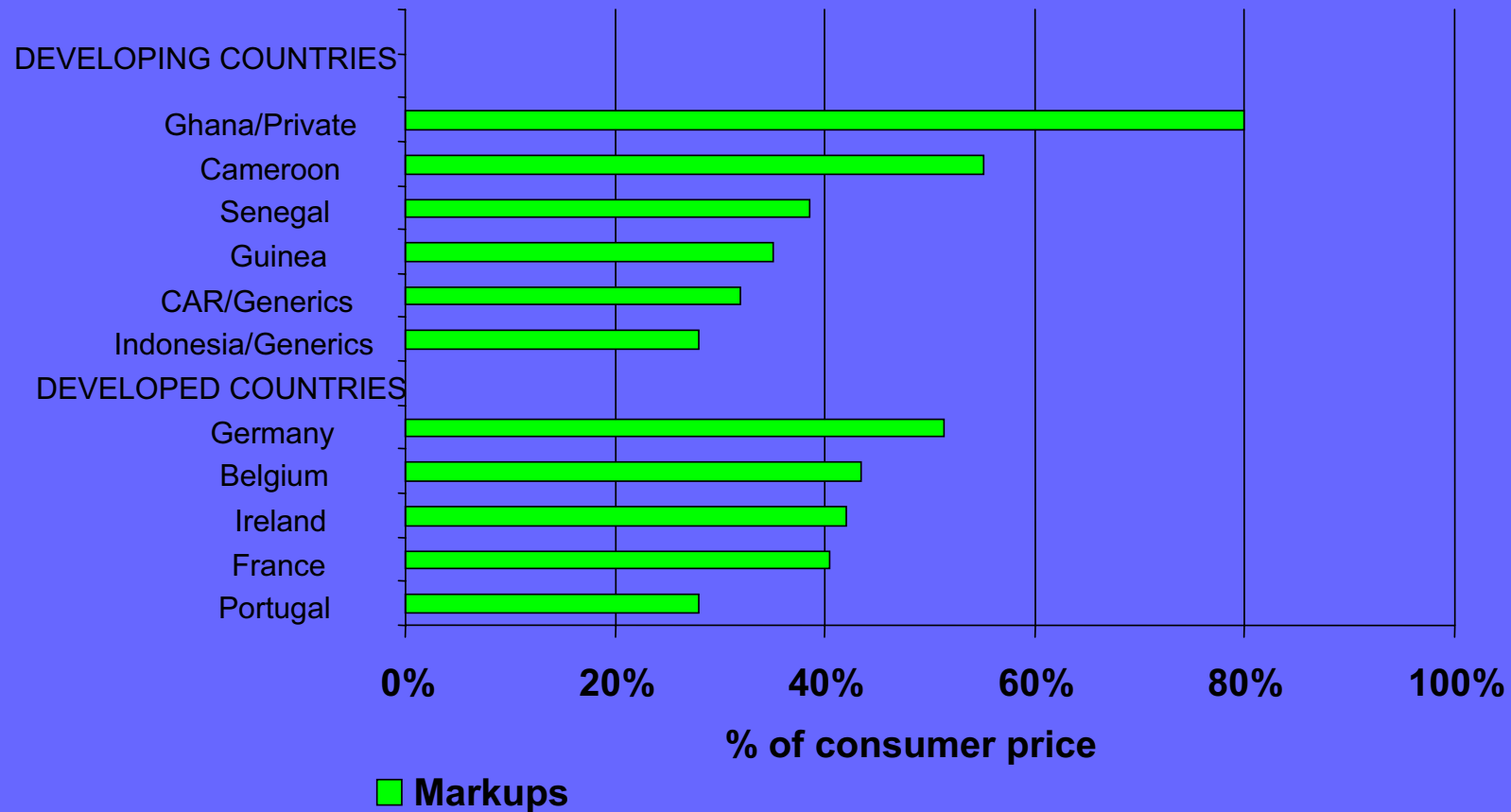


Source: WHO

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AFFORDABILITY

*Up to 80% of consumer price due to markups
(wholesale margins, retail margins and tax)*

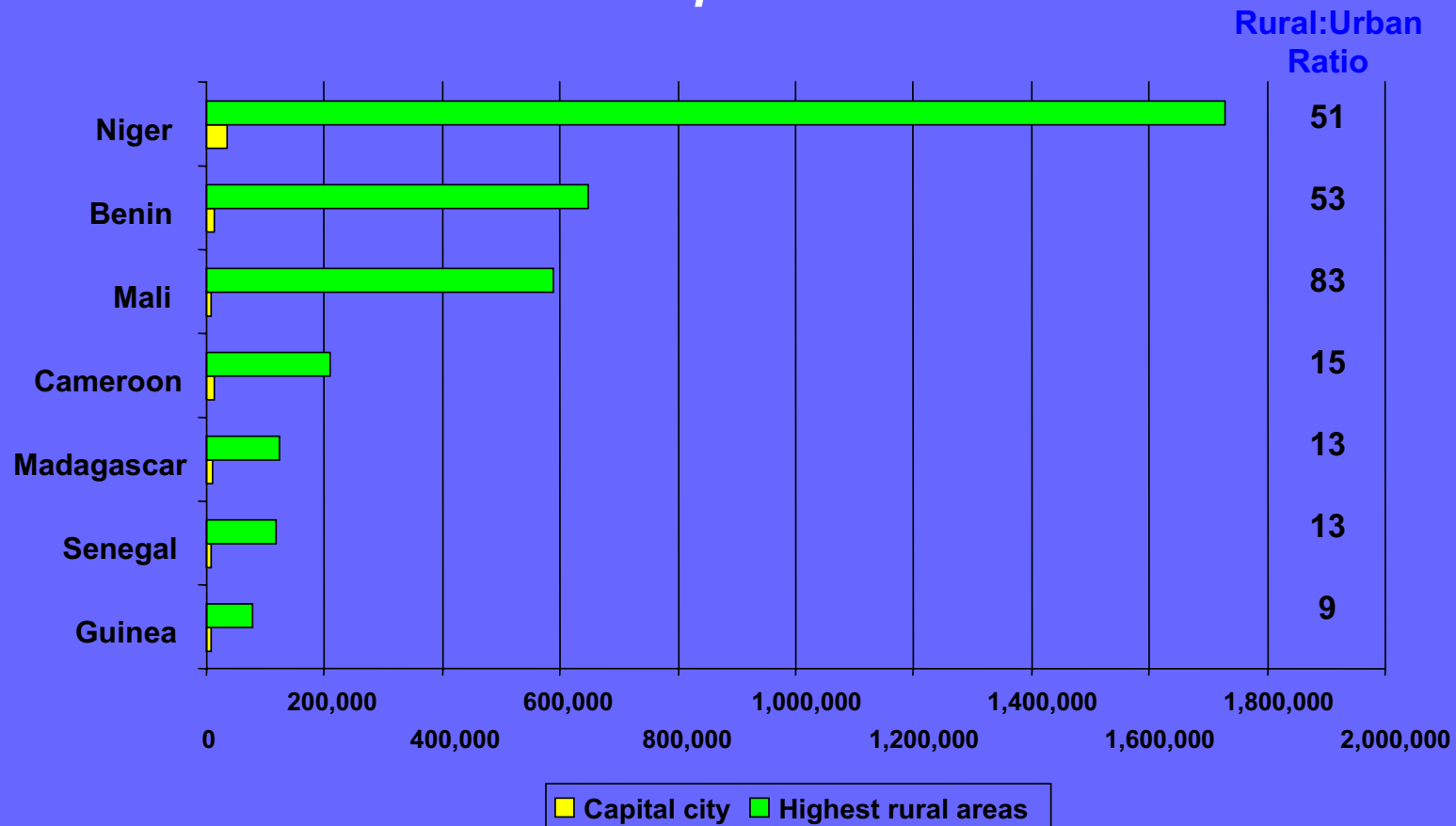


Source: WHO

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AVAILABILITY

Geographical inequity of private drug distributors: evidence from francophone Africa



Source: WHO

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RESPONSE FROM CANADA

- Plea from Ambassador Lewis
- Prime Minister Chretien accepted the challenge
- Move to reform Canada's intellectual property laws to accommodate the need for antiretrovirals in developing countries

TAKE-AWAYS

- Despite spectacular progress in science and technology, access to medicines in developing countries remains limited
- Limited access due to both government and market failures
- Countries need to address issues of affordability of drugs and their availability
- Comprehensive strategies are needed to address these issues
- Not one single quick fix
- Solutions are possible if the requisite trust, cooperation, funding, and political will are present