

Yale Global Health Working Group

# Global Health: What We Must Know ... and Do

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# 1

**The Global  
Health Impact of  
Poverty is Huge**

# The Effects of World Poverty

Among ca. 6800 million human beings, about

1020 million are chronically undernourished (**FAO 2009**)

2000 million lack access to essential drugs

(**[www.fic.nih.gov/about/plan/exec\\_summary.htm](http://www.fic.nih.gov/about/plan/exec_summary.htm)**),

884 million lack safe drinking water (**WHO/UNICEF 2008, 32**),

924 million lack adequate shelter (**UN Habitat 2003, p. vi**),

1600 million have no electricity (**UN Habitat, "Urban Energy"**),

2500 million lack adequate sanitation (**WHO/UNICEF 2008, p. 7**),

774 million adults are illiterate (**[www.uis.unesco.org](http://www.uis.unesco.org)**),

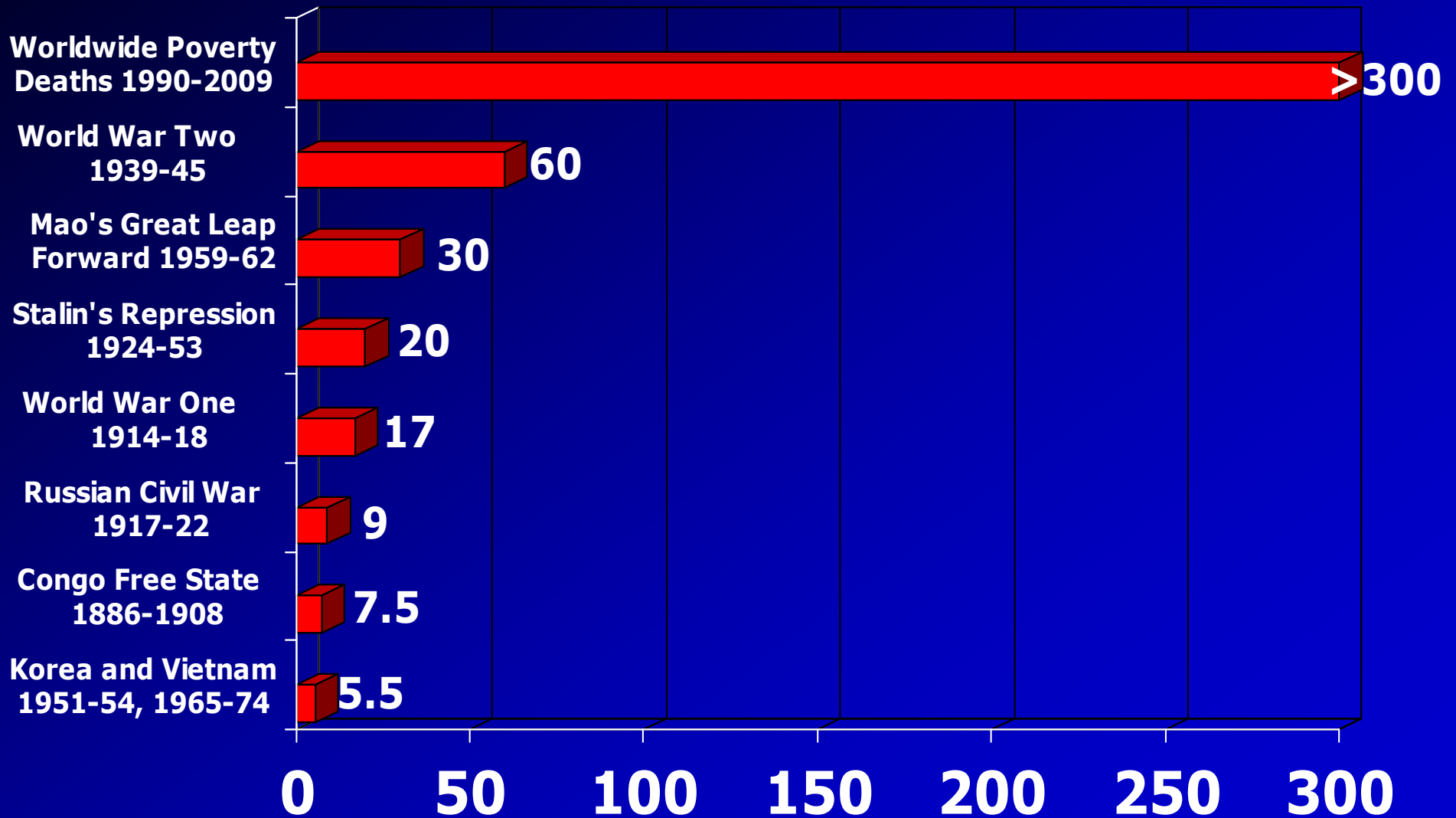
218 million children (aged 5 to 17) do wage work outside their household — often under slavery-like and hazardous conditions: as soldiers, prostitutes or domestic servants, or in agriculture, construction, textile or carpet production (**ILO: *The End of Child Labour, Within Reach*, 2006, pp. 9, 11, 17-18**).

# At Least One Third of Human Lives

—some 18 million per year or 50,000 daily—  
are ended prematurely by poverty-related  
causes, often cheaply preventable through  
more adequate nutrition, safe drinking  
water, oral rehydration, better sanitation,  
vaccines, medicines, or other health  
services.

**(WHO: World Health Organization, *Global Burden of Disease: 2004 Update*, Geneva 2008, Table A1, pp. 54-59)**

# Millions of Deaths



# The Most Underfulfilled HR

“Everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing and medical care and necessary social services, and the right to security in the event of unemployment, sickness, disability, widowhood, old age or other lack of livelihood in circumstances beyond his control”

**(Article 25(1), *Universal Declaration of Human Rights 1948*)**

# 2

**The Problem  
is Tiny in  
Economic Terms**

Using its latest International Poverty Line (**\$1.25** per day or \$38 per month, in 2005 int'l dollars), the World Bank counts **1.4 billion** poor people living **28%** below this line on average. Total deficit: **\$70 billion p.a. or 0.15% of world product** (0.33% at PPP).

With a more realistic poverty line of **\$2.50** per day or \$76/month (2005 int'l dollars), the Bank counts **3.14 billion** poor living **45%** below this line on average. Total deficit: **\$500 billion p.a. or 1.1% of world product** (2.2% at PPP).

**[econ.worldbank.org/docsearch](http://econ.worldbank.org/docsearch); Paper 4703, pp. 23, 34-5.**

# Global Inequality

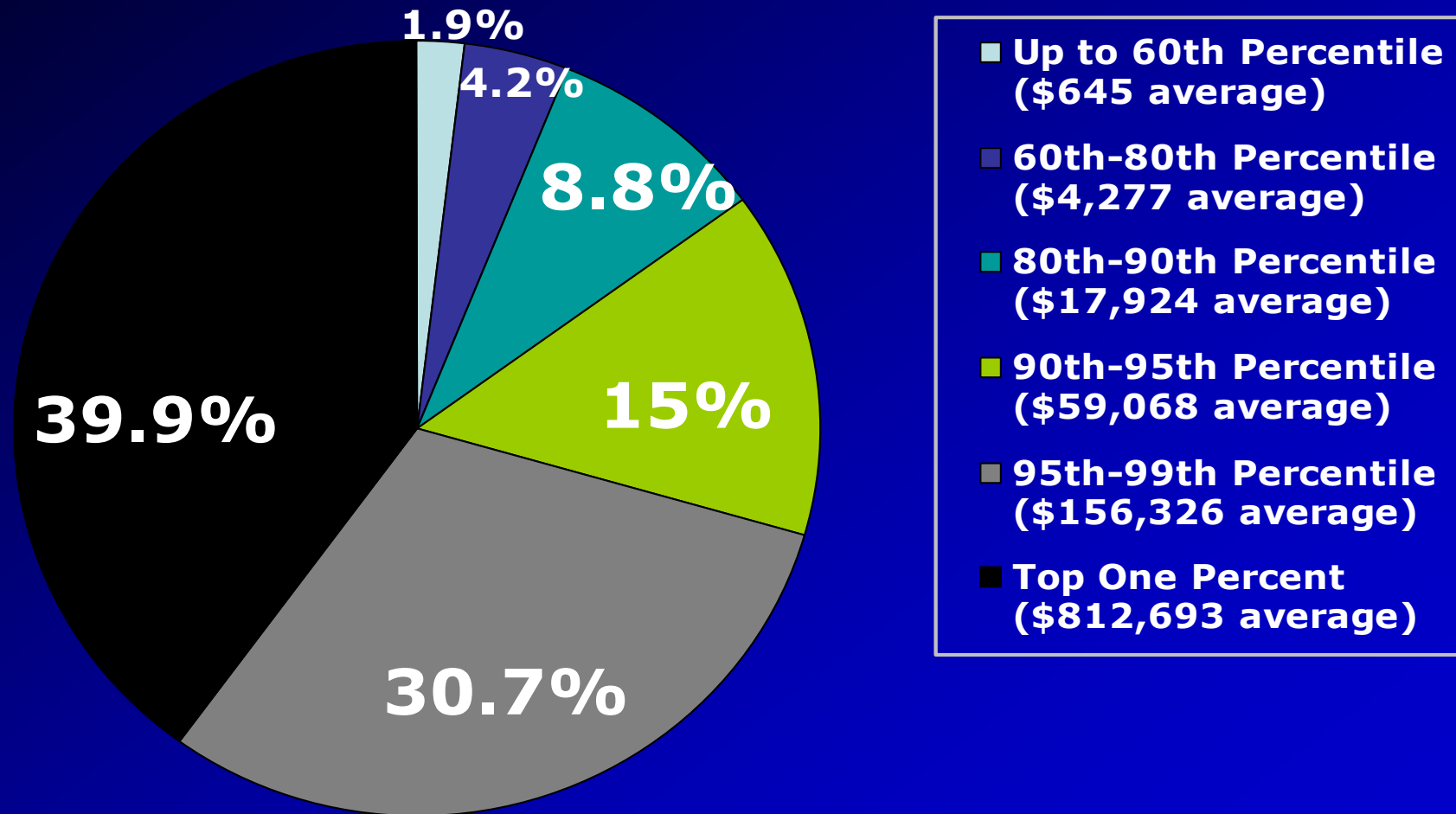
At current exchange rates, the poorest half of world population: **3,400 million, have under 3%** of global household income—as against **2% had by the most affluent 0.01% (30,000) in the US**. The per capita income ratio between the **top 5% and the bottom 40% is 200:1**.

Spreadsheets from Branko Milanovic, World Bank  
Saez "Tables and Figures Updated", [elsa.berkeley.edu/~saez/](http://elsa.berkeley.edu/~saez/)

At current exchange rates, the poorest half of the world's population, some **3,400 million, have ca. 1%** of global wealth — as against **3% had by the world's 1125 billionaires (2007!)**.

[www.iariw.org/papers/2006/davies.pdf](http://www.iariw.org/papers/2006/davies.pdf), table 10A, p. 47  
[www.forbes.com/2008/03/05/richest-billionaires-people-billionaires08-cx\\_1k\\_0305intro.html](http://www.forbes.com/2008/03/05/richest-billionaires-people-billionaires08-cx_1k_0305intro.html)

# Shares of Global Wealth 2000; poorest versus richest households



Calculated in market exchange rates so as to reflect avoidability of poverty. Decile Ineq. 2837:1. Quintile Ineq. 85:1. Year 2000, \$125 trillion total. ([www.iariw.org/papers/2006/davies.pdf](http://www.iariw.org/papers/2006/davies.pdf), table 10A, p. 47)

**3**

**The Goal Posts  
Have Been  
Moved**

# MDG-5

**“TARGET: Reduce by three quarters, between 1990 and 2015, the maternal mortality ratio”**

*(The Millennium Development Goals Report 2008, p. 24)*

**“By the year 2015, to have reduced maternal mortality by three quarters, and under-five child mortality by two thirds, of their *current* rates.”**

*(United Nations Millennium Declaration, A/res/55/2, dated 8 September 2000, article 19(3))*

# The Grand Promise to Halve Poverty by 2015: Third Version

1996 World Food Summit in Rome: the *number* of extremely poor is to be halved during *1996-2015*. This implies an annual reduction by 3.58%.

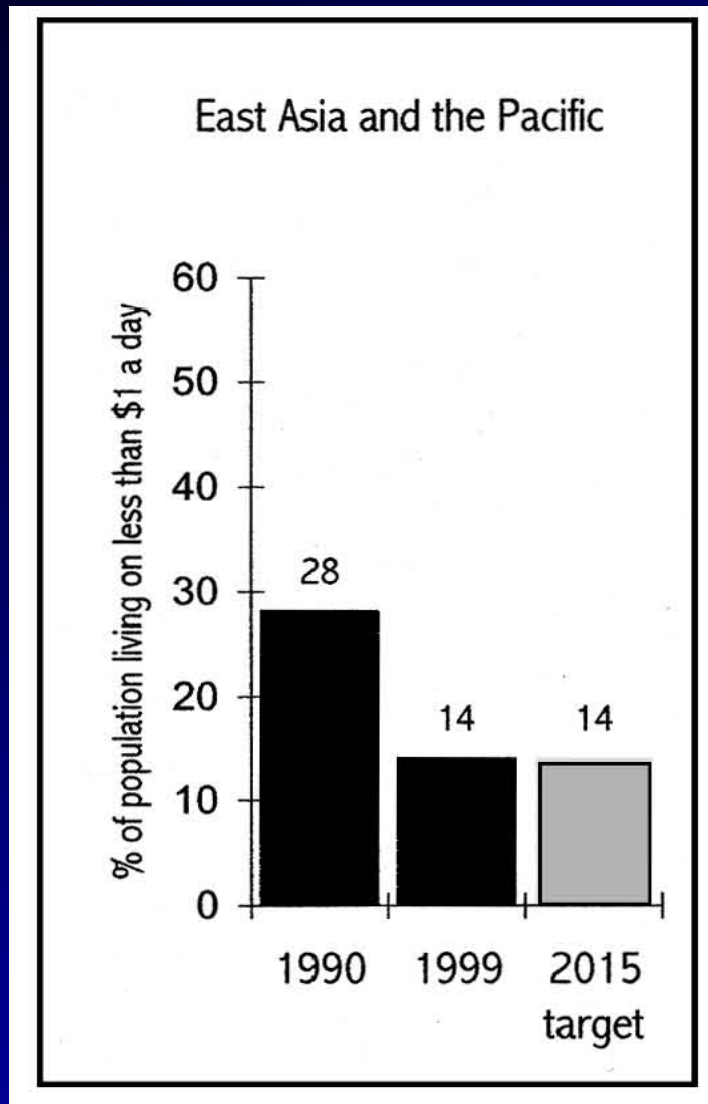
2000 Millennium Development Goal 1 (MDG-1): the *proportion* of extremely poor among the *world's people* is to be halved *2000-2015*. This implies annual reduction by 3.35% (40% 15 yrs).

MDG-1 as subsequently revised by the UN: the *proportion* of extremely poor among the *population of the developing countries* is to be halved *1990-2015*. This implies an annual reduction by 1.25% (27% over 25 years).

# MDG-1: A Promise Diluted

	Baseline Year	Baseline Number of Poor (millions)	Promised Reduction in number by 2015	Target for 2015 (millions)	Required annual rate of reduction
World Food Summit	1996	1672	50% in 19 yrs	836	3.58%
MDG-1 as adopted	2000	1673	40% in 15 yrs	1004	3.35%
MDG-1 as revised	1990	1817.5	27% in 25 yrs	1327	1.25%

[www.un.org/millenniumgoals/MDG-Page1.pdf](http://www.un.org/millenniumgoals/MDG-Page1.pdf)  
[www.un.org/millenniumgoals/sgreport2002.pdf?OpenElement](http://www.un.org/millenniumgoals/sgreport2002.pdf?OpenElement)



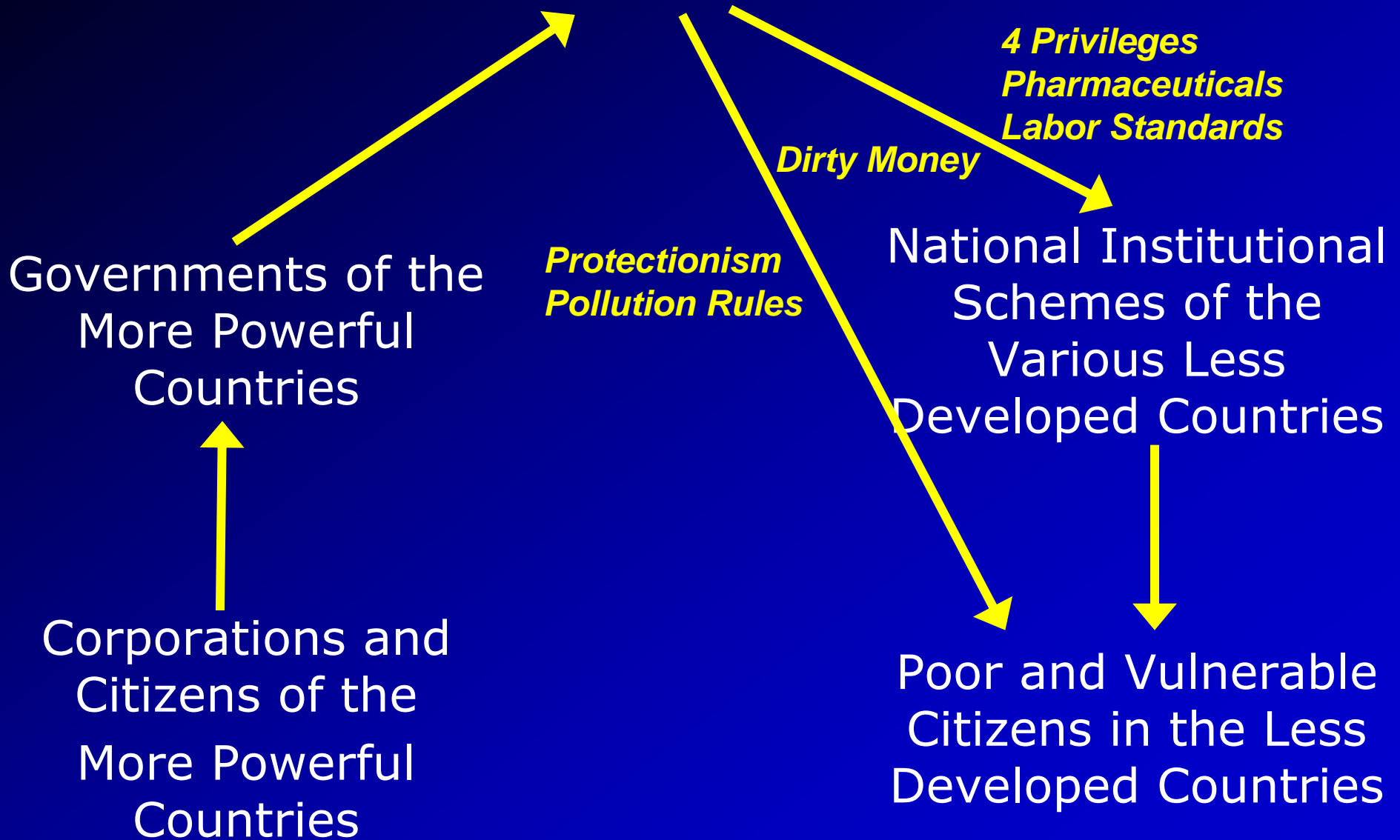
Source: Report of the Secretary-General on implementation of the Millennium Declaration. Data based on World Bank estimates.

<sup>1</sup>\$1 a day is expressed in Purchasing Power Parity (PPP)

# 4

**The “First World”  
is not Merely  
Potential Helper**

# Global Institutional Order



# Human Rights as Moral Claims on (Global) Institutional Arrangements

“Everyone is entitled to a social and international order in which the rights and freedoms set forth in this Declaration can be fully realized” (**Article 28**)

# We Should Focus Our Political Efforts on a Reform that

- constitutes an enduring *structural* reform;
- effectively symbolizes the idea that all human lives are of equal value;
- benefits a strong, well-organized faction of the global elite (new profit opportunities and image improvement for pharma industry);
- is scalable and can be increased and/or adjusted as experience warrants;
- strengthens those with objective interest in reform (empowerment of the global poor);
- is exemplar of realistic moral leadership, genuine moralization, global public good.

# 5

## **The Pharmaceutical Innovation / Access Dilemma**

# **Rules Governing the Development and Distribution of New Medicines**

Under the TRIPS agreement – part of the WTO Treaty and a paradigm example of regulatory capture – the intellectual property regime of the affluent countries was globalized by being made a mandatory condition of WTO membership. Pharmaceutical innovators must be granted 20-year product patents in all WTO member states.

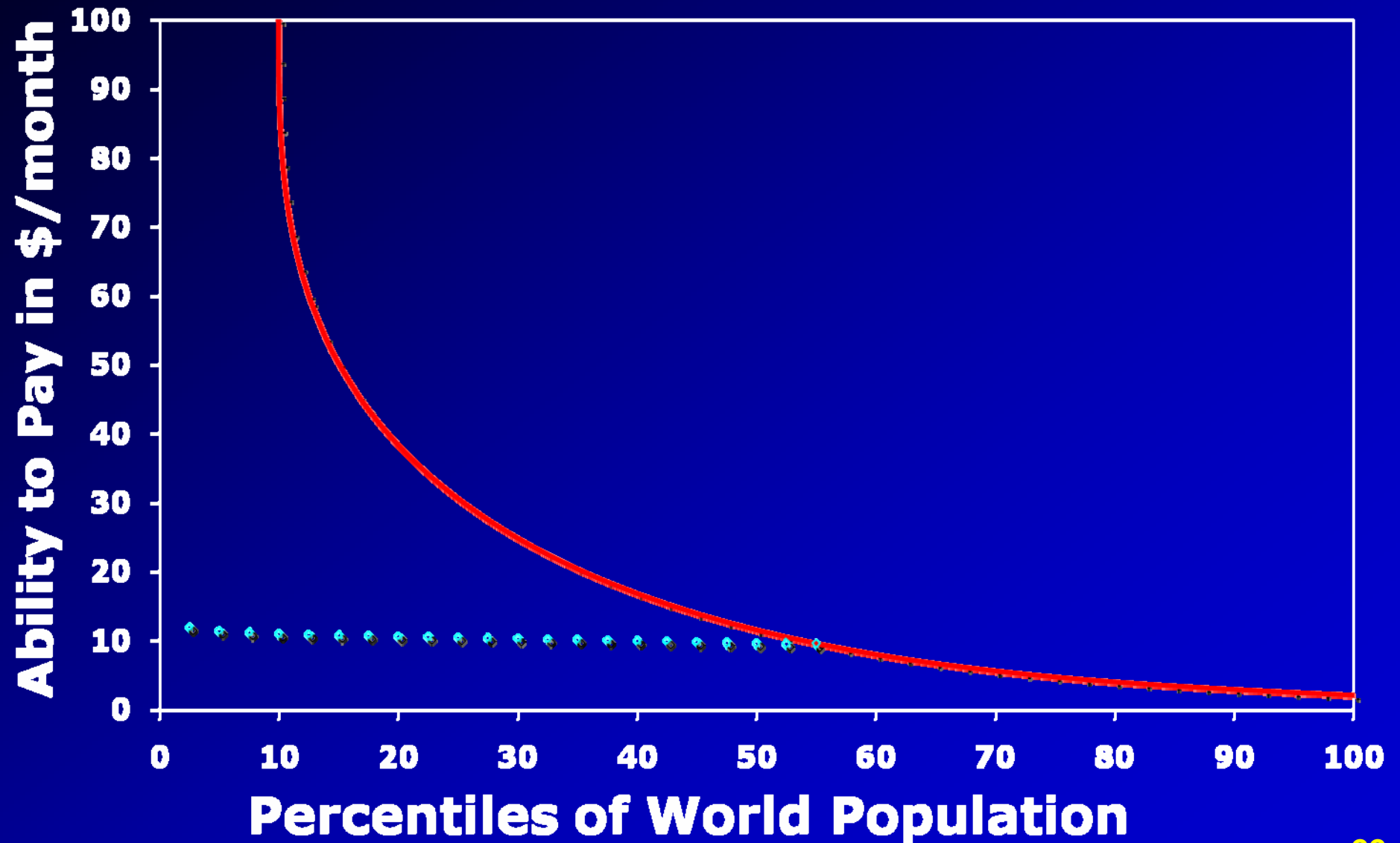
# Seven Problems with TRIPS-Pure

1. High prices impede *access* by poor people for the duration of the patent

## Why are prices so high?

Patented medicines for global diseases are priced to maximize profit (= mark-up times sales volume). For important medicines, optimal mark-up is high because of high economic inequality and low price elasticity among the affluent.

# Global Pharmaceutical Demand Curve



# Seven Problems with TRIPS-Pure

2. Pharmaceutical *innovation* is neglecting diseases concentrated among the poor.

## Why?

Medicines for diseases concentrated among the poor are not lucrative targets for pharmaceutical R&D: innovator gets tiny mark-up or tiny sales volume.

# **Distribution of Pharma Research**

Diseases accounting for 90% of the global disease burden receive only 10% of all medical research worldwide. Pneumonia, diarrhea, tuberculosis and malaria, which account for over 20% of the global burden of disease, receive less than 1% of all public and private funds devoted to health research. Of the 1556 new drugs approved between 1975 and 2004, only 18 were for tropical diseases and 3 for TB.

# Seven Problems with TRIPS-Pure

1. High prices impeding access by the poor
2. Neglected diseases (90/10 Problem)
3. Bias toward maintenance drugs
4. Patenting, litigation, deadweight losses
5. Cost-price differential → counterfeiting
6. Cost-price diff'l → excessive marketing
7. Last-mile problem, perverse incentives

# TRIPS versus Pre-TRIPS

Medicine may be	<i>Citizens of affluent countries (with access to patented medicines)</i>		<i>Citizens of developing countries with access to patented medicines</i>		<i>Citizens of developing countries w/o access to patented medicines</i>	
	<i>early</i>	<i>later</i>	<i>early</i>	<i>later</i>	<i>early</i>	<i>later</i>
Patented everywhere instead of only in affluent countries	=	=	worse (price)	=	very much worse	=
Patented everywhere instead of not existing at all (?)	better	much better	much better	very much better	=	very much better
<b>percentages 16/6/78 COMPARISON OVERALL</b>	<b>BETTER</b>	<b>BETTER</b>	<b>BETTER</b>	<b>(much?) BETTER</b>	<b>VASTLY WORSE</b>	<b>(much?) BETTER</b>

# Should the Harm Not Count?

## 1. A Natural Right of the Inventor?

- Libertarian worries
- Fair opportunity worries (tainted inequality)

## 2. Argument from Rational Consent (*volenti*)

- Governments of poor countries often
  - lack expertise
  - lack bargaining power
  - lack democratic legitimacy
- Most of the deprived are children
- Human rights understood as inalienable

## 3. Argument that the poor are doomed anyway

# The Appeal to the Good of All

- Those who cannot afford to buy medicines still under patent constitute some 78 percent of the human population
- “Everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing and medical care and necessary social services, and the right to security in the event of unemployment, sickness, disability, widowhood, old age or other lack of livelihood in circumstances beyond his control”  
*Universal Declaration of Human Rights Article 25(1)*
- There may be an institutional alternative superior to both (pre-TRIPS and current TRIPS-pure) options.

# 6

## **The HIF: Funding Innovation without Obstructing Access by the Poor**

# The Economics of Drug Development

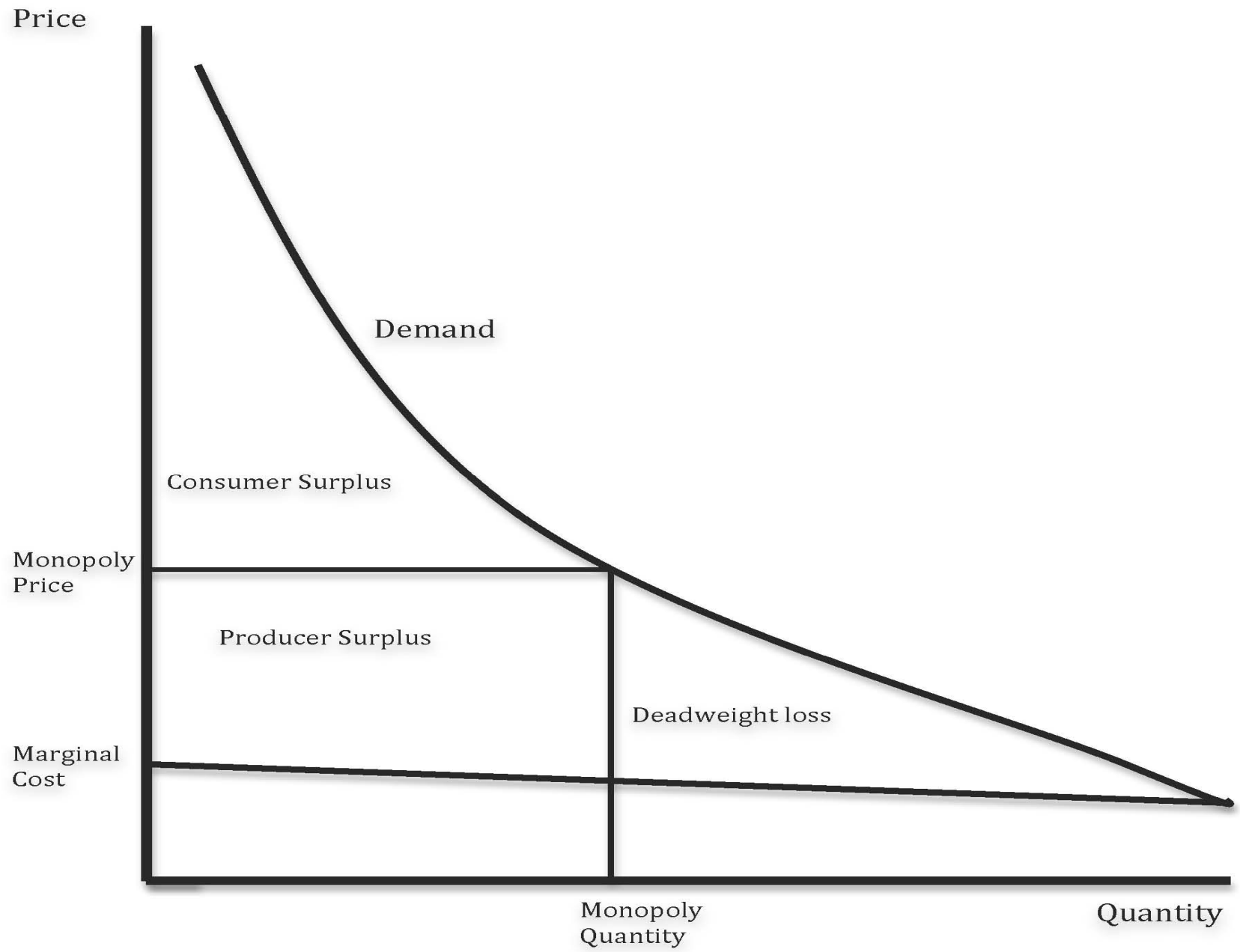
- Estimates of average drug R&D costs range from \$200 to \$1300 million per product (plausible \$800m)
- About half of this cost relates to clinical trials (mainly phase 3).
- Any solution must address the need to pay for these costs (including for unsuccessful products) and must create incentives for firms to invest in R&D including clinical trials.

# The Health Impact Fund (HIF)

- Funded by willing governments at minimally \$6 billion per annum (0.01% of GNI, if universal)
- Promises to reward (upon registration) any new medicine on the basis of its *global health impact*
- Registering a new medicine with the HIF is *voluntary* for the innovator, who need not give up any intellectual property rights
- Registrant must agree to make the new medicine available wherever it is needed at the lowest feasible cost of manufacture and distribution, and to grant zero-priced licenses after reward period
- [www.HealthImpactFund.org](http://www.HealthImpactFund.org)

# Financing

- \$6 billion a year is about 0.01% of global income, not even 1% of current worldwide expenditures on pharmaceuticals.
- Full incentive effects on potential innovators require long-term commitment by funders.
- Only governments (of affluent and developing countries) can plausibly commit large sums long-term. We propose a small share of GNI, perhaps 0.03%, for each partner country.
- All or most of this comes back to taxpayers through lower prices for medicines, insurance, national health systems, and foreign aid.



# HIF Resolves Critical Problems in Prize Determination

Which health problems to target;  
How to define the “finish line”;  
How large to make the reward (self-adjusting).

The HIF is a market-based solution: payments are determined by competition among all registered products for the available rewards.

- A drug for malaria can directly compete against a drug for HIV/AIDS.
- This regulates relative rewards for registered products, rewarding each at the same rate per QALY, creating efficient incentives.

# The “Last Mile” Problem in Drug Delivery

- Proper prescribing and compliance are essential to drug effectiveness.
- The HIF pays on the basis of each medicine’s *actual* health impact as assessed not only through sales data, but also through sampling of actual use and benefits as well as through population health data
- Firms therefore have incentives to promote appropriate use of their registered products, as well as to develop products that are effective in resource-poor settings.

# TRIPS+HIF versus TRIPS-pure

Medicine may be	<i>Citizens of affluent countries (with access to patented medicines)</i>		<i>Citizens of developing countries with access to patented medicines</i>		<i>Citizens of developing countries w/o access to patented medicines</i>	
	<i>early</i>	<i>later</i>	<i>early</i>	<i>later</i>	<i>early</i>	<i>later</i>
Patented everywhere	=	=	=	=	=	=
HIF-registered instead of patented everywhere	worse (tax)	=	? (tax vs. price)	=	very much better	=
HIF-registered instead of not existing at all	? (tax vs. assurance)	better	much better	very much better	very much better	very much better
<b>percentages 16/6/78 COMPARISON OVERALL</b>	<b>WORSE?</b>	<b>BETTER</b>	<b>BETTER</b>	<b>BETTER</b>	<b>VASTLY BETTER</b>	<b>VASTLY BETTER</b>

# Problems Solved?

1. Price = lowest feasible variable cost
2. Diseases of the poor become profitable
3. No bias toward maintenance drugs
4. Patenting, litigation, deadweight losses
5. No cost-price differential: counterfeiting
6. No cost-price differential: marketing
7. Last-mile problem, wholesome incentives



# How to Constrain the Selling Price

Three design options:

- The HIF sets a price ceiling equal to estimated average cost of production
- The HIF requires open licensing of all relevant patents and data to create generic competition
- The HIF requires the registrant to issue tenders for production; registrant controls distribution but must sell product at no more than cost of acquisition plus a supplement to cover distribution

Cost of production and distribution is to be minimized and registrant is not to profit from selling the drug, only from HIF-rewards.

Incentive to lower price iff  $\delta Q(R+p-c) > Q\delta p$

# Assessing Health Impact

- Health impact would be assessed in QALYs through comparison to outcomes that could have been expected to occur given the state of technology two years before the drug was introduced, and excluding the firm's own products.
- Quality-Adjusted Life Years: All health states are rated on a 0-1 scale. 2 QALYs = two extra years in good (1.0) health = four extra years in poor (0.5) health = ten years in improved (+0.2) health.

# Assessment

- Health impact will be assessed annually based on available information and inference
- Assessment will rely on data from
  - Clinical trials
  - Pragmatic or practical trials
  - Audited data on sales aided by serial numbers and mobile phone technology
  - Stratified sampling of use of the product in different environments
  - Global burden of disease data

# Assessment Cost

- The assessments would be expensive to run, consuming probably about 10% of the fund payout, or \$600 million per year. Judged to be feasible by experts (IHME)
- But assessment of health impact is a priority in almost all countries already.
  - Clinical reasons
  - Budgetary reasons
- Assessment costs are therefore partly balanced by collateral benefits.

# Allocation Rules

“Because pharmaceutical companies negotiate under a virtual veil of ignorance with respect to as yet uninvented medicines, their collective interests will shape their negotiating strategy. They will want to design the allocation rules so as to maximize their collective harvest of rewards. In particular, they will want these rules to be clear and transparent so as to reduce uncertainty. They will want the incentives to be shaped so as to foster efficient collaboration and synergies among themselves. They will want to set up a cheap and reliable arbitration mechanism so as to avoid costly disputes.”<sup>43</sup>