

Medicines for Neglected Diseases Workshop

Financing Pharmaceutical Innovation also for the Poor: the Health Impact Fund

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to have a copy
of this PPT**

The Current Situation

- In the current Global Financial Crisis, the world's affluent are even more focused on their own problems and even less concerned for the world's poor.
- It is crucial therefore to look for win/win opportunities that can bring gains to the poor and the affluent.
- The Health Impact Fund proposal is a structural reform that would release large collective benefits by modifying how pharmaceutical innovations are rewarded. The idea of a regulated market system is retained, but monopoly mark-up powers are replaced by impact rewards.

1

**TRIPS-Pure, & why
Change is Needed**

Rules Governing the Development and Distribution of New Medicines

Under the TRIPS agreement – part of the WTO Treaty – the intellectual property regime of the affluent countries was globalized by being made a mandatory condition of WTO membership.

Pharmaceutical innovators must now be granted product patents of minimally 20-year duration 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 high-impact medicines, the optimal mark-up is high because of **high economic inequality** and **low price elasticity** among the affluent.

GLOBAL INEQUALITY

Share of Global Household Income 2005

Segment of World Population

(in proportion to average)

Richest Ventile

46.36 (9x)

Next Four Ventiles

43.98 (2x)

Second Quarter

6.74 (1/4)

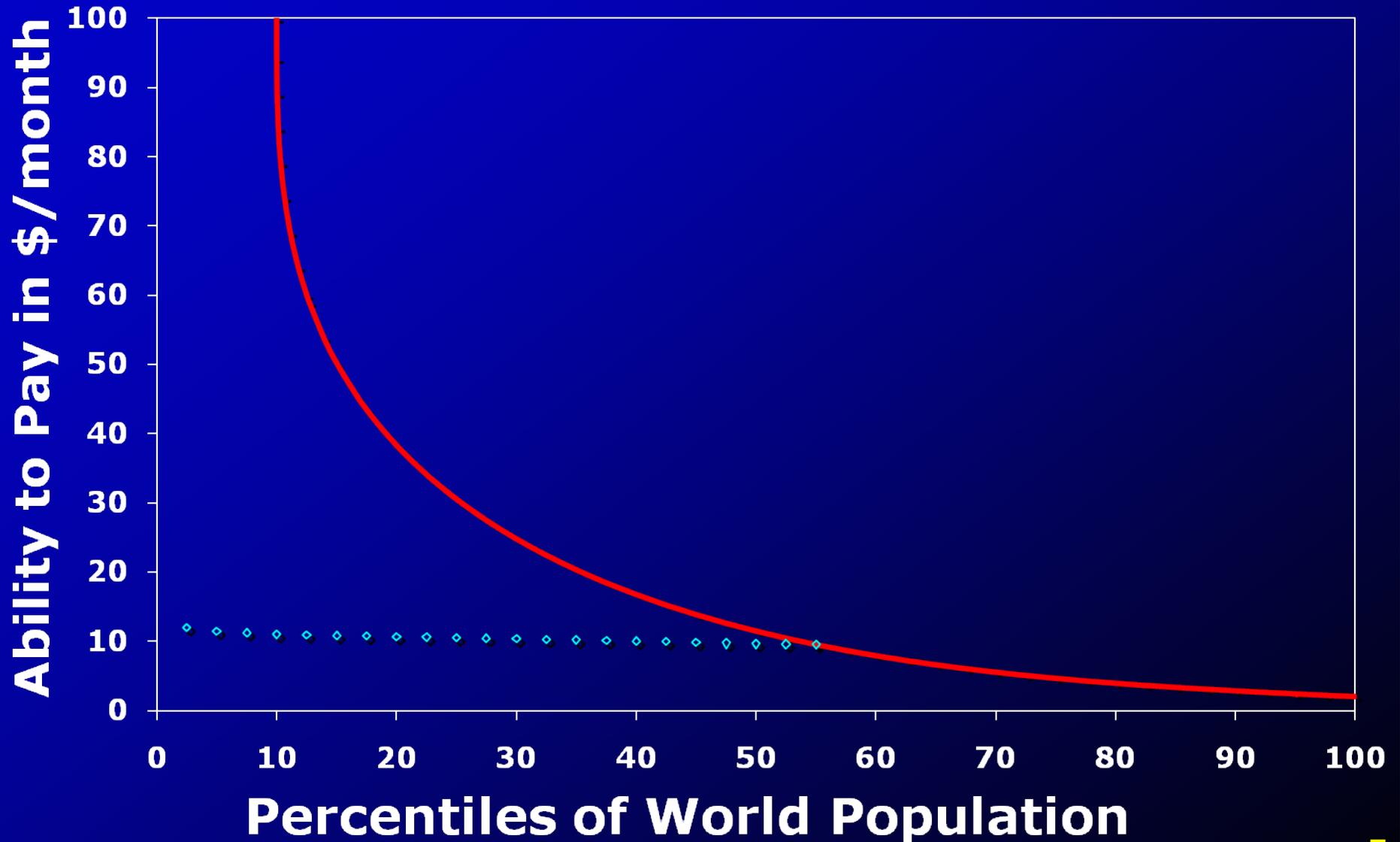
Third Quarter

2.14 (1/12)

Poorest Quarter

0.77 (1/32)

Global Pharmaceutical Demand Curve



Seven Problems with TRIPS-Pure

1. High prices impede access by the poor.
2. Pharmaceutical *innovation* is neglecting diseases concentrated among the poor.

Why?

Medicines for such diseases are not lucrative targets for pharmaceutical R&D: innovator gets *tiny mark-up* or

tiny sales volume.

Distribution of Pharma Research

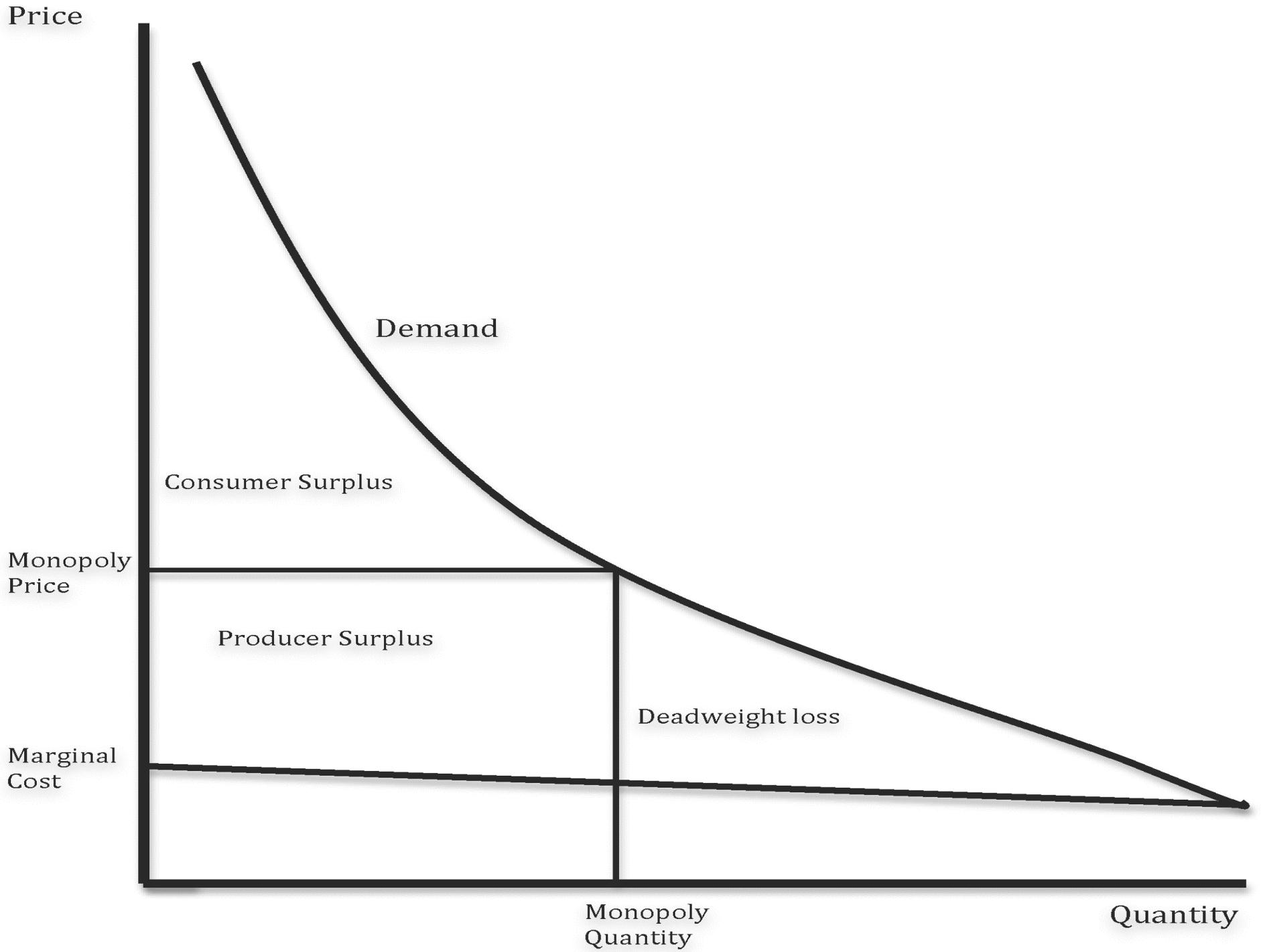
Diseases accounting for 90% of the global disease burden receive only 10% of all medical research worldwide. ***The 10/90 Gap.***

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. NB, this was recently disputed with the claim that there were 16 more in the 1975-99 period. See www.plosone.org/article/info:doi/10.1371/journal.pone.0010610

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



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 diff'l → excessive marketing
6. Cost-price differential → counterfeiting
7. Last-mile problem, perverse incentives

How Poverty Affects Health

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),
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),
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 a Third of Human Deaths

— some 18 (out of 57) million per year or 50,000 daily
— are due to poverty-related causes, cheaply preventable through safe drinking water, better sanitation, more adequate nutrition, rehydration packs, vaccines or other medicines. In thousands:

diarrhea (2163) and malnutrition (487),
perinatal (3180) and maternal conditions (527),
childhood diseases (847 — half measles),
tuberculosis (1464), meningitis (340), hepatitis (159),
malaria (889) and other tropical diseases (152),
respiratory infections (4259 — mainly pneumonia),
HIV/AIDS (2040), sexually transmitted diseases (128)

WHO: World Health Organization, Global Burden of Disease: 2004 Update, Geneva 2008, Table A1, pp. 54-59¹⁴.

2

The Basic Idea of the Health Impact Fund

The Health Impact Fund Proposal

- ... is a team effort involving about a dozen people from different countries and academic disciplines.
- ... has been supported by grants from the Australian Research Council, the BUPA Foundation and the European Commission.
- ... is supported by a Scientific Committee, chaired by Harvey Rubin, and an Advisory Board including Jim Yong Kim (Pres of Dartmouth), Paul Martin (former PM of Canada), John DeGioia (Pres of Georgetown), James Orbinski, Sir Michael Rawlins (NICE), Baroness Onora O'Neill, Amartya Sen (Nobel), and Heidemarie Wieczorek-Zeul (former Minister in Germany).

The Health Impact Fund (HIF)

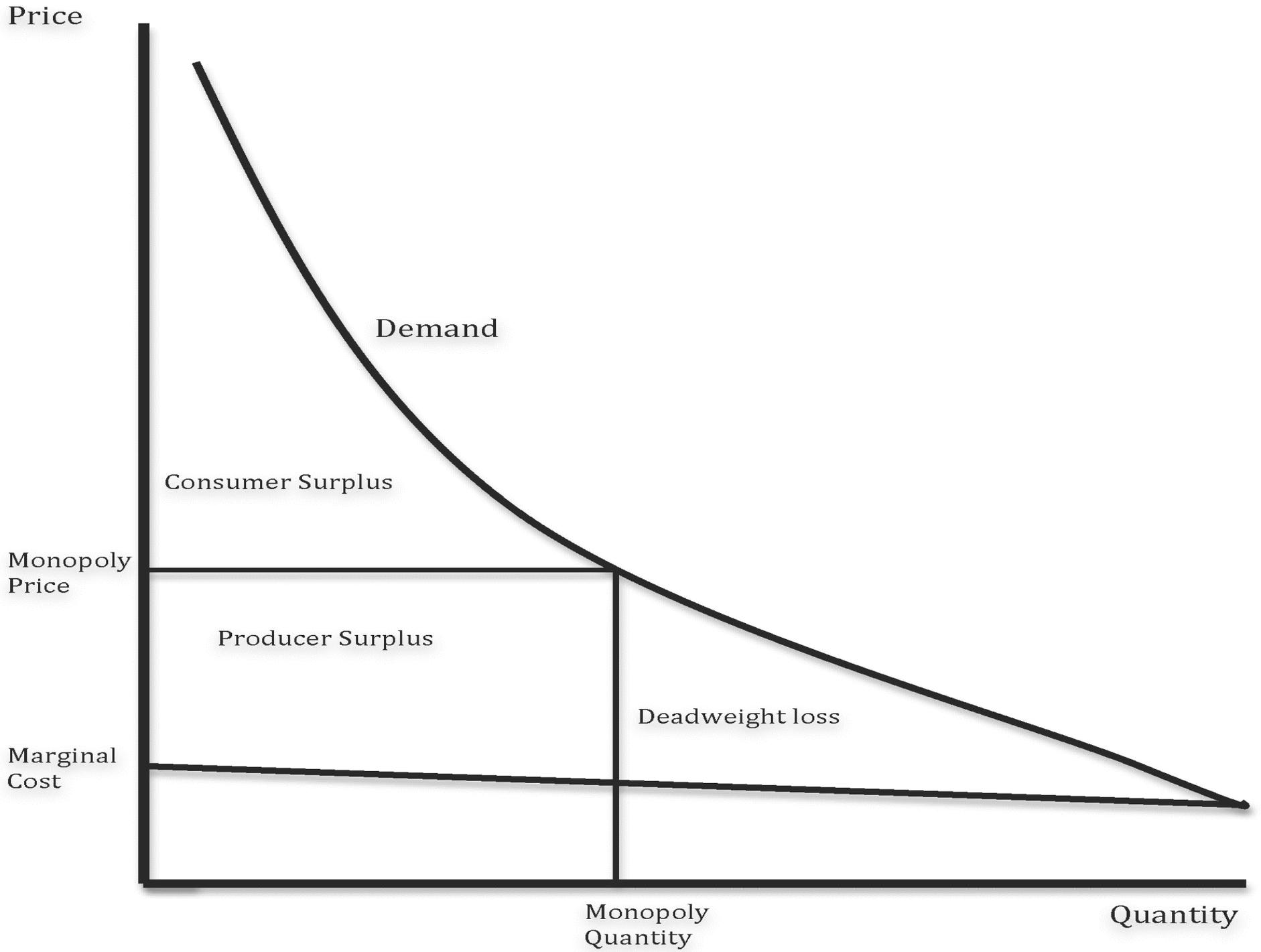
- ... is a **complement** to TRIPS. Innovator may **voluntarily** register any new medicine with the HIF & need not give up any intellectual property rights.
- ... is funded by willing governments at minimally **\$6 billion** per annum (0.01% of Σ GNI, if universal).
- ... promises to reward (upon registration) any new medicine annually for ten years on the basis of its **global health impact**.
- Registrant must agree to sell the new medicine wherever it is needed at the **lowest feasible average cost of manufacture and distribution** and to grant zero-priced licenses after reward period.
 - **www.HealthImpactFund.org**

The Economics of Drug Development

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

Financing

- \$6 billion a year is about 0.01% of global income (Σ GNI), well under 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.



The HIF Alleviates Last Mile Problems in Drug Delivery

- Local availability as well as proper storage, prescribing and compliance are essential to drug effectiveness.
- Dilemma: drugs are either too expensive or “too cheap,” hence *unaffordable* or *unpromoted*, among the poor.
- The HIF pays on the basis of each medicine’s *actual* health impact as assessed through sampling of actual use & 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.

3

**More Details
about the HIF**

The HIF Resolves Three 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 reward pools.
 - 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 unit of health impact, creating efficient incentives.

Metric for Assessing Health Impact

- Health impact is to 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. For example, 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.

How to Assess Health Impact

- Health impact is to be assessed annually based on collected data and inference
- Assessment will rely on data from
 - Clinical trials
 - Pragmatic or practical trials
 - Audited data on sales aided by serial numbers on packages 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 up to 10% of the fund payout, or \$600 million per year. Judged to be feasible by experts (IHME).
- Better health impact monitoring is a priority in almost all countries already.
 - Clinical reasons
 - Budgetary reasons
- Assessment costs are therefore partly balanced by collateral benefits.

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 $\delta Q(R+p-c) > Q\delta p$

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 favor allocation rules that maximize their collective harvest of rewards:
 - They will want these rules to be clear and transparent so as to reduce uncertainty.
 - They will want the incentives to be shaped 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.

Problems Avoided?

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

Piloting the HIF

- Piloting the HIF proposal would involve a company distributing a medicine at a very low price in some particular developing country and being rewarded on the basis of this drug's health impact there. We are seeking plausible product candidates for this test, and would be pleased to speak with you about any candidates you think would be worth further exploration.

4

**The Larger
Picture**

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, genuine *moralization*;
- *benefits* a strong, well-organized faction of the global elite (new profit opportunities, positive image in new and established markets);
- is *scalable* and can be expanded and/or adjusted as experience warrants;
- strengthens those with objective interest in reform (*empowerment* of the global poor);
- is an exemplar of *realistic* moral leadership: *replicable* creation of a global public good.

Two Different Adaptations

- Extension to *clean/green technologies*: free access to patented knowledge in exchange for rewards proportioned to emissions averted.
- Extension to *agricultural innovation*: pay innovators on the basis of incremental nutrients produced, and/or use of pesticides and fertilizers avoided, through use of their invention on the fields where it is deployed.

5

**The Relevance
of Social Justice**

Should the Harm Not Count?

1. A Natural Right of the Inventor?

- Libertarian worries
- Fair opportunity worries (tainted inequality of chances)

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)
- The TRIPS+HIF option is superior to both the pre-TRIPS and the current TRIPS-pure options.

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
percentages 16/6/78 COMPARISON OVERALL	BETTER	BETTER	BETTER	(much?) BETTER	VASTLY WORSE	(much?) BETTER

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
percentages 16/6/78 COMPARISON OVERALL	WORSE?	BETTER	BETTER	BETTER	VASTLY BETTER	VASTLY BETTER