

Financing Chagas disease drug R&D

Framework and principles

LA Chagas Funding Panel

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Why neglected disease R&D is... neglected

Most drug development is carried out by the for-profit pharmaceutical industry, with private capital.

- ▶ Return on investment largely determines priorities: focus on drugs with lucrative, patent-protected markets.
- ▶ Drugs for diseases of the poor in developing countries offer small and uncertain markets.
- ▶ Price can be barrier to access when drugs are developed.

In addition, rich-world public funding of basic research naturally focus on rich-world health priorities

Result: the 90/10 R&D funding gap

Approaches to neglected disease R&D

1. Public sector/university drug development

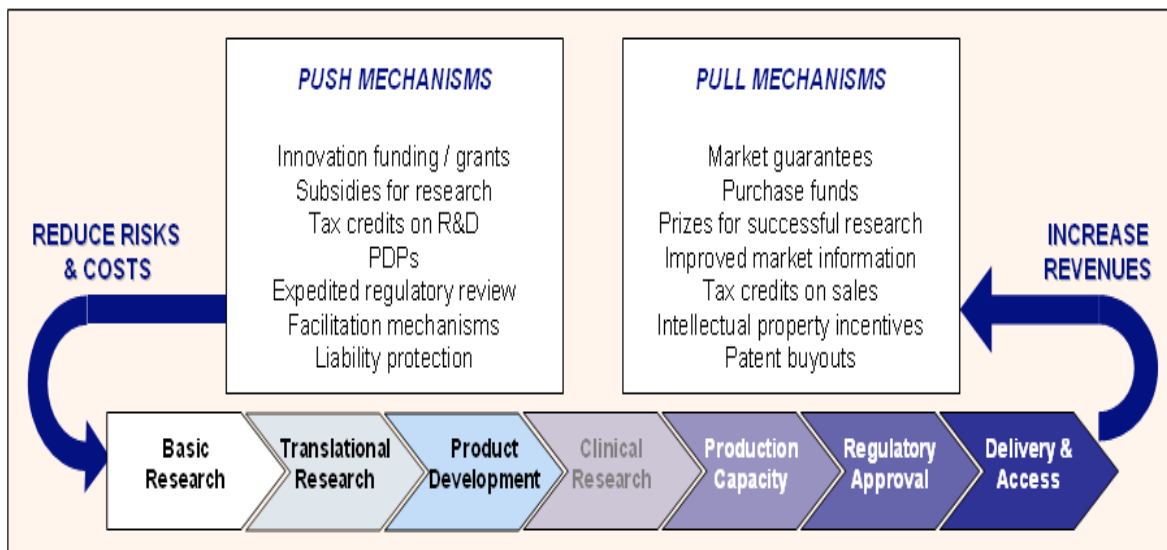
- Essential for basic research, important for manufacturing in some cases.
- But many critical skills are now primarily in the private sector.

2. Incentives for private sector R&D on neglected diseases

- But public sector retains responsibility to set priorities (and finance if necessary).

3. Wholesale transformation of the market/IP system: solve price problem as well as R&D priorities problem

PUSH and PULL mechanisms for increasing private sector R&D on neglected diseases



New and proposed financing mechanisms

- Product development partnerships like DNDi
- Neglected Disease R&D Fund
- Advanced Purchase/Market Commitments
- Prizes and prize funds
- Priority review vouchers (FDA)
- Patent pools

Chagas

Obstacles other than market size

- Inadequate diagnostics
- Lack of clarity about appropriate use of existing drugs
- No test of cure: uncertainty about trial design

Nature of endemic countries

Middle-income LA countries

- May be able to contribute to R&D
- Could help fund R&D
- Offer a modest but not negligible public sector market for new drugs
- Constitute an increasingly important market for big pharma

Elements of an R&D financing solution for Chagas

PULL

- Assurance of purchase by endemic country governments (PAHO Strategic Fund)
- Development and consolidation of market in high-income countries, establishment of differential pricing
- Prizes and prize funds, for registered products and for milestones

PUSH

- Funding of university research
- Product development partnerships like DNDi
 - Sustainable funding for PDPs
 - Incentives for industrial collaborators

NEW SOURCES OF FUNDS

- Currency transaction tax

Assessing financing mechanisms: the big questions

- 1. Effectiveness:** Would it work to bring us new treatments? Would it help to ensure that new treatments reach those who need them most?
- 2. Source:** Who would pay for it? Is the source adequate, sustainable, and fair?
- 3. Governance:** Who would make decisions, set priorities?
- 4. Role of endemic countries:** How do they participate? How do they take responsibility?
- 5. Broader contribution:** Does it bring us closer to a comprehensive solution to the problem of neglected disease R&D?

Back-up slides

A new source of funds: the currency transaction tax

- First proposed by James Tobin as way to moderate financial flows, stabilize financial system in wake of Asian crisis
- Now supported primarily as way to raise money
- A tax of .005% on the four major currencies could raise \$33-60 billion a year
- Would be relatively easy to implement, and would have little or no effect on economic activity (only small fraction of currency transactions related to flows of goods and services)
- Significant interest from several governments, including France

Challenges

- Overcoming resistance from financial sector?
- Deciding how money would be spent: governance
- Reserving share for health R&D

PDP funding is not secure

PDPs have been well supported so far by the Gates Foundation and by governments, but:

- Funding is short-term and unpredictable, while developing the needed drugs and vaccines will take many years.
- The PDPs will need more money as their products move into expensive clinical trials.
- Donors are squeezed by the economic crisis, and their priorities may change (climate change, energy, food security).

➔ **PDPs need a source of long-term, stable funding.**

PUSH: Product Development Partnerships (PDPs) (TB Alliance, International AIDS Vaccine Initiative)

PDPs conduct, organize, and promote R&D for neglected disease drugs and vaccines:

- Manage a portfolio of product candidates, pool donor funds and allocate across projects
- Conduct research, product development, clinical trials through partnerships, often with private industry
- Work with national governments, international agencies to prepare for product adoption and uptake
- Account for two-thirds of the new drug compounds in development for neglected diseases of poor countries