

# Strategy for a Treaty on R&D

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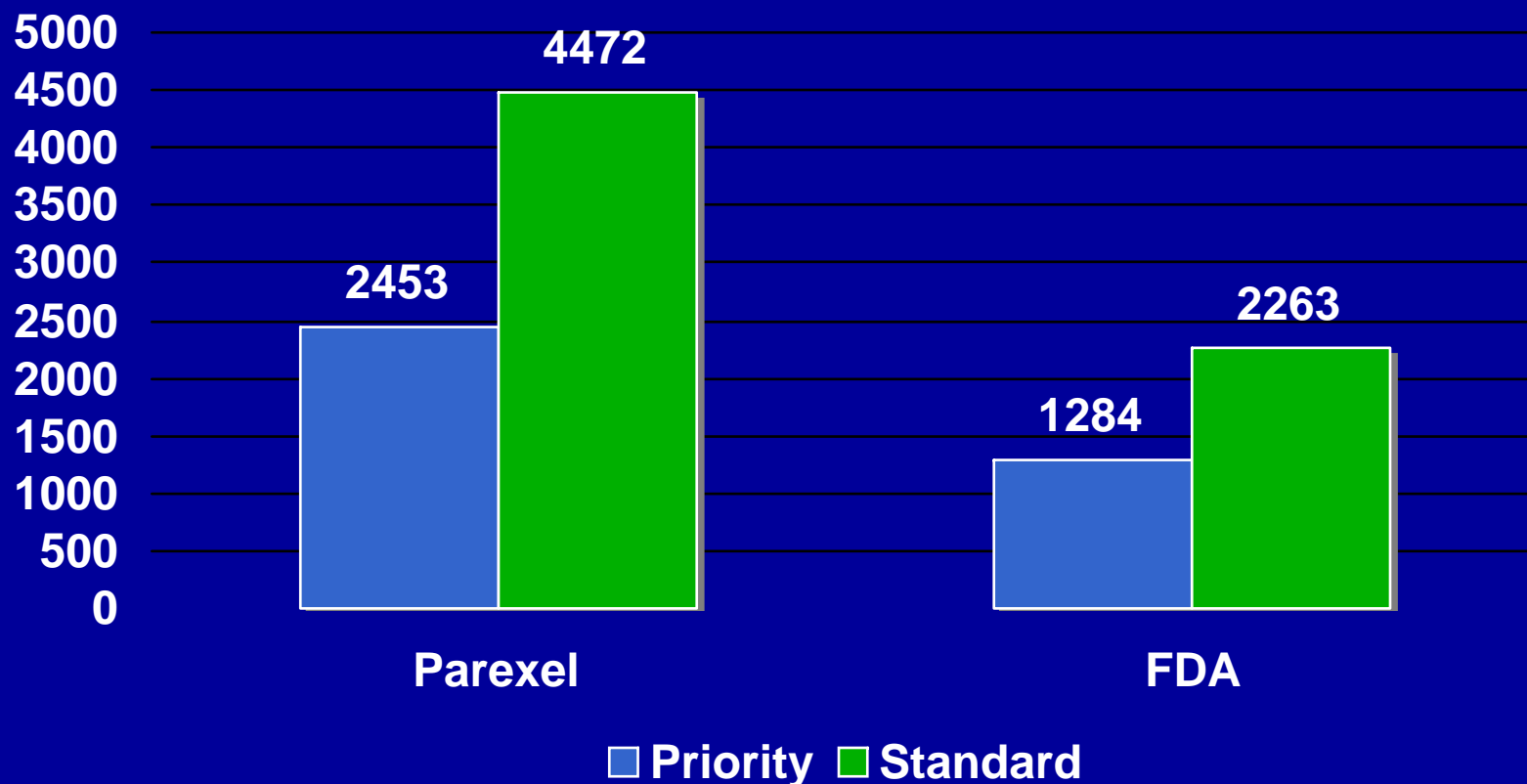
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But before getting to my topic,  
here are some data on clinical  
trials

The number of patients in clinical trails for “standard” approvals are nearly twice as large as the number for priority products.



*Love, Patel, 2007, median number of patients in clinical trials - 1998 to 2004 FDA approved NMEs. Chart presents data from 101 products for which Parexel published data on trial sizes.*

# Back to the topic of the R&D Treaty

# Nature of the problem

- WHO CIPIH refers to three types of diseases
  - Type I - Rich and poor countries have roughly similar burden of disease
    - High prices in wealthy countries stimulates R&D
    - High prices in poor countries are access barrier
  - Type II - Some patients in rich countries, but most in poor countries
    - R&D effort is too small give public health needs
  - Type III - Nearly all patients are poor, living in developing countries
    - No private sector R&D stimulated by patent monopolies

# Proposals to change global trade framework

- 2005 proposal by 170 organizations and experts calls for new global trade framework that focuses on R&D, rather than high drug prices
- Many proposals for global agreements or treaties to support R&D for type II or III diseases.

The World Health Organization  
Inter-governmental Working  
Group (IGWG) on Public  
Health and Innovation and  
Intellectual Property

# What is the IGWG?

- Created by WHA in May 2006 to do two things
  - Implement recommendations of CIPIH
  - Address proposal for new R&D framework proposed by Kenya and Brazil

### 3. [The Fifty-ninth World Health Assembly] DECIDES:

(1) to establish, in accordance with Rule 42 of the Rules of Procedure of the World Health Assembly, an intergovernmental working group open to all interested Member States to draw up a global strategy and plan of action in order to provide a medium-term framework based on the recommendations of the Commission. Such a strategy and plan of action aims at, inter alia, **securing an enhanced and sustainable basis for needs-driven, essential health research and development relevant to diseases that disproportionately affect developing countries, proposing clear objectives and priorities for research and development, and estimating funding needs in this area;**

# Timing

- (3) that the above-mentioned working group shall report to the Sixtieth World Health Assembly through the Executive Board on the progress made, giving particular attention to needs-driven research and other potential areas for early implementation action.
  
- (4) that the working group shall submit the final global strategy and plan of action to the Sixty-first World Health Assembly through the Executive Board;

# Participation

- Rocky start, with many excluded from initial discussions
- In December 2006, IGWG asked EB to create a fast-track process for accreditation, modeled after rules for Tobacco convention

# Schedule

- Online submissions fall 2006
- First meeting of IGWG in December, 2006
- Counties can make proposals to the IGWG
- Some regional consultations (e.g. EMRO August 2007), WHA discussions, etc.
- Meeting in the fall of 2007

# Politics of IGWG effort

- The good:
  - Very constructive and collegial start for IGWG. Everyone was civil and constructive.
  - US, France, Netherlands, Canada, Switzerland, UK, NZ, AU, and other countries wealthy countries made nice contributions to meeting.
  - 31 developing countries called for treaty on R&D.
- The unknown:
  - New Dr. Chan has yet to indicate her views on the process.
- What is needed:
  - Entire effort still makes focus, and high level political leadership

# Big ideas

- Patent pools
  - SARS/Avian Flu, UNITAID, CARICOM, EMILA, etc
- R&D Treaty
  - Big, small
- Prize funds
  - Hubbard, Love, Sanders, Hollis, Pogge, Stiglitz, etc

# One proposal puts all three together

- Create global patent pool for essential medical inventions.
- Create large “prize” fund to reward innovations that improve health care outcomes in developing countries.
  - Only inventions licensed to the pool are eligible for the prizes.
- Global agreement to support funding for R&D prizes.
  - Agree to have expectations that developing countries who support the R&D prize fund will not face TRIPS or TRIPS plus pressures.

# Relevance for TB effort

- Need to identify the global needs for R&D funding
  - Both “push” and “pull” funding
- Need to identify preferred incentive systems
  - Endorse **prize** mechanisms, as superior to mechanisms that rely upon high prices