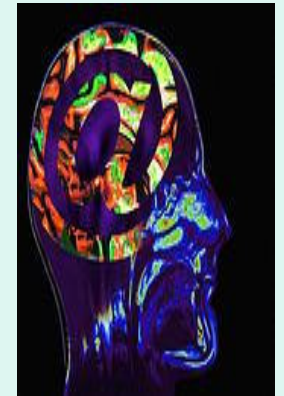


# **The IGWG debate on innovation, access and IPRs in the field of pharmaceuticals**



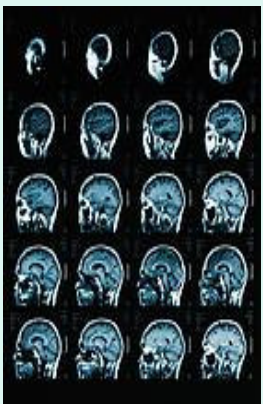
## **The Process and Impact of the WHO Intergovernmental Working Group (IGWG) on Public Health, Innovation and Intellectual Property - An Assessment**



**April 15<sup>th</sup>, 2008, Maastricht**

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**Senior Lecturer, University of Haifa  
Director of Research, Stockholm Network**



## Some facts



**Pharmaceutical sales will reach \$735 billion in 2008 (7% growth from 2007)\***



**Emerging markets (esp. China, Brazil, India, Mexico, S. Korea, Turkey and Russia) are growing faster than ever - 13% on average (China 17% growth in 2007) - US growth is only 4% \***



**29 new specialised products are expected to be launched in 2008 (focus on oncologics, anti-diabetics, angiotensin II antagonists, respiratory agents and anti-psychotics)\***



**Industry will invest approx \$US 100 billion on R&D\*\***

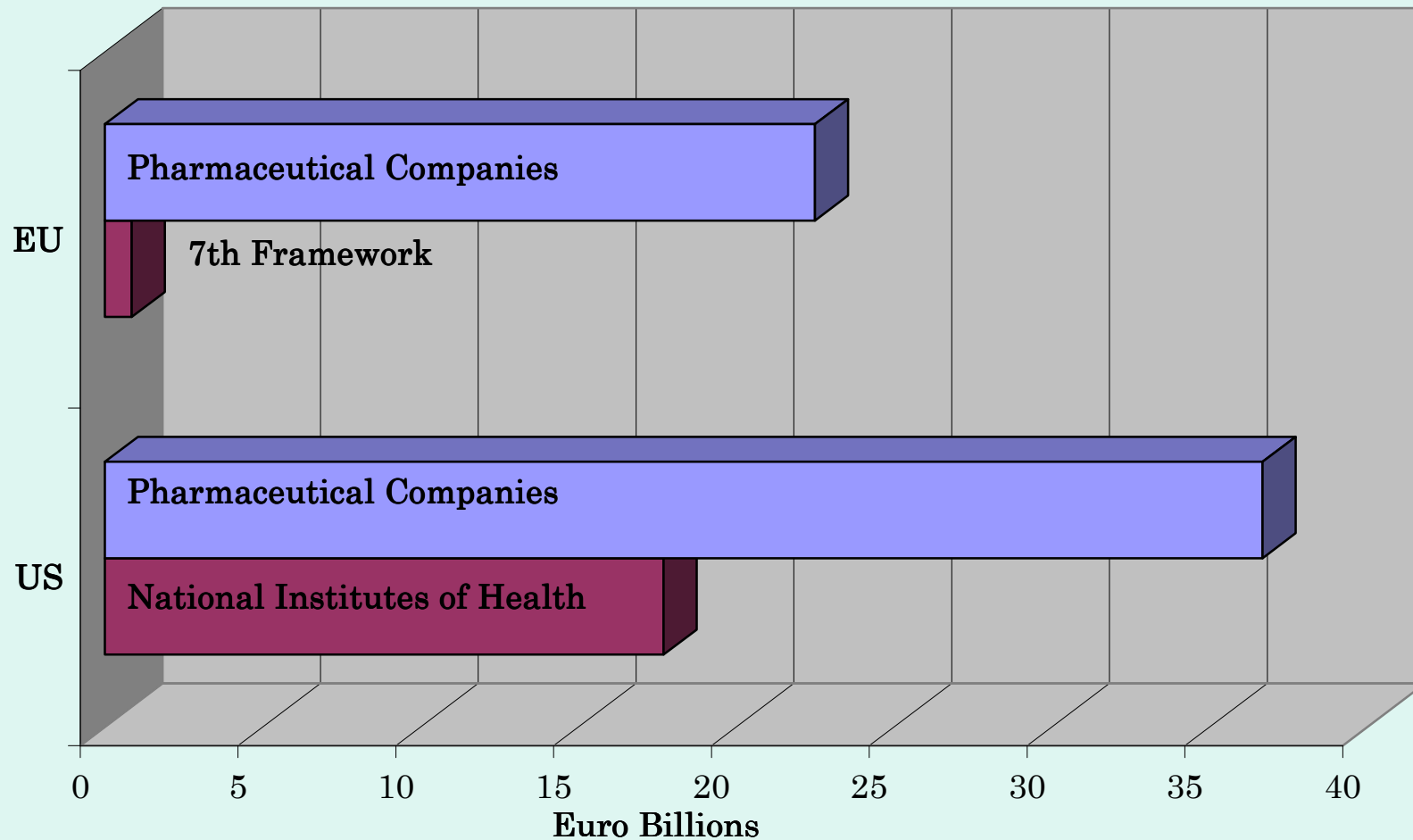
# Approval of New Chemical and Biological Entities in the United States

Calendar Year	Priority	Standard	
	Number Approved	Number Approved	Total
y1993	13	12	25
y1994	12	9	21
y1995	10	19	29
y1996	18	35	53
y1997	9	30	39
y1998	16	14	30
y1999	19	16	35
y2000	9	18	27
y2001	7	17	24
y2002	7	10	17
y2003	9	12	21
y2004	21	15	36
y2005	15	5	20
y2006	10	12	22

*\* Personal caclusations based on FDA - CDER Approval Times for Priority and Standard NMEs and New BLAs Calendar Years 1993 - 2006\* - <http://www.fda.gov/cder/rdmt/NMEapps93-06.htm>*

# Private Vs. Public Funding

Private vs. Public Funding of Bio-Pharmaceutical Research in the EU and the US (2007)



•Sources: EFPIA, PhRMA, NIH  
and DG Research

	Industry	Public
US	36.68	17.7 (National Institutes of Health)
EU	22.5 (2006)	0.85 (7th Framework-Health)

# Human health is the driver



Health is in demand....



Health is in demand, by more people....



Health is in demand, by more people, and for a longer period of time....



Health is in demand by more people, for a longer period of time, and for more medical conditions....



Pharmaceuticals are part of the solution....



# Trends

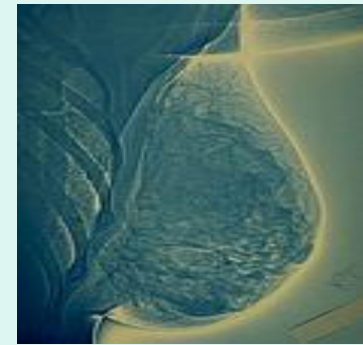
**Ageing population = greater % of the population**

**Demand for medicines is on the rise...**



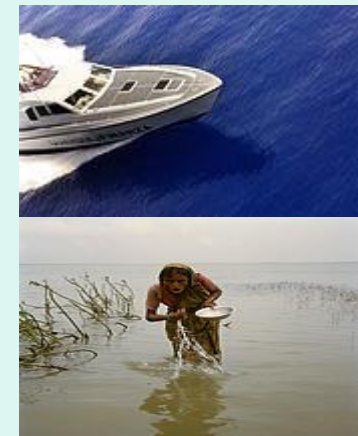
**“Non-curable” diseases are becoming chronic (cancer)**

**People are prepared to live with the disease**



**A small percentage of the (developed) world population still consumes the lion’s share of medicines (though this is now changing)**

**Pharma markets are targeted to “Western-world” diseases**



# Challenging times

Public (Gov.) ability and willingness to allocate resources for drug reimbursement is decreasing (especially in the developed world)

Pressures on companies to curb prices down are increasing

Risks associated with product R&D are getting bigger (including in clinical and post clinical phases...)

Likelihood of developing mega blockbusters (the next Lipitor...) is decreasing

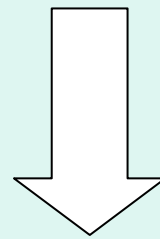
Competition is of a “cut-throat” nature – i.e. more companies are in a “make or break” situation



## **A noble question**

How do we encourage research and development leading to the creation of new products aimed at combating diseases that disproportionately affect developing countries?

**(wrong) Answer**



We establish a new Committee! – the IGWG

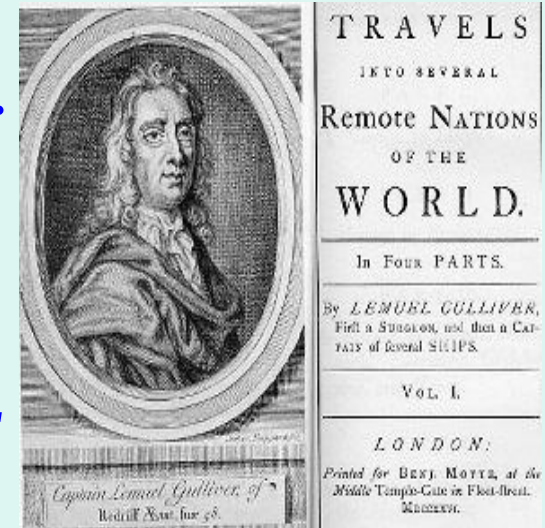
# IGWG set to examine/challenge the concepts of

- Innovation
- Research and Development
- Technology transfer
- Intellectual property rights



## Gulliver's travels - the Lagado Academy

*“Theses persons upon their return began to dislike the management of every thing below; and fell into scheme of putting all arts and sciences, languages and mechanics upon a new front. To this end, the procured a royal patent for erecting an academy for projectors in Lagado....” (part III, chapter iv)*



# The IGWG debates

**Innovation** - is it a bottom up process or a top down one? Can a “new” innovation model be created – one that is “suitable” for developing countries? Can innovation be “de-linked” from the market needs (and the quest for profits)?

**Research and development** - should R&D in developing countries be dependent on the efforts/grants of developed ones? Should R&D be centrally planned and executed? Should we make an “institutional” dichotomy between upstream and down-stream R&D (upstream good, downstream bad....)?

**Technology transfer** - should it be based on voluntary or compulsory practices? Should the public sector assume a new role in the tech transfer process (i.e. control the manner in which technologies are used in the market)?

**Intellectual property rights** - are IPRs part of the solution or part of the problem? Should the use and protection IPRs in the pharmaceutical field become more “flexible”? Should we re-define the underlying rationale of IPRs (and patents)?

## IGWG draft text

Proposed text: *“identify IP-related provisions at different levels – national, regional and international - that might negatively affect increased research on public health, and suggest ways to facilitate access to research results and research tools”*

(Element 2. Supporting Research and Development, paragraph 30(2.2)(c))

## The Lagado Academy

*“In another apartment I was highly pleased with a projector, who had found a device of plowing the ground with Hogs, to save the charges of plows, cattle, and labour...It is true, upon experiment they found the charge and trouble very great, and they had little or no crop. However, it is not doubted that this Invention may be capable of great Improvement”*

(Gulliver’s travels part III, chapter v)



## IGWG draft text

Proposed text: “*examine the feasibility of [voluntary] patent pools of upstream and downstream technologies to promote innovation [and access to] health products and medical devices [for diseases [disproportionately] affecting developing countries]*”

(Element 4. Transfer of Technology, paragraph 34(4.3)(a))

## The Lagado Academy

“*There was a most ingenious Architect who had contrived a new method for building houses, by beginning at the roof, and working downwards to the foundation; which he justified to me by the like practice of those two prudent insects, the Bee and the Spider*” (Gulliver’s travels, part III, chapter v)



## Getting serious – the IGWG will fail because:

- **Detached from the day to day realities of R&D in developing countries (as well as of developed ones)**
- **Political dialogue, not a scientific one (there are some serious discussion today on how R&D can be improved from a scientific point of view, but they are not reflected in the IGWG)**
- **The IGWG document is impossible to implement - it talks about everything and will end up achieving nothing**



*“The only inconvenience is, that none of these projects are yet brought to perfection; and in the mean time, the whole Country lies miserably waste, the houses in ruins, and the people without food or clothes (Gulliver’s travels , part III, chapter v)*

## What can be done at this stage

With less than a month to go - the focus should be on the adoption of a non-harmful strategy (this is the maximum that can be achieved at this stage):

- World Health Assembly to adopt only a small proportion of the text (use the rest as a “backgrounder”)
- Text should be general and “non-obligatory”/compulsory
- Text should not focus on IPRs (or just mention them in brief) as they are the least relevant component in this exercise
- Later on, identify best practices that currently take place in developing countries (including of public-private collaborations via the so called Bayh-Dole framework)/attempts to “localize” existing treatments

# Thank you for your time!

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