

# We need a responsible R&D model



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The Berne Declaration / Health Action International

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## The problem(s)

- Misalignment of financial incentives and public health
  - ⇒ Largely due to the patent-based system
  - ⇒ Geared towards profit-driven research priorities
  - ⇒ Monopolies leading to high prices, issues of access to medicines
  - ⇒ Massive – and sometimes illegal – promotion practices
- Conflicts of interests
  - ⇒ Companies design their trials and test their own products, with the risk to maximising benefits and downplaying harm
  - ⇒ Proximity with authorities, influence power, industry-friendly rules

# Financial Incentives vs. Public Health



*“(...) are the incentives provided by the patent system appropriate...? Sadly, the answer is a resounding “no”*

Joseph E. Stiglitz, *Prizes, not patents*,  
Project Syndicate, 6 March 2007

*“Objectionable corporate strategies are the product not of rogue corporations, but rather of systemic market incentives”*

Marc-André Gagnon, *Corruption of Pharmaceutical Markets: Addressing the Misalignment of Financial Incentives and Public Health*,  
Journal of Law, Medicine & Ethics 41, no. 3, 1 October 2013

- The price of certain “new” medicines has exploded...
- Whilst the number of clinically superior drugs is small...
- And costs of pharmaceutical research remain a black box...
- Patent monopolies are undermining competition, leading to high prices ...
- Whilst regulatory mechanisms suffer from conflicts of interests...
- Alternative models of innovations exist but lack political foothold...

## Ways forward?



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## Drug prices:

# Burden on healthcare systems



- 2000-2009: public pharmaceutical expenditure has increased on average by 76% in the EU.  
=> 2011: 3<sup>rd</sup> post in EU Member States' health care budgets<sup>1</sup>
- The rise in expenditure of patented medicines has outpaced savings due to promotion of generics' use<sup>2</sup>
- Influential oncologists have recently described current prices of new patented cancer medicines as *'astronomical, unsustainable and even immoral'*<sup>3</sup>

<sup>1</sup> Kanavos, P. et al. *Differences in costs of and access to pharmaceutical products in the EU*. Policy department economic and scientific policy, Brussels, 2011

<sup>2</sup> Carone, G. et al. *Cost- containment policies in public pharmaceutical spending in the EU*. European Economy: Economic papers 461, Brussels, September 2012

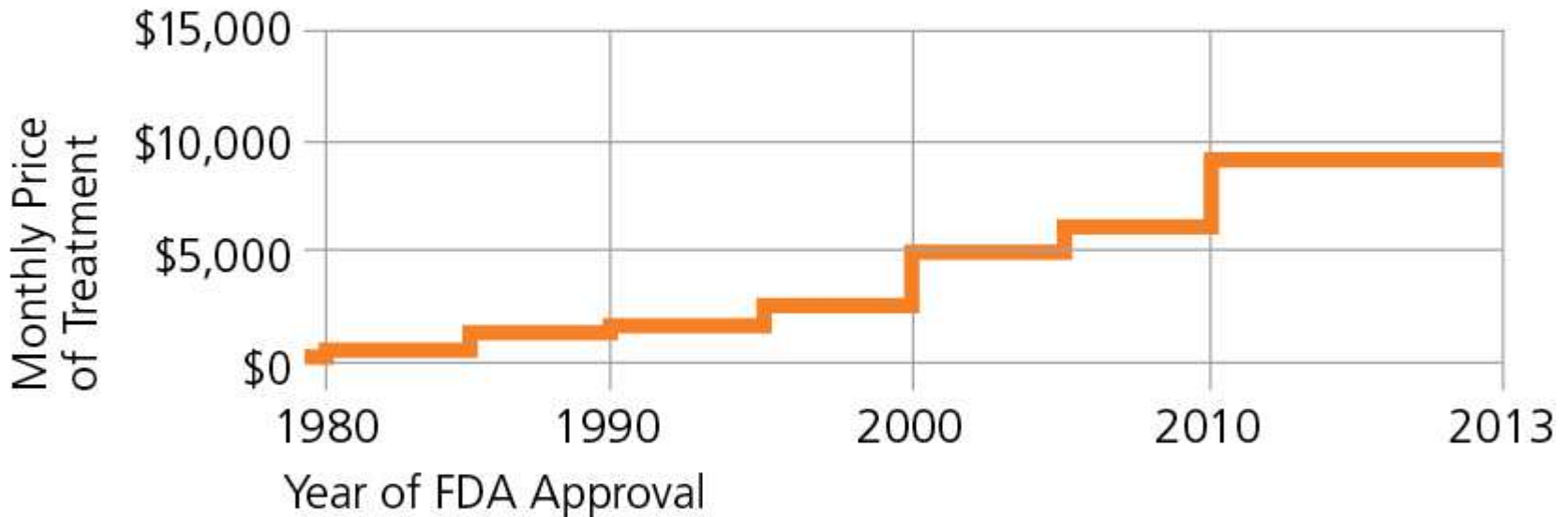
<sup>3</sup> Laurance, J. *Makers of anticancer drugs are "profiteering," say 100 specialists from around the world*. British Medical Journal (BMJ) 346:f2810, 2013.

# Cancer drug price increases 1980 - 2013



Rapid Rise

Median Monthly Price between 1985-2010: **+1330%**



Source: Memorial Sloan-Kettering Cancer Center; 2013.



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## R&D is no excuse



*“Are we the pharmaceutical companies out of touch with reality? (...) Pharma must bear all the research costs. But this is not a license for pharmaceutical companies to demand excessive prices. Especially now that our government has fiscal difficulties”*

Julien Brabants, Director of GSK-Belgium  
De Standaard, 20 May 2015 (translation)



# Myth of high prices to recoup R&D investment



- Prices set according to what the market is ready to pay
- Industry estimates of average R&D costs for a new molecule (\$2.6bn) highly inflated and controversial
  - ⇒ not-for-profit estimates are 15 to 20-times less<sup>1</sup>
  - ⇒ “(...) companies have been spending only 1.3% of revenues on basic research to discover new molecules, net of taxpayer subsidies”<sup>2</sup>
- The real costs of R&D remain unknown
- Companies spend more on marketing than on R&D

<sup>1</sup> Drug for Neglected Diseases initiative (DNDi). *An Innovative Approach to R&D for Neglected Patients: Ten Years of Experience & Lessons Learned by DNDi*. January 2014

<sup>2</sup> Light D. & Lexchin J., *Pharmaceutical research and development: what do we get with all that money?*, British Medical Journal, BMJ 2012; 344: e4348

## Drug prices related to R&D costs?



*“The \$1 billion price tag [for developing a single new medicine] is one of the great myths of the industry”*

Andrew Witty, GSK chief executive  
Reuters, 14 March 2013

*“There is a tremendous amount of waste in the system”*

Joe Jimenez, Novartis chief executive & new president of EFPIA  
The Financial Times, 7 June 2015

## Example of Sovaldi Hepatitis C



- Between €25,000 - €56,000 for 12 week course in EU
- Costs of R&D limited (buy-out, few trials, public R&D)
- Manufacturing costs between \$68 - \$136 per treatment
- Even rich countries can't afford it at this price tag
- Rationing in the vast majority of EU countries (advanced liver cirrhosis)
- Same trend for combinations & competitors' medicines

# Hepatitis C Treatments

**Table 11. Prices for 12 weeks of treatment**

	SIM		SOF		SOF/LDV		Viekira Pak®
	Original currency	US\$	Original currency	US\$	Original currency	US\$	US\$
USA		\$ 66 360 \$ 31 500**		\$ 84 000 \$ 45 612**		\$ 94 500 \$ 69 636**	\$ 83 319
Canada			\$ 55 000	± \$ 49 730			
Egypt				\$ 900			
France			€ 56 000 € 41 000*	± \$ 71 630 ± \$ 52 440*	€ 48 000	± \$ 61 400	
Japan		\$ 11 244					
Spain	€ 25 000*	± \$31 980*					
Switzerland			CHF 57,600	± \$60 390			
United Kingdom	£ 22 398	± \$ 36 560	£ 34 983	± \$ 57 100			

\* Negotiated for government reimbursement scheme. \*\* Lowest reported price negotiated by the USA Department of Veterans. Conversions to US\$ based on average exchange rates for Quarters 1–3, 2014 (OANDA).

- *“The public sector now has a much more direct role in the applied-research phase of drug discovery”<sup>1</sup>*
  - Public sector’s share (discovery, tax discounts) really taken into account in the industry R&D estimates?
  - *“44% of innovative drugs recommended for marketing authorisation in the EU originated from small or medium sized enterprises, academia, public bodies, and public-private partnerships”<sup>2</sup>*
- ⇒ Importance of publicly-funded research, upstream but also downstream (clinical trials)

<sup>1</sup> Ashley J. et al., *The Role of Public-Sector Research in the Discovery of drugs and Vaccines*, The New England Journal of Medicine 2011; 364: 535-41

<sup>2</sup> Lincker H et al., *Regulatory Watch: Where Do New Medicines Originate From in the EU*, Nature Reviews Drug Discovery, 31 January 2014

# Public R&D



- Total global investments in health R&D (both public and private sector) in 2009 : US\$240 billion.
- Of the US\$214 billion invested in high-income countries, 60% came from the business sector, 30% from the public sector, and about 10% from other sources (including private non-profit organisations)

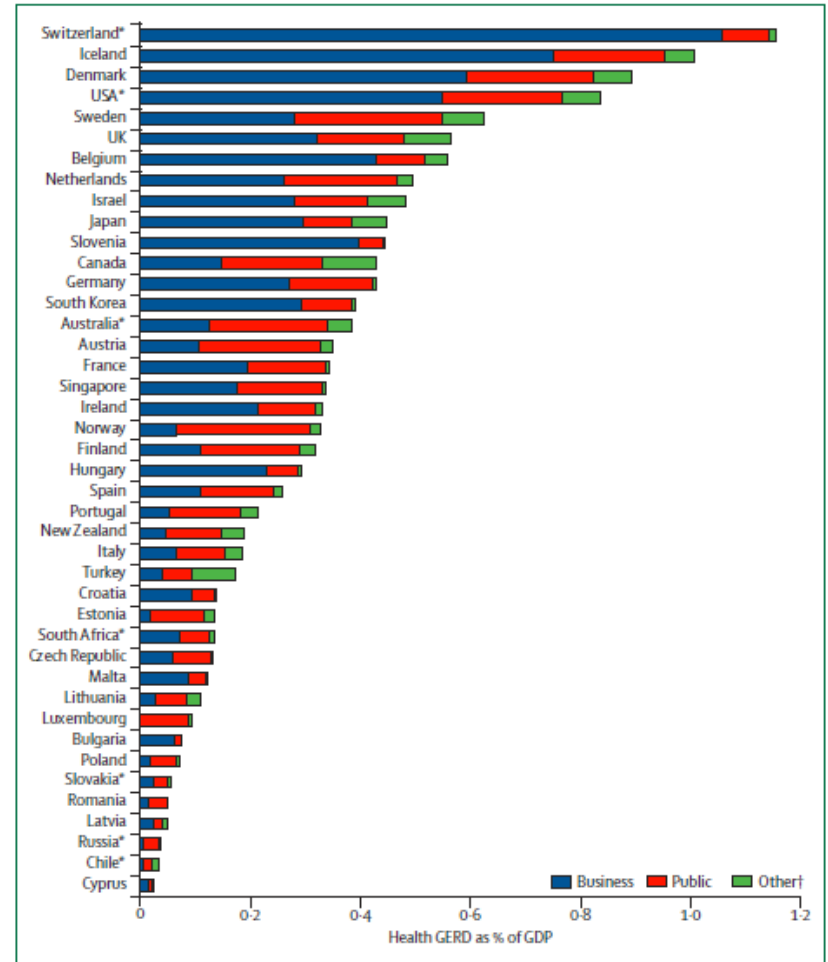


Figure 3: Health GERD by estimated broad funding source  
Data are from 2009 unless indicated otherwise. GERD= gross domestic expenditure on research and experimental development. GDP=gross domestic product. \*Indicates data from different years: Slovakia 2010; Russia 2009-10; Australia and South Africa 2008-09; Switzerland, USA, and Chile 2008. †“Other” encompasses estimated research and development funds received by government, higher education, and private non-profit institutions from higher education (including the institutional funds of private universities), private non-profit organisations, and from abroad.

Røttingen J.-A. et al. *Mapping of available health research and development data: what's there, what's missing, and what role is there for a global observatory?* The Lancet online, May 2013.



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## R&D effectiveness



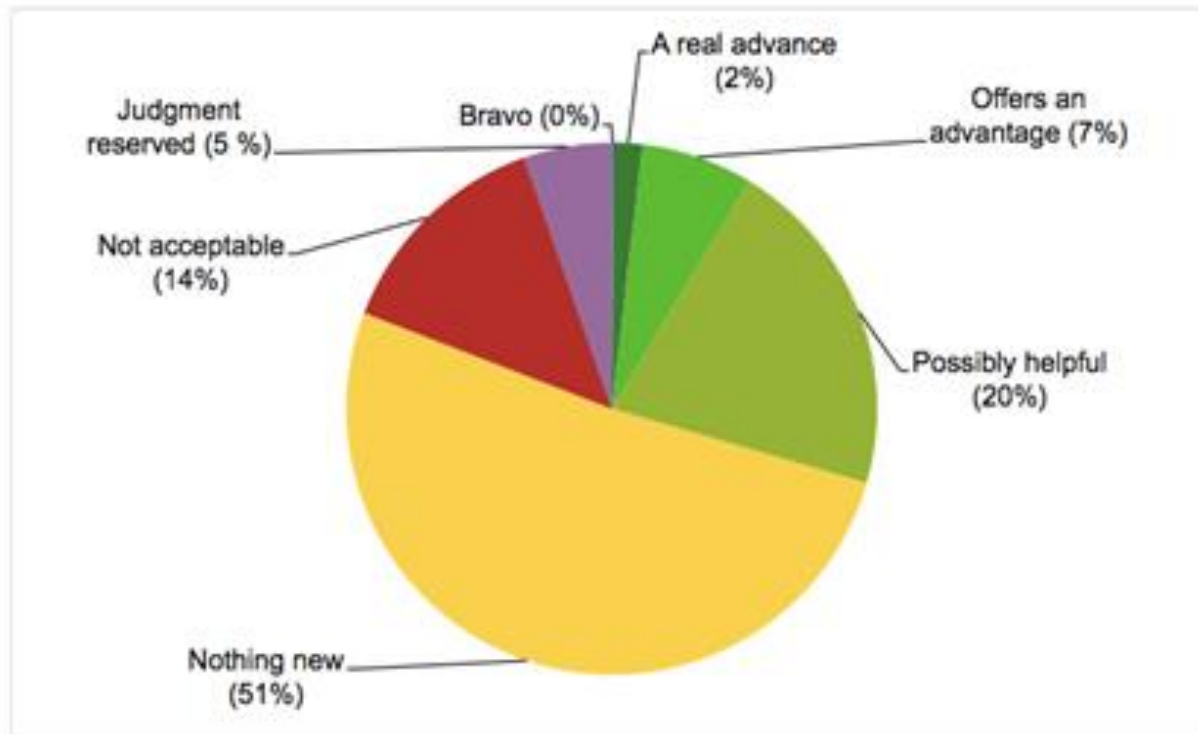
- *“By the 1980s drugs were less than four times better than placebo; by the 1990s, twice as good, and by the 2000s just 36 percent better than a placebo”<sup>1</sup>*
- Non-inferiority trials merely showing the drug is not worse than existing ones (but not necessarily superior)
- Neglected areas of R&D despite of public health importance
  - ⇒ Antibiotic resistance
  - ⇒ Combination of drugs (patents!)
  - ⇒ ....

<sup>1</sup> Olsson M. & Marcus S., *Decline In Placebo-Controlled Trial Results Suggests New Directions For Comparative Effectiveness Research*, Health Affairs, June 2013 vol. 32 no. 6 1116-1125

# New medicines – few benefits 2000-2013

2

Prescrire's ratings 2000 to 2013  
Percentages per category  
N=1345

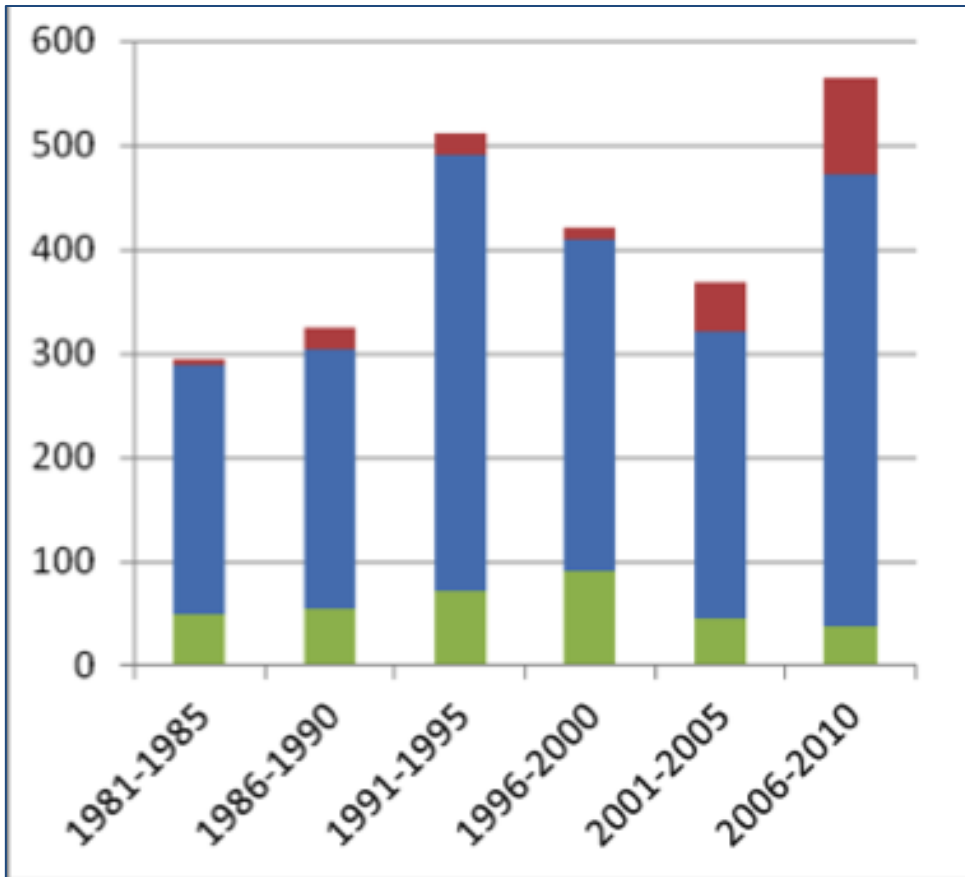






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# New medicines – few benefits II 1981-2010



- Negative Added Therapeutic Value
- Positive Added Therapeutic Value
- Neutral Added Therapeutic Value



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# Problems linked with patenting



- Profit-driven innovation model

- ⇒ ↗ secondary patenting (*'me-too'*) with little therapeutic advance
- ⇒ Some priority health needs are not or insufficiently addressed
- ⇒ Investment protection mechanism, “*broken social contract*”
- ⇒ Resources wasted in patent litigations

- High prices

- ⇒ Lack of competition (monopoly)
- ⇒ Practices to delay entry of generics into the market
- ⇒ Cumulative patenting on single drugs

<sup>1</sup> Geiger C., *Implementing Intellectual Property Provisions in Human Rights Instruments: Towards a New Social Contract for the Protection of Intangibles*, Center for International Intellectual Property Studies (CEIPI) – University of Strasbourg; Max Planck Institute for Innovation and Competition, June 2014

## European Commission Enquiry



*“ Citizens waited more than seven months after patent expiry for cheaper generic medicines, costing them 20% in extra spending.”*

*“ The inquiry showed that originator companies use a variety of instruments to extend the commercial life of their products without generic entry for as long as possible.”*

*“The inquiry also confirms a decline of novel medicines reaching the market”*

*“Overly restrictive intellectual property rights actually slow new discoveries, by making it more difficult for scientists to build on the research of others and by choking off the exchange of ideas that is critical to innovation”*

Joseph E. Stiglitz, *Don't Trade Away Our Health*,  
New York Times, 30 January 2015

# Alternatives to patent models



# Among the WHO Experts recommendations<sup>1</sup>



- Need for alternative biomedical R&D models that de-link the cost of R&D from the price of medicines
  - ⇒ Various ‘push’ and ‘pull’ mechanisms proposed: public and indirect (tax-based) funding, inducement prizes, patent pools, ...
  - ⇒ Principle of open knowledge innovation: generating knowledge free of restrictions, publication of data, transparency
- EU has recognised the need for new biomedical R&D models in *Horizon 2020* (including prizes)<sup>2</sup>

<sup>1</sup> World Health Organization. *Research and Development to Meet Health Needs in Developing Countries: Strengthening Global Financing and Coordination*. Report of the Consultative Expert Working Group on Research and Development: Financing and Coordination, WHO, April 2012

<sup>2</sup> European Commission, *Horizon 2020 – The Framework Programme for Research and Innovation*, Brussels, November 2011

- The pharma industry should be held accountable to their corporate responsibility to respect human rights
  - ⇒ *“In order to identify, prevent, mitigate and account for how they address their adverse human rights impacts, business enterprises should carry out human rights due diligence process”<sup>1</sup>*
- Needs-driven, open models of innovation that can bring more affordable medicines for unmet medical needs
  - ⇒ Models promoting the ‘de-linkage’ of R&D costs from price of medicines
  - ⇒ Increased public funded health R&D that should result in public good and medical products that are suitable, more affordable and accessible

<sup>1</sup> United Nations, *Guiding Principles on Business & Human Rights: Implementing the United Nations “Protect, Respect and Remedy” Framework*, Human Rights Council, Geneva, 2011



- Independence, transparency and accountability of decision-making processes and bodies
  - ⇒ Reinforce public health and consumers' trust in medicines policy
  - ⇒ Transparency (R&D costs, access to data)
  - ⇒ Patients organisations
- Refrain from increasing monopoly protections
  - ⇒ IP and beyond patenting (data exclusivity, trade secrets, ...)
  - ⇒ Promote the use of existing flexibilities to improve public health





Thank you

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