Panel: Building an Ideal World for Improving Patient Outcomes in Oncology

Patient Leader Education Summit
Toronto, March, 31rst, 2017

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Conflicts of interest

- Work in a governmental HTA agency for many years.
- Work as a consultant with different companies over the last 12 months. No active contract.
- Ongoing work with the Institute for Clinical and Economic Review in Boston.

For improving patient outcomes…..

We need **access** to **better treatments**.

Access to Better Treatments

- Innovation
- Market Access
- Coverage

Access and Coverage depend on

- Evidence on Safety
- Evidence on Effectiveness
- Price

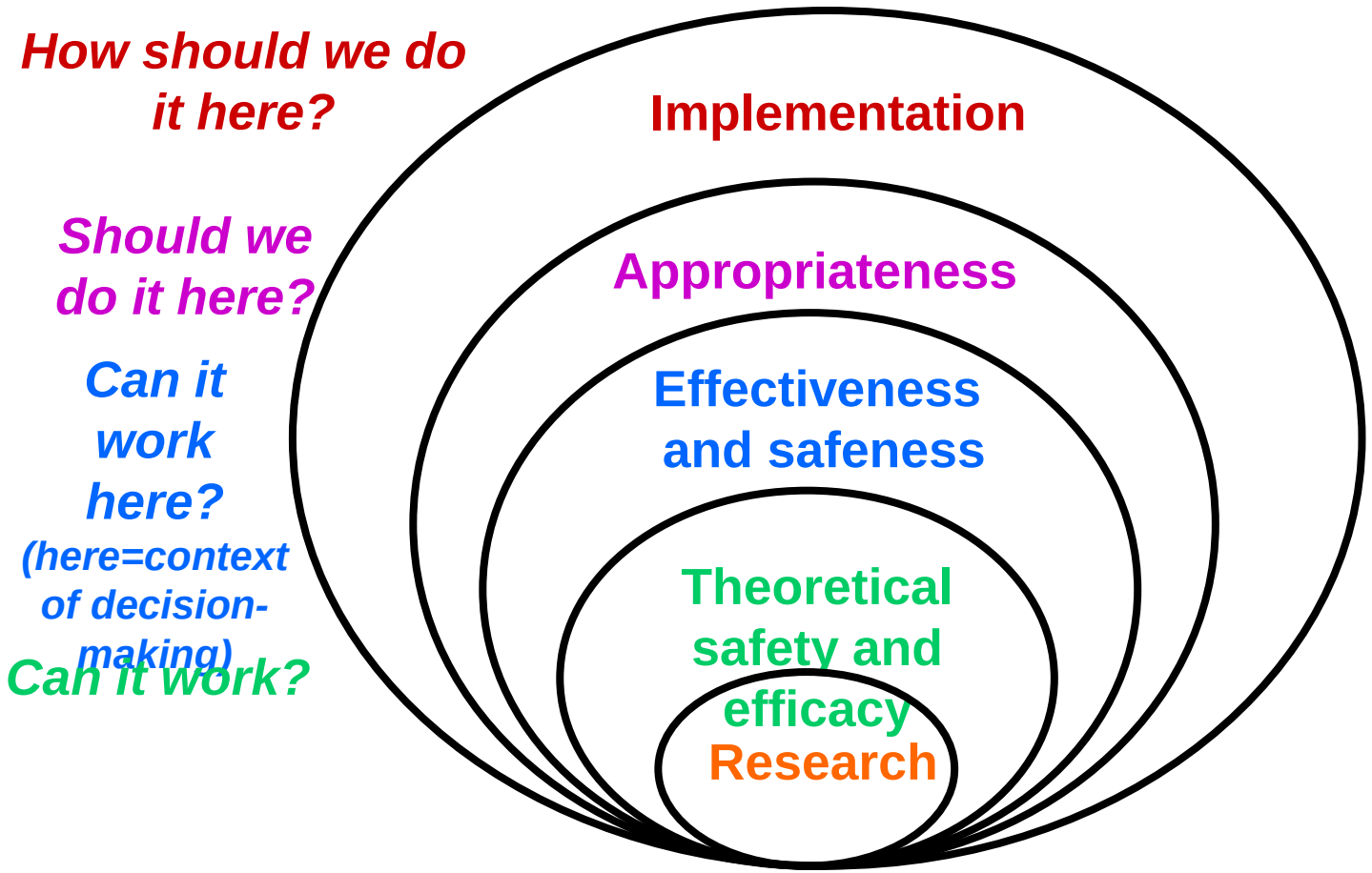
The origin of Health Technology Assessment

Request of the US Congress Senate Committee on Human Resources to OTA in 1974: « whether a reasonable amount of justification should be provided before costly new medical technologies and procedures are put into general use»

Decisions based on needs expressed by physicians

Decisions based on (informed by) a formal and transparent assessment of the evidence

Reasoning in HTA



- HTA depends on available primary studies.
- HTA must deal with uncertainties in knowledge.
- HTA can be a hurdle or an enabler for innovations.

Adapted from Health technology assessment of medical devices. WHO Medical device technical series, 2011. Available at: http://whqlibdoc.who.int/publications/2011/9789241501361_eng.pdf

Current challenges

- Precision medicine deals with small groups of patients
- Tradeoff between time and uncertainties
- Connecting research and innovation to patient care
- Affordability

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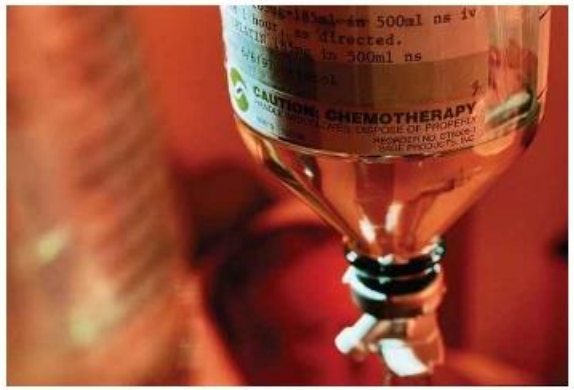

Will the cost of cancer drugs break the economy?

By Elizabeth Whitman | March 14, 2017

If left unchecked, the rising cost of cancer drugs could have devastating implications for individuals, societies and national economies, a group of cancer physicians and researchers said.

In a new paper published Tuesday in Nature Reviews: Clinical Oncology, the cancer experts excoriated the pharmaceutical industry for pricing oncology drugs at rates that make them inaccessible and are unjustifiably high given the often scant benefit some of these drugs bring patients.

"The findings of empirical analyses struggle to link the high costs of anticancer drugs with any rational considerations," the authors wrote. "Instead, the cost of anticancer drugs seems to be driven by what companies believe the market will bear."

RELATED CONTENT

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A Better Balance Between Accelerated Access And High-Priced New Drugs: A New Conditional Approval Option

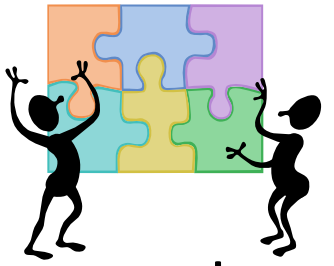
Robert Bohrer

March 20, 2017

- **US AIDS Coalition to Unleash Power: get drugs out to patients before all of the safety and efficacy data are in**
- **1992 parallel track initiative used only once for stavudine, a still-experimental drug**
- **Drug price limited to cover cost for trial**
- **Physicians had to provide data on their patients and patients' responses to treatment**
- **21st Century update of the 1992 HIV-only Parallel Track: Conditional approval with price restriction**

http://healthaffairs.org/blog/2017/03/20/a-better-balance-between-accelerated-access-and-high-priced-new-drugs-a-new-conditional-approval-option/

Necessary conditions for Conditional Approval with Price Restriction



1. Developing the vision
2. Developing Trust (probably the biggest challenge)
3. Transparency and patient participation at all steps
4. Collaborative, patient-centered evidence-development pathways
5. Methods and infrastructure:
    a) innovative trial designs, ex randomized register trials;
    b) information systems based on Big Data, Open Data and Linked Data
    c) processes based on Living Lab style approaches
6. Patient organisation acting as catalyzers between the economic, scientific, administrative and political perspectives

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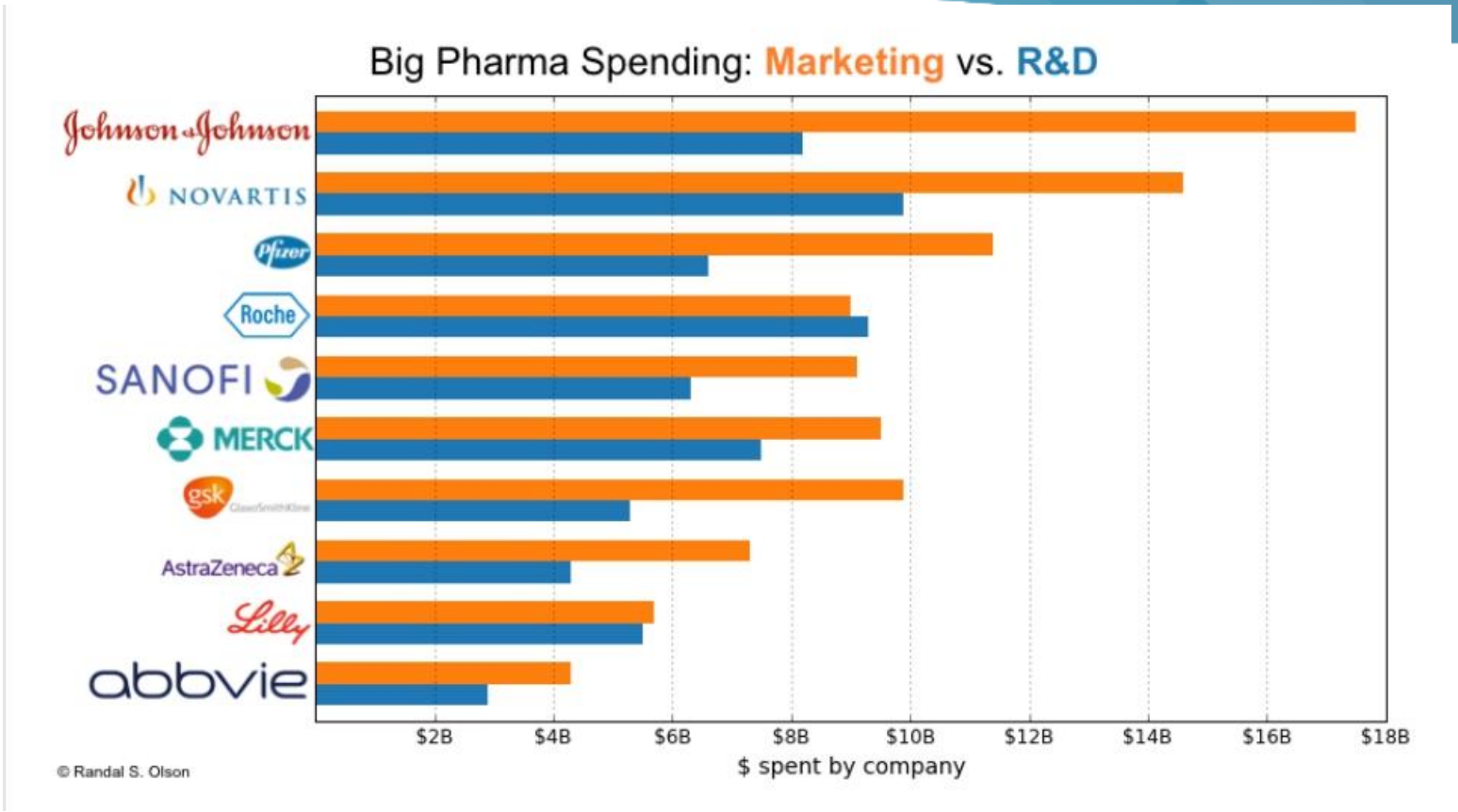
Additional Slides

“Putting Big Pharma spending in perspective”



Beyond Regulation, HTA and Negotiation

1. Health Canada cannot diminish drug prices.
2. PMBRB's tools are very limited concerning the typical new drugs with high price tags.
3. HTA and related processes provide pharmaco-economic information to inform decision-making.
4. PCPA can lower prices, but often not to the extend needed for enabling coverage.
5. Industry is using the market mechanisms that allow the current evolution in pricing.
6. Innovative mechanisms are needed for enabling innovative drug development and market access.
7. Lowering development time and development cost may enable significantly decreased drug prices.

Progressive field evaluation

Slide from INESSS work with the Advisory committee on HTA and innovative technologies 2012-2015
http://www.inesss.qc.ca/en/networks-andpartnerships/bridging-mechanisms/advisory-committee-on-hta-and-innovative-technologies.html

Objectives:

- Align the value proposal of an innovative technology with the needs of the users
- Integrate the knowledge and the experience of the partners involved
- Identify optimal conditions and adapt the use of a technology accordingly
- Collect information about the effectiveness of a technology, as well as contextual and organizational elements relevant to decision makers

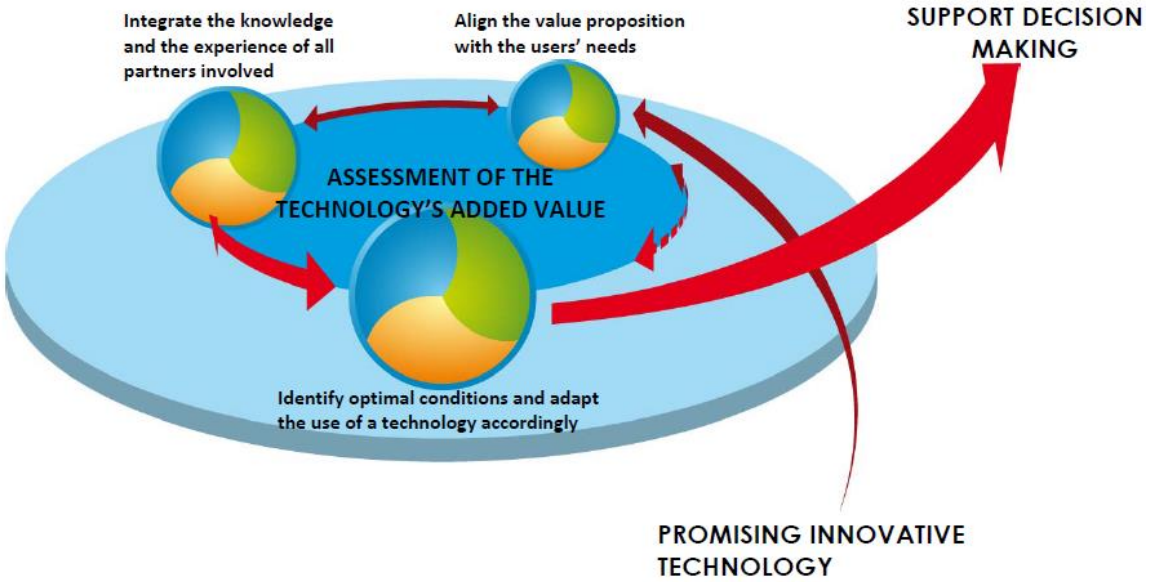


Image adapted from the Living Lab Methodology Handbook, Ståhlbröst et Holst, 2012, available at http://www.ltu.se/cms_fs/1.101555!/file/LivingLabsMethodologyBook_web.pdf