Institute of Health Economics

The Future of Biologic and Biosimilar Therapies for the management of Rheumatoid Arthritis in Alberta Health Care

May 29, 2014

Value Based Healthcare - What to do with Subsequent Entry Biologics

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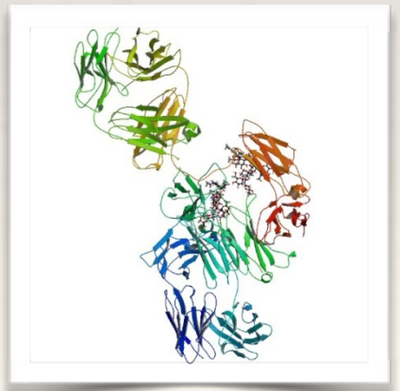
Alberta Health Services

Conflict of Interests

- Have presented on this topic to BIOTECanada on two previous occasions
- Alberta Health Services employee
- Views expressed today are my personal opinions and are not that of my employer



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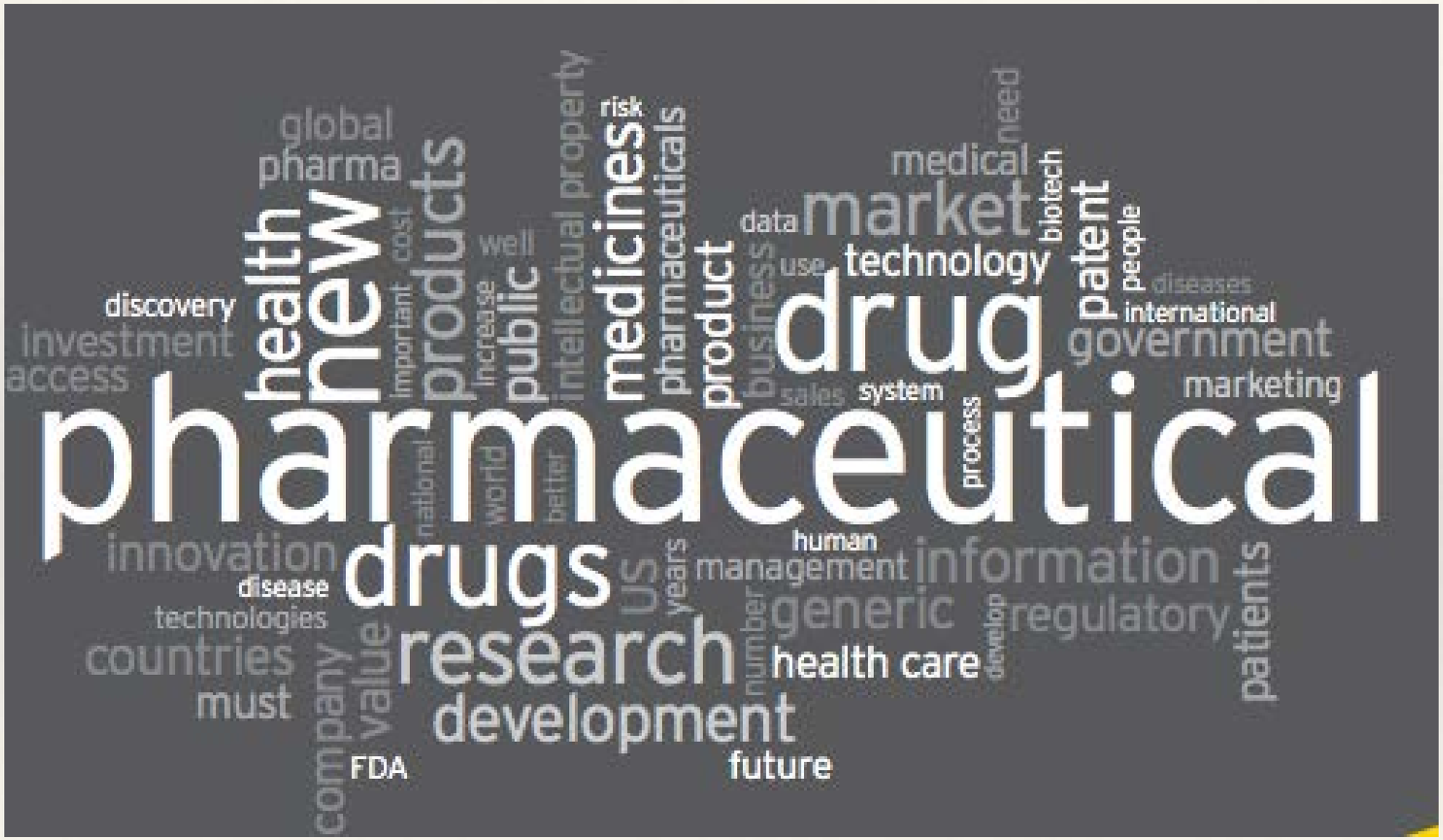
Then - 10 years ago



EY Pharmaceutical Survey results - 2014 Global Report

"Progression - Navigating the payer landscape"

SourceURL:

http://www.ey.com/Publication/vwLUAssets/EY_-_Progressions_2014:_Navigating_the_payer_landscape/$FILE/EY-progressions-2014.pdf

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Now - 2014

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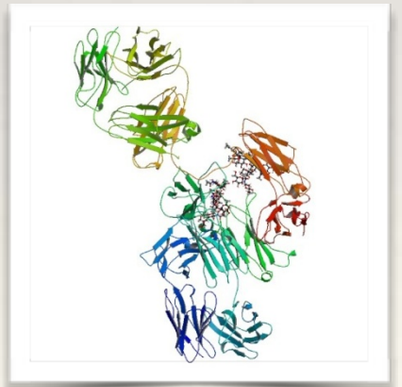
The Era of Value Based Healthcare (VBH)

Today getting market authorization is just the start

- National Institute for Health and Care Excellence
- CADTH
- Australia
- New Zealand
- Comparative effectiveness in USA
- IHE



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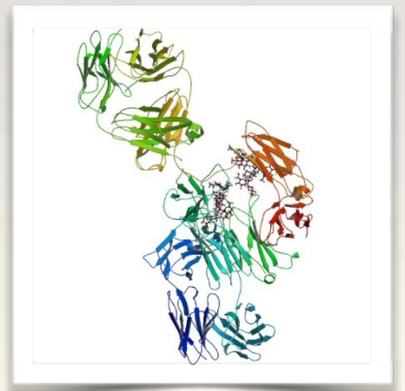
Value

At its heart, VBH involves a simple equation:

Value = Outcomes/Cost (1)



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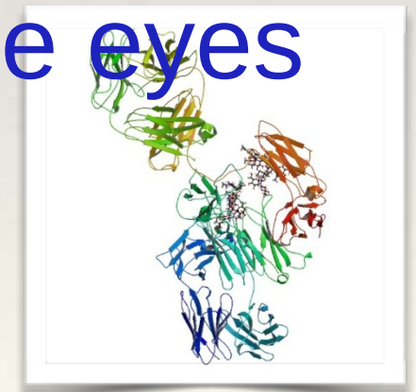
1. Value-based healthcare - The implications for pharma strategy - The Economist/ Intelligence Unit March 2014 White Paper - http://pages.eiu.com/PharmaStrategyVBH2014.html accessed March 14, 2014

Value

Value = Outcomes/Cost

Outcomes: Safety and Effectiveness

When data surroundings outcomes are unknown or limited the value becomes questionable in the eyes of patients, payers and prescribers.



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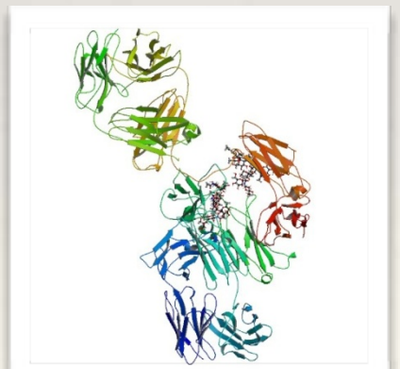
Value of Biologics

- 10 years on as biologics become “standard of care” we still see “restrictions” in place by institutional payers
- Thus “Value” is a continual and long-term struggle as the three key stakeholders often do not have a common perspective



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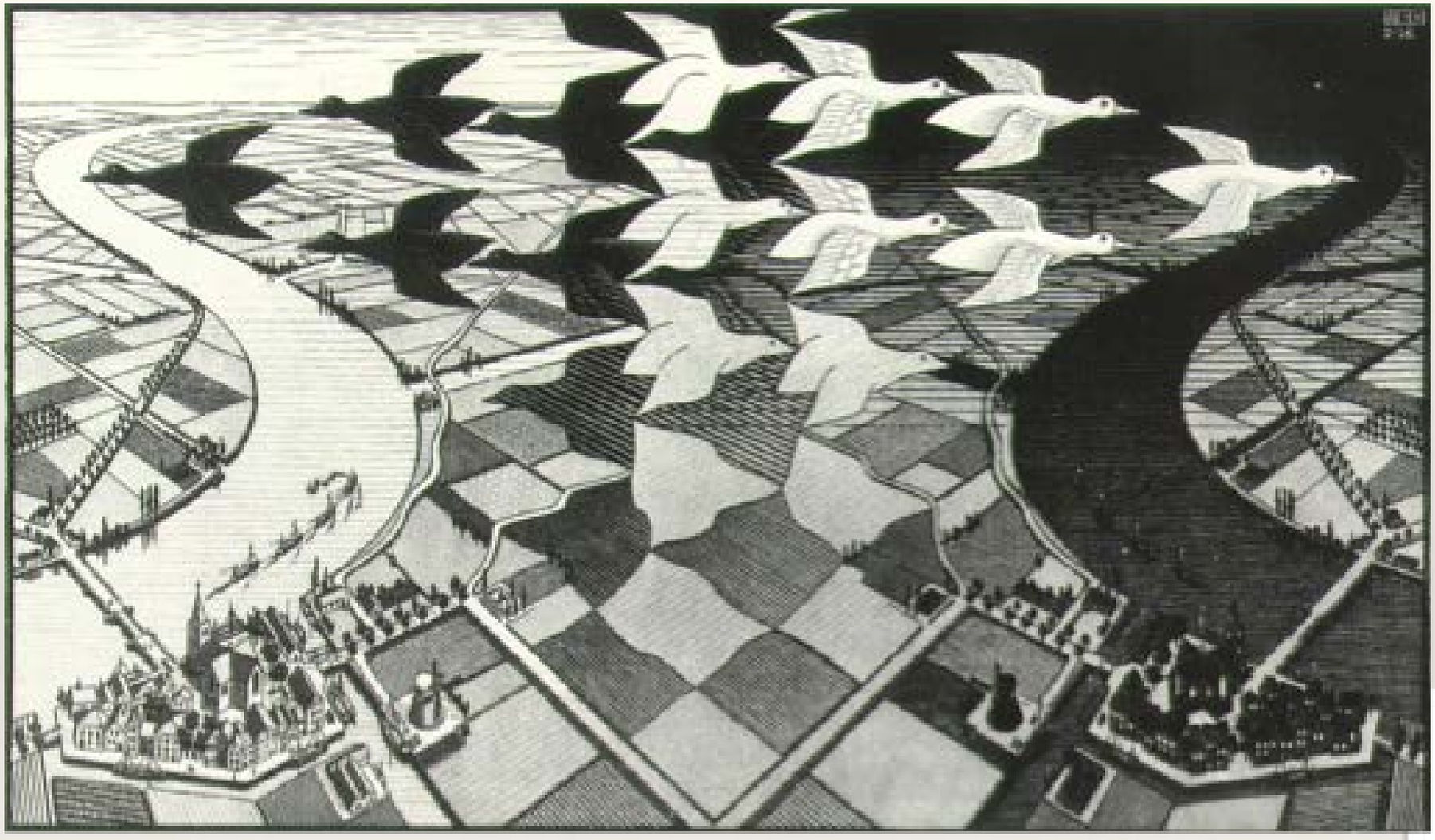
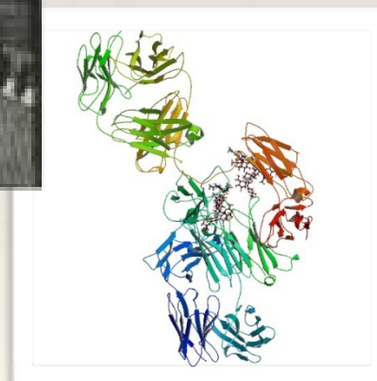
Perspectives



M.C. Esher 1898 –1972 http://deskarati.com/2012/03/27/maurits-cornelis-escher/ Accessed April 30, 2012



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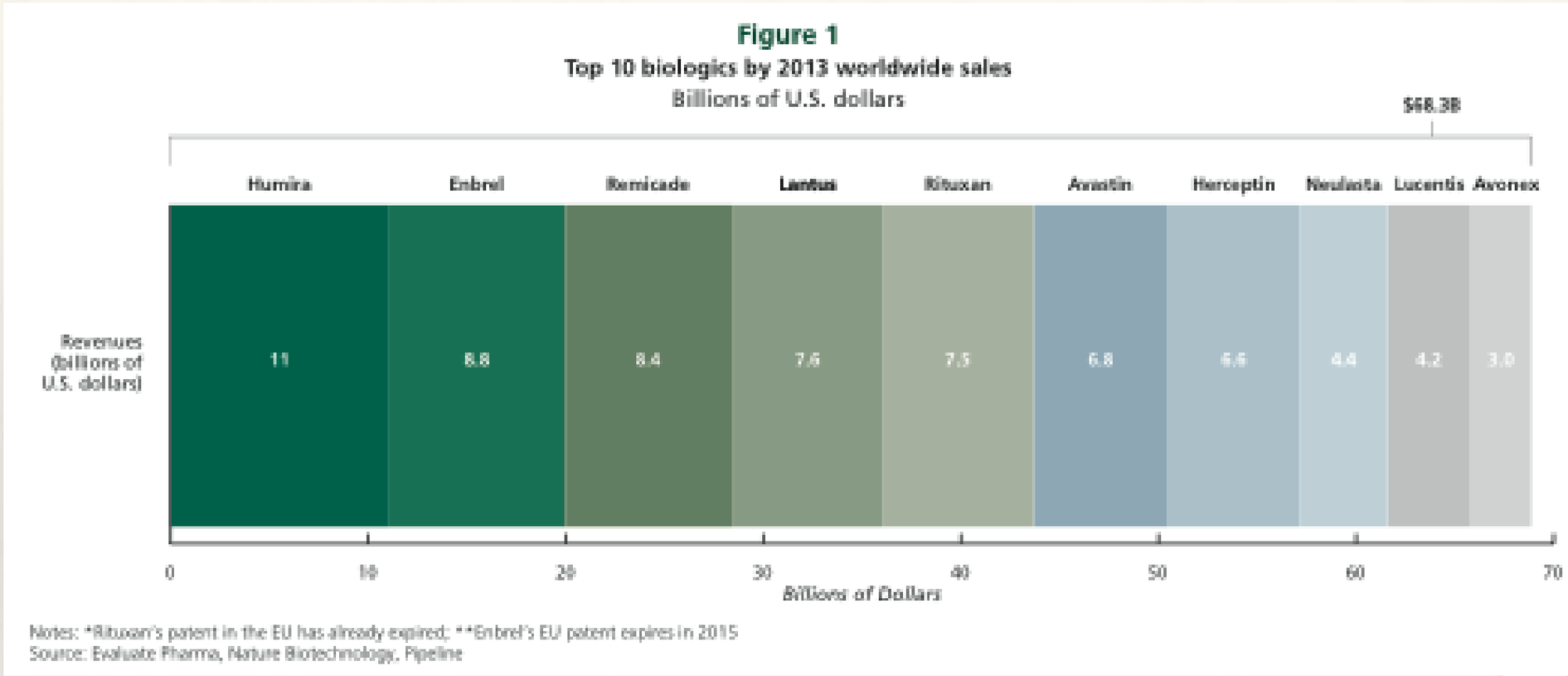
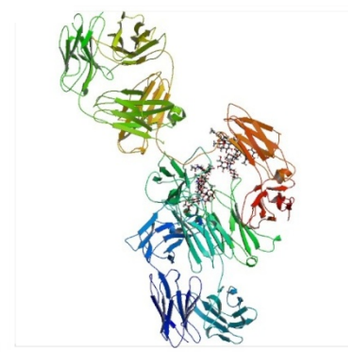
What is at stake ?





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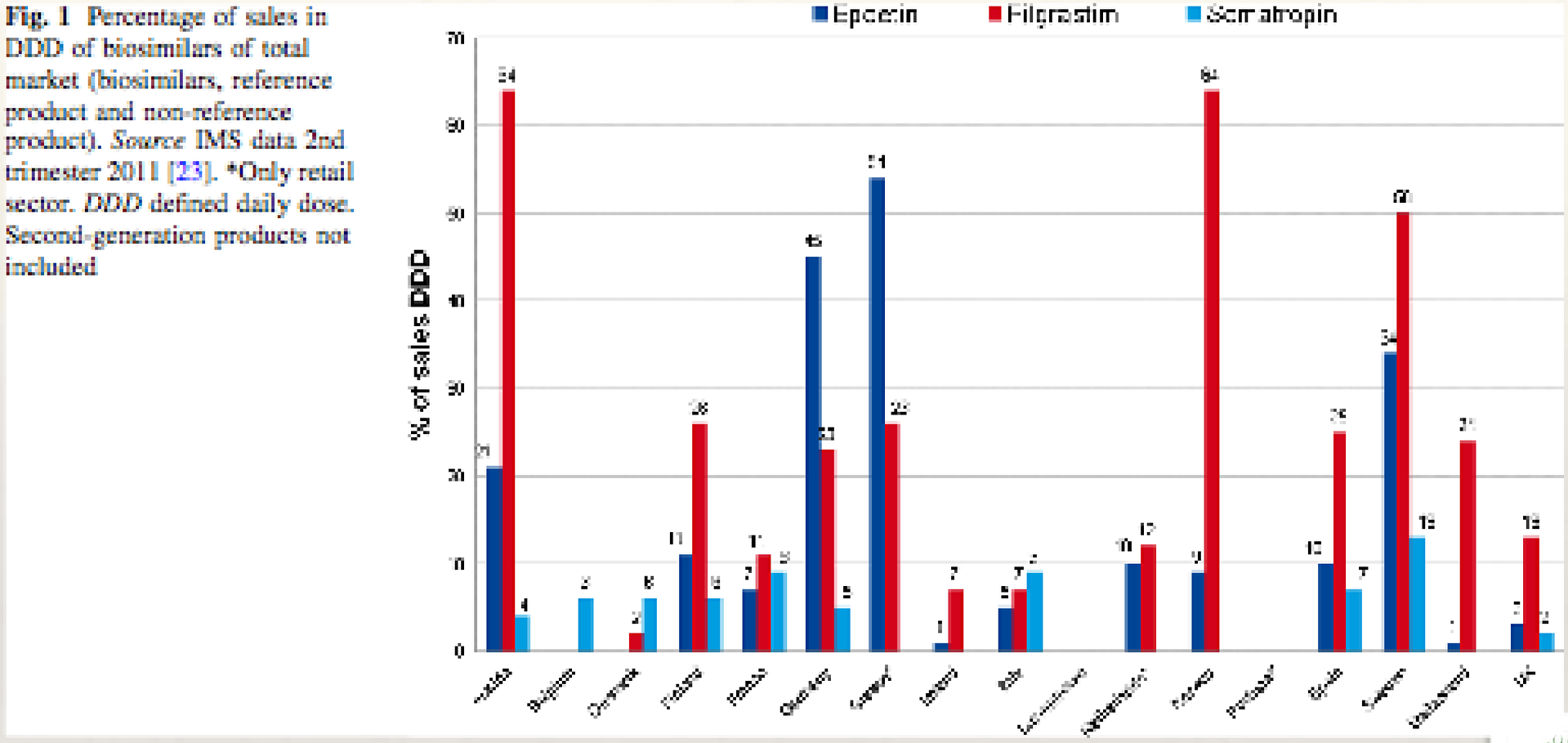
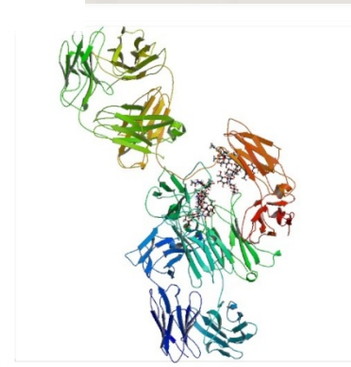


Fig. 1 Percentage of sales in DDD of biosimilars of total market (biosimilars, reference product and non-reference product). *Source* IMS data 2nd trimester 2011 [23]. *Only retail sector. *DDD* defined daily dose. Second-generation products not included

- 10- 30 % price reduction is observed in the market due to a biosimilar entry
- In eight EU countries between 2007 and 2020 - estimated savings could be between 11.8 - 33.4 Billion Euros

Eur J Health Econ (2014) 15:223–228



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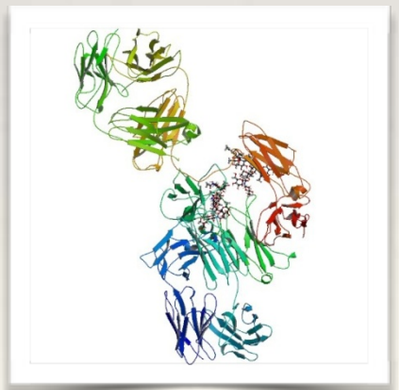
Subsequent Entry Biologics (SEB)
Canadian Perspective

- First SEB approved in 2008 - Omnitrope (Sandoz)
- Anti-TNF SEBs approved Jan 15, 2014



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Perspectives Stakeholders
- Payers -

Safety and Efficacy ?
Long term data ?
Patient Support ?

Reduced Cost

Value Scale

Health Canada Approval
CADTH Review

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Payers are starting to look at options

- Pharmacists in France will now be allowed to substitute a biosimilar for the prescribed biological as long as the prescribing physician has not marked the prescription as ‘non-substitutable

- Most US states are requiring physician notification — On 12 October 2013, California Governor Jerry Brown vetoed legislation known as SB 598, a bill that some believed would have impeded access to biosimilars.

- Alberta states that SEBs are not interchangeable

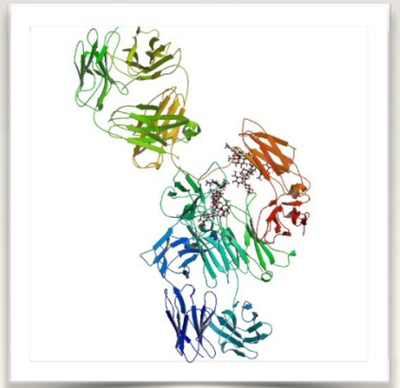
Table 1: US state legislation on biosimilars substitution

State*	Status**	Key votes	Physician notification period (after substitution)	Record-keeping period
Arizona	Not enacted	Passed Senate committee	3 days	7 years
Arkansas	Not enacted	None	3 days	2 years
California[1,2]	Under consideration by the Governor	Passed Senate chamber and several House committees	5 days	3 years
Colorado	Not enacted	Passed House chamber	3 days	5 years
Delaware[1]	Not enacted	None	2 days	3 years
Florida[3]	Enacted		N/A	2 years
Illinois[1]	Under consideration	None	5 days	5 years
Indiana	Not enacted	Senate passed Study Resolution	5 days	5 years
Maryland	Not enacted	Passed Senate chamber	5 days	5 years
Massachusetts[1,2]	Under consideration	None	Reasonable time	1 year
Mississippi	Not enacted	None	5 days	10 years
North Dakota	Enacted		1 day	5 years
Oregon	Enacted		3 days	3 years
Pennsylvania[1]	Under consideration	None	3 days	5 years
Texas	Not enacted	Passed Senate chamber and House committee	3 days	2 years
Utah	Enacted		3 days	5 years
Virginia	Enacted		5 days	2 years
Washington[1]	Not enacted	None	3 days	2 years

*Data updated 30 July 2015. **Details on legislation reflect the most recent versions of bills as amended in legislatures; N/A: Not available.
[1]States with 2-year sessions (2015 and 2014) where legislation may be active for 2014 consideration; [2]Multiple bills with different provisions were introduced; [3]Physician notification was not included in the enacted law.

FDA

- Guidelines are still being developed



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Perspectives Stakeholders
- Prescribers -

Safety and Efficacy ?
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Patient Support ?

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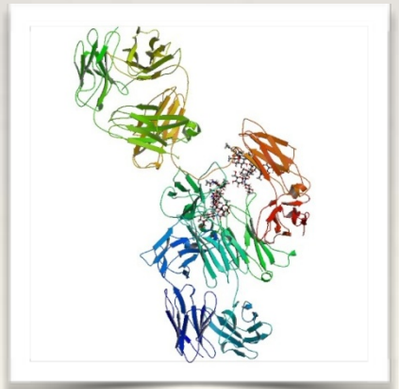

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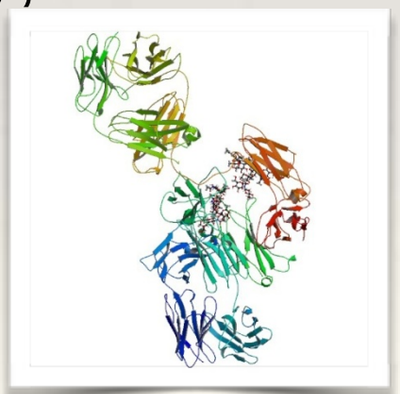
European Physicians Survey on Biosimilars

- October to November 2013

- 470 prescribers, surveyed equally across 5 countries in Western Europe (France, Germany, Italy, Spain and United Kingdom)

- This sample included specialists in nephrology, rheumatology, dermatology, neurology, endocrinology and oncology



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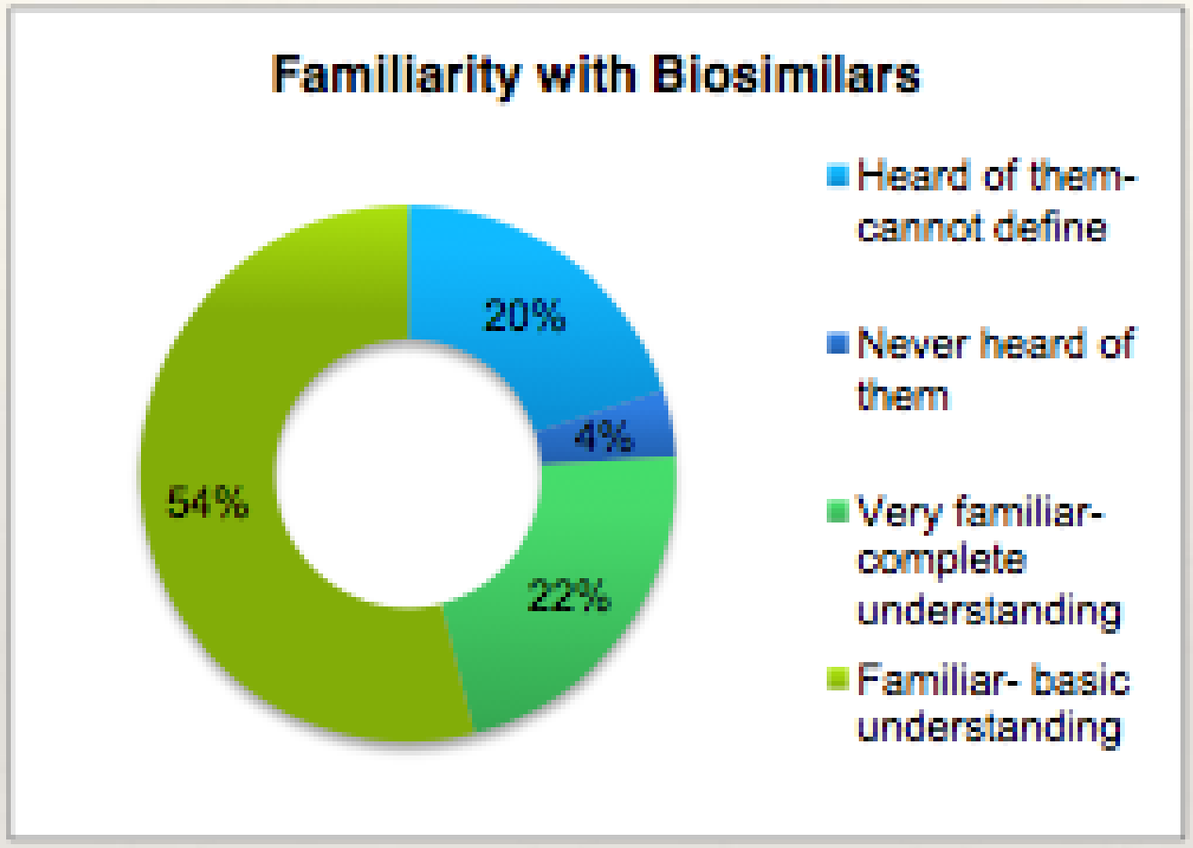
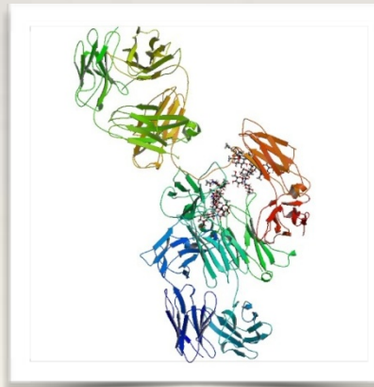
Prescriber thoughts on SEBs





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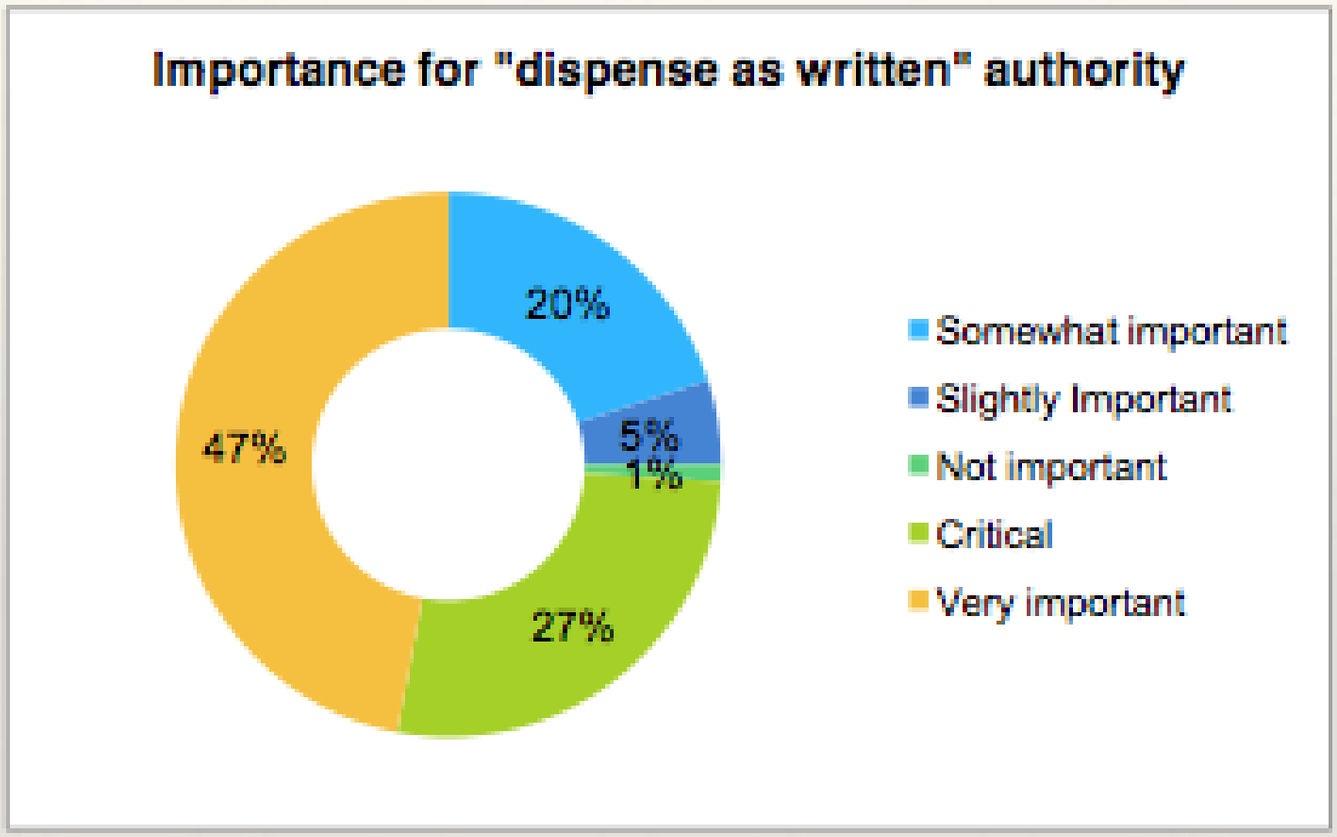

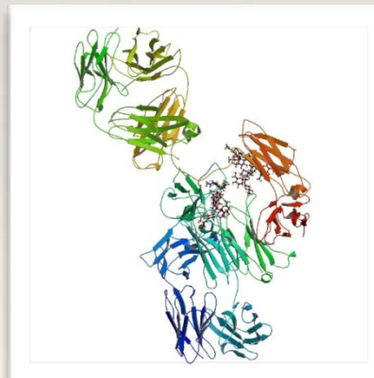

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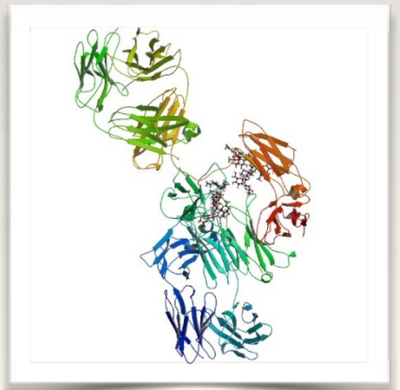
What are the next steps?

- Need to frankly discuss the various perspectives of the stakeholders
- Find a place for the use of SEBs
- Can not ignore the perspective of each member of this trio of stakeholders



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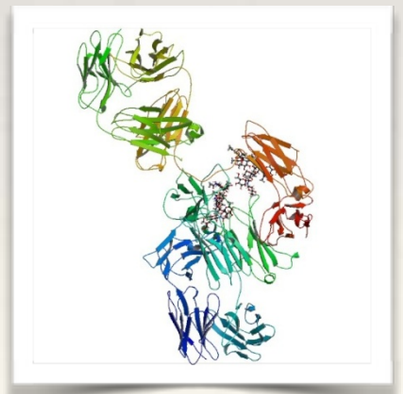
Relationship are needed

- In AHS I have been part of a process of prospectively engaging stakeholders to understand their prospectives
- It is a starting point, but we want to have a discussion early



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Questions