A photograph of two young girls with long blonde hair hugging in a field of white daisies with yellow centers. The girl in the foreground is wearing a patterned dress and has her arms around the girl behind her. The girl behind her is wearing a colorful patterned top. They are both smiling. The background is a clear blue sky and a line of trees in the distance.

Προκλήσεις και τάσεις στο χώρο της Βιοφαρμακευτικής και της Υγείας: Ευκαιρίες για την Ελλάδα

1ο Συνέδριο ΕΛΕΦΙ, 30 Μαΐου 2014

Dr. Andreas Persidis

CEO Biovista Inc., President HBio



The Perfect Storm

Pharma

Innovation deficit
Patent cliff

Investors

**HEALTHCARE
INDUSTRY**

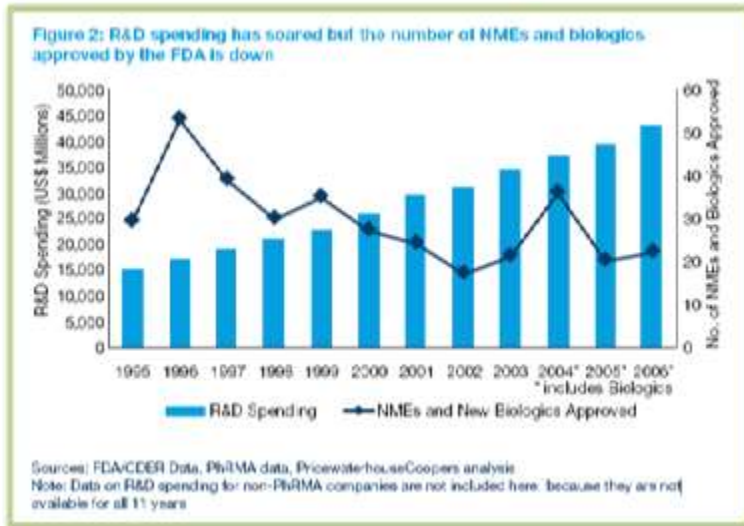
HMOs/PAGs

Regulators



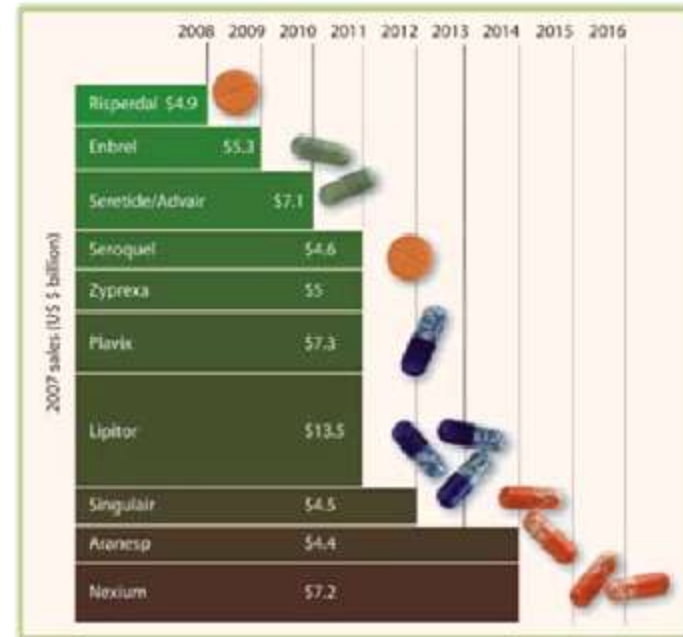
We need new treatments

Innovation Deficit



Source: PWC report: Pharma 2020: The vision Which path will you take?*

The patent cliff



The pharma industry will see over \$63 billion of annual income washed away due to patent erosion by 2014 . Source www.rsc.org



Old Strategies are becoming less tenable



It's a tough environment

Patent cliff / innovation deficit / stakeholders pressure

PLE/LCM - Product differentiation

Meaningful therapeutic benefit

Reference pricing -> **appropriate comparator**

Stricter CT design and execution – no switching/selection of endpoints

Better risk assessment

Surrogate markers accepted less willingly



Bad Pharma™

Ben Goldacre

Bestselling author of *Bad Science*

How drug companies
mislead doctors and



The Truth About the Drug Companies



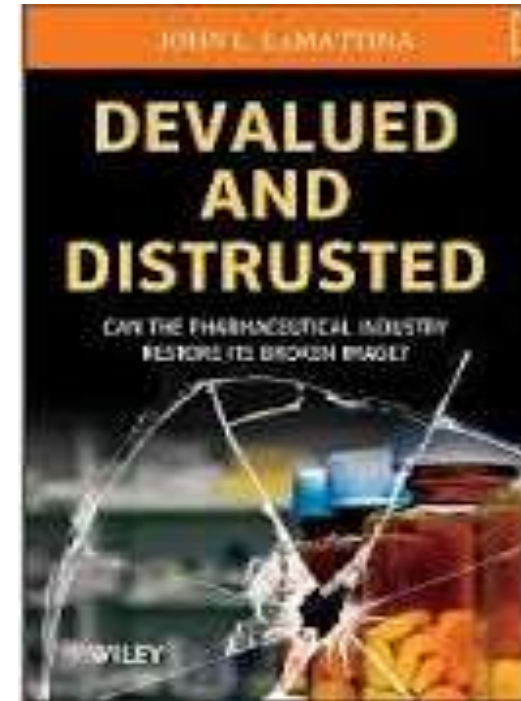
HOW THEY DECEIVE US
AND WHAT TO DO ABOUT IT

MARCIA ANGELL, M.D.

Former editor-in-chief of the New
England Journal of Medicine
Winner of the Nobel Prize

Revised and updated
Includes tips on what you can do to protect your interests

Vs





Strategies to date for weathering the storm

Buy-outs (“The quick Fix”)

Carpet-bombing patent practices

LCM / PLE

Generics / Orphan Diseases

Serendipitous (re)-positioning

Out-Sourcing



The health sector is undergoing a major shake-up

4 major drivers

1

Increased drive to **reduce inefficiencies in the system**

2

From symptoms to **Mechanism of Action**

3

From isolated therapies to **integrated treatments**

4

From individual players to **novel collaborative combinations**



Know

Don't Know

Know

Know
what I
Know

QED

Know
what I
don't know

Ask the right questions

Don't Know

Don't know
what I
Know

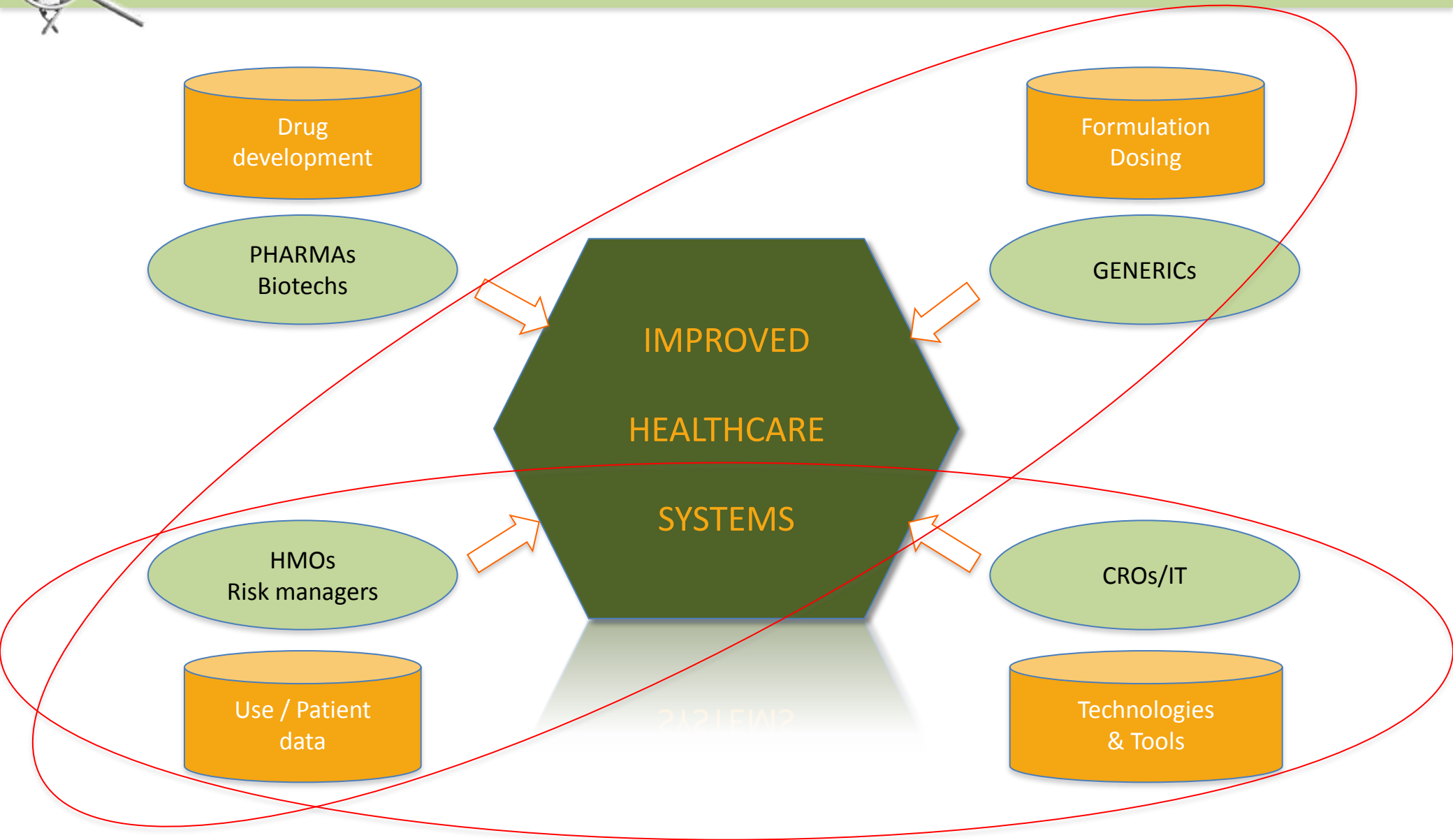
Overcome company silos

Don't Know
what I
Don't know

Blue Sky research



Which will the winning combination be?





September 12, 2011

Combination 1: HMO + IT

WellPoint and IBM Announce Agreement to Put Watson to Work in Health Care navigation

Wellpoint Inc(NYSE: WLP), and IBM (NYSE: IBM) announced an agreement today to create the first commercial applications of the IBM Watson technology. Under the agreement, WellPoint will develop and launch Watson-based solutions to help improve patient care through the delivery of up-to-date, evidence-based health care for millions of Americans.

<http://www-03.ibm.com/press/us/en/pressrelease/35402.wss>



December 6, 2011

Combination 2: Biotech + Electronics

Today's Top Stories.

Biogen Idec signs up with Samsung on \$300 million biosimilars venture

By John Carroll [Comment](#) | [Forward](#) | [Twitter](#) | [Facebook](#) | [LinkedIn](#)

Biogen Idec CEO George Scangos (photo) has made good on his vow to hammer out a major joint venture on biosimilars. The biotech has announced it is joining forces with South Korean conglomerate Samsung, biting off \$45 million of a \$300 million investment to ramp up a new operation to develop, manufacture and market biosimilars--one of the hottest areas in biopharma for a select group of players with the money needed to play the game. Biogen (\$BIIB) will go to work with Samsung Biologics, a newly minted development and manufacturing group forged by the Korean conglomerate and CRO Quintiles. Samsung officials initially talked up plans to develop a biosimilar of Rituxan, a blockbuster treatment developed in partnership between Biogen and Genentech, though Biogen went to some pains this morning to make clear that their work with Samsung would not involve Rituxan or any of Biogen's therapies. Samsung has laid out plans to invest close to \$2 billion in the biosimilar business in expectation of developing a new subsidiary that can earn roughly that amount annually in about a decade. "We are taking a significant step toward becoming a major player in the biopharmaceutical industry and investing in an important growth engine for our company," Samsung Biologics CEO Tae-han Kim said ...

http://www.fiercebiotech.com/story/biogen-idec-signs-samsung-300-million-biosimilars-venture/2011-12-06?utm_medium=nl&utm_source=internal



Combination 3: Player 1 + Player 2 + ...

Foldit

January, 2012



The Good Judgment Project™

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nature International weekly journal of science

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News & Comment | News | 2012 | January | Article

NATURE | NEWS

Victory for crowdsourced biomolecule design

Players of the online game Foldit guide researchers to a better enzyme.

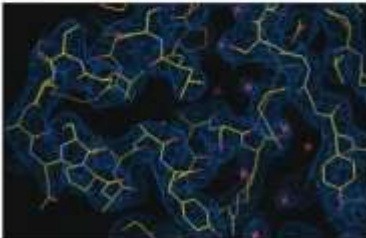
Jessica Marshall

22 January 2012

Obsessive gamers' hours at the computer have now topped scientists' efforts to improve a model enzyme, in what researchers say is the first crowdsourced redesign of a protein.

The online game Foldit, developed by teams led by Zoran Popovic, director of the Center for Game Science, and biochemist David Baker, both at the University of Washington in Seattle, allows players to fiddle at folding proteins on their home computers in search of the best-scoring (lowest-energy) configurations.

The researchers have previously reported successes



An enzyme designed by players of the protein-folding game Foldit was better than anything scientists could come up with.

HARNESSING THE WISDOM OF THE CROWD TO FORECAST WORLD EVENTS

The Good Judgment Project is a four-year research study organized as part of a government-sponsored forecasting tournament. Thousands of people around the world predict global events. Their collective forecasts are surprisingly accurate.

[Read more about the IARPA ACE Project](#)

NOVA scienceNOW | Wisdom of the Crowds | PBS

He found the wisdom of the crowds.

Press

"If I were President Obama or John Kerry, I'd want the [Good Judgment Project] predictions on my desk."

— [David Brooks](#), *The New York Times*

"With some confidence, we can predict that another landmark of applied social science will soon be reached."

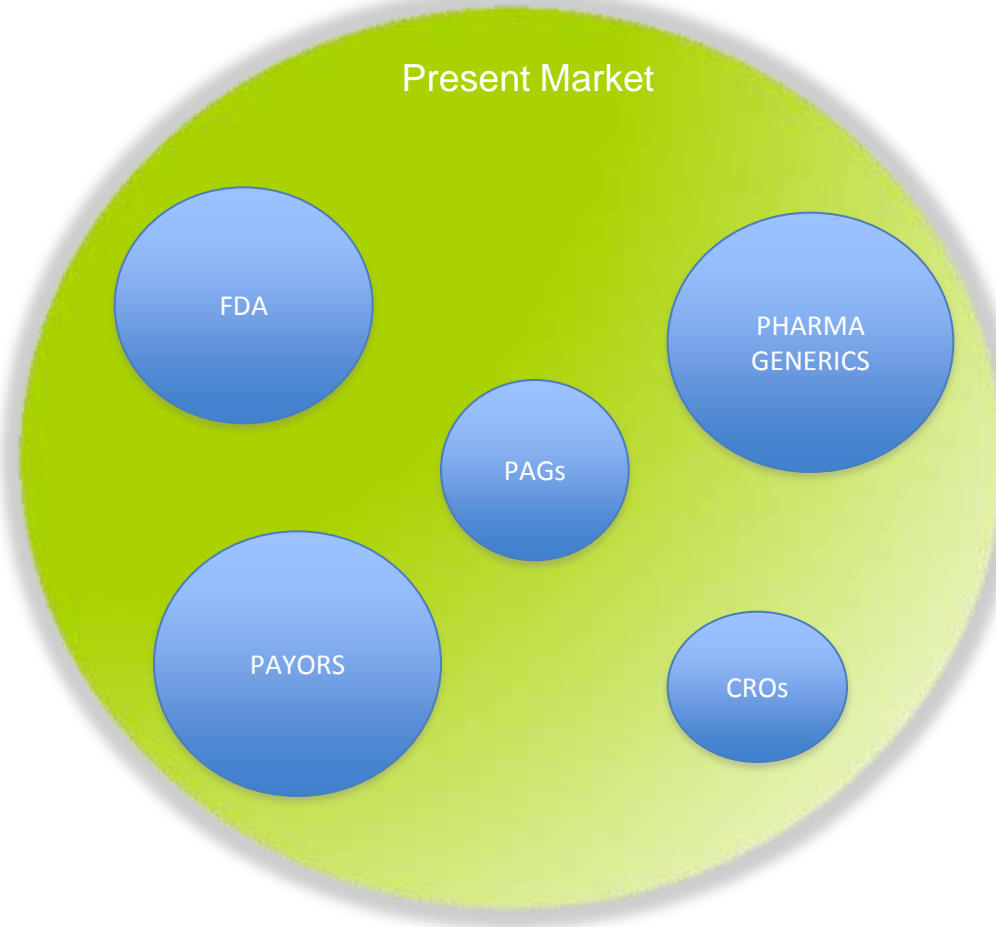
— [Daniel Kahneman](#), Nobel laureate and author of "Thinking Fast and Slow," writing

"... the human dimension in forecasting is again taking center stage."

— [Michael Peck](#), writing about IARPA's ACE program and forecasting tournament

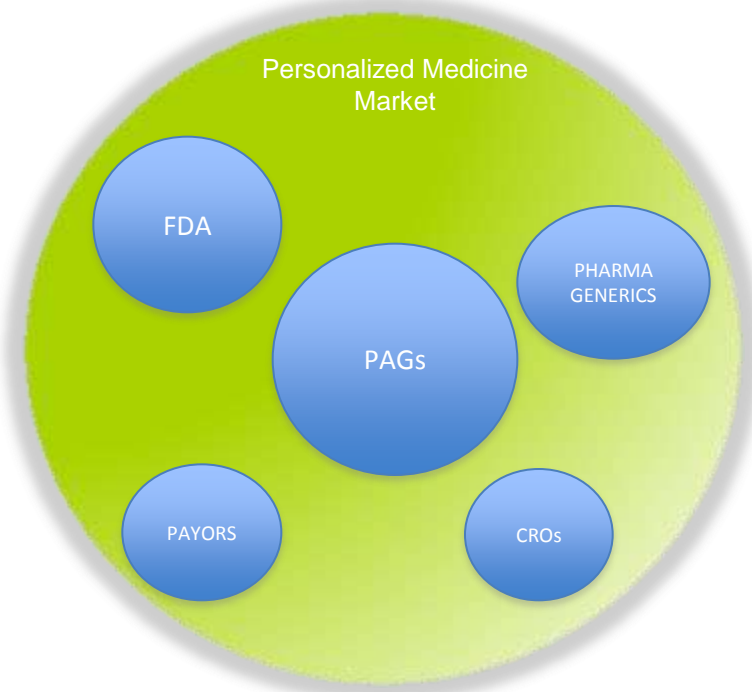


Possible futures for market stakeholders



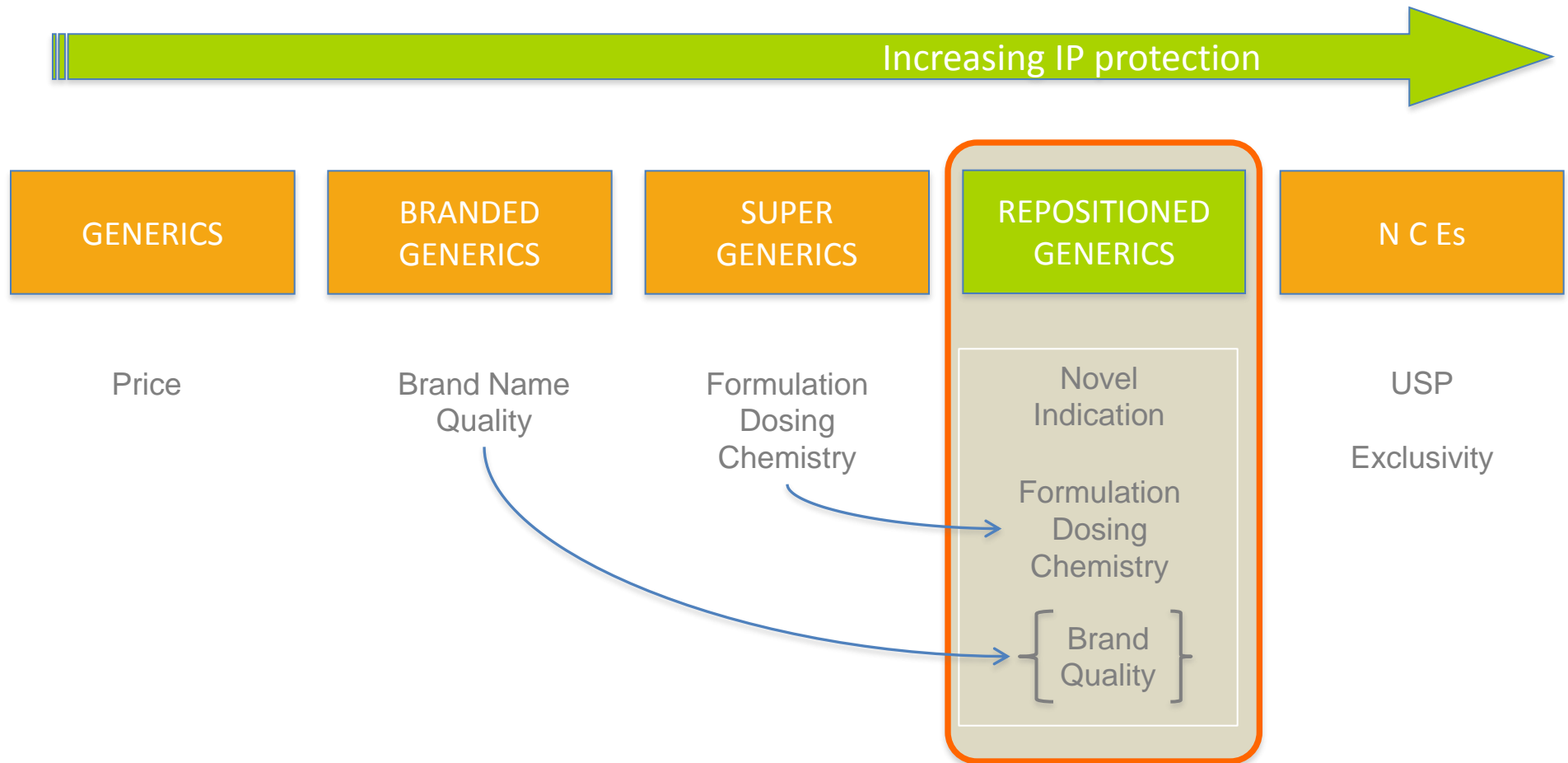


Possible futures for market stakeholders



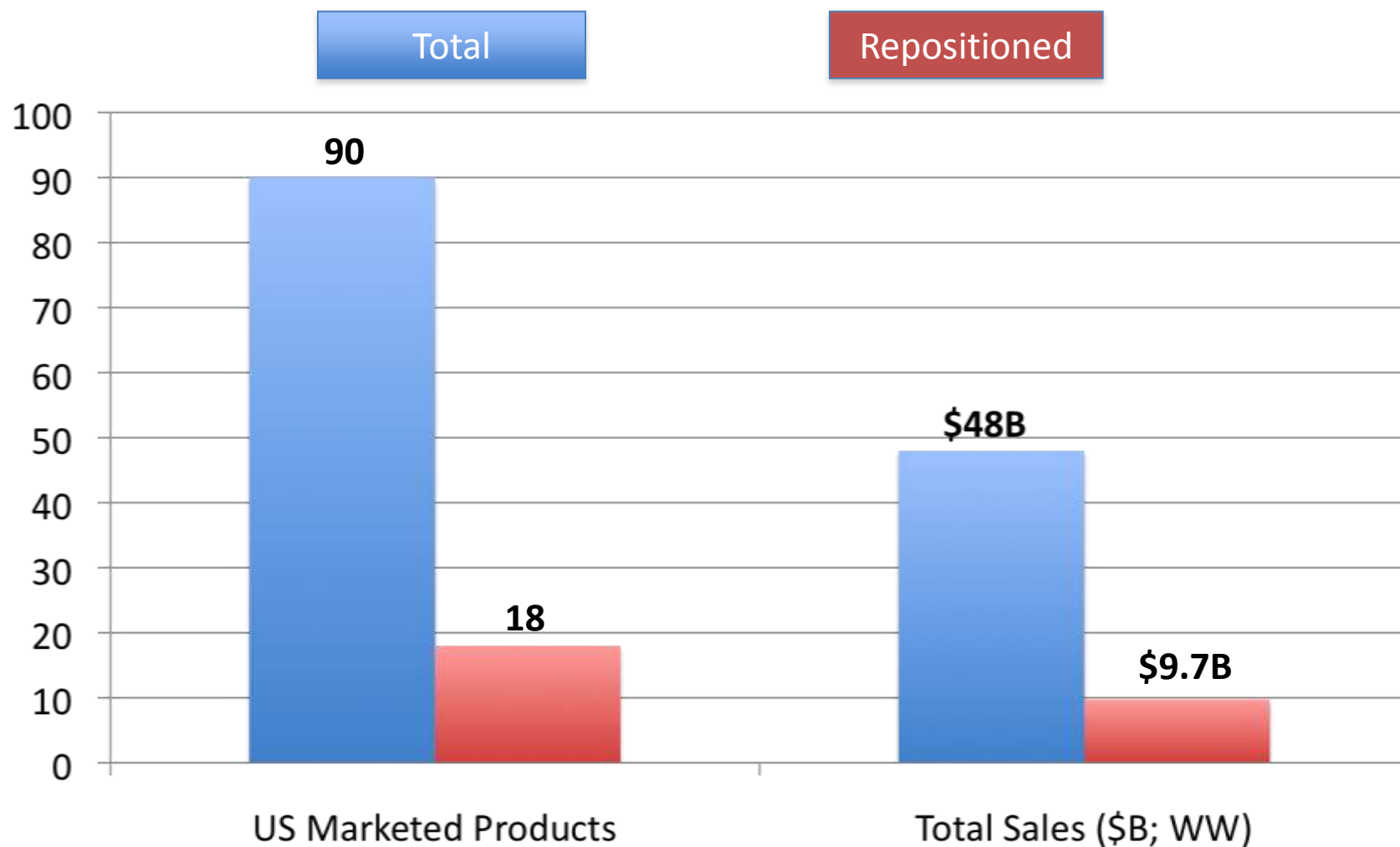


- Value added therapies (generics)
- Departure from small molecule single target “dogma”
- Towards p-medicine
- Big data analytics / better predictors (animal models, markers, diagnostics etc.)





Contribution of Repositioning to Merck: \$9.7B 2011 Sales



Source: MRK SEC Filings 2011, FDA NDA Filings, Biovista



□ On Average...

a Top Pharma

earns 28% of its revenue

from 24% of its drugs, which are repositioned



Biology

we tend to treat biological systems as if they are like this:



... when they tend to be like this:

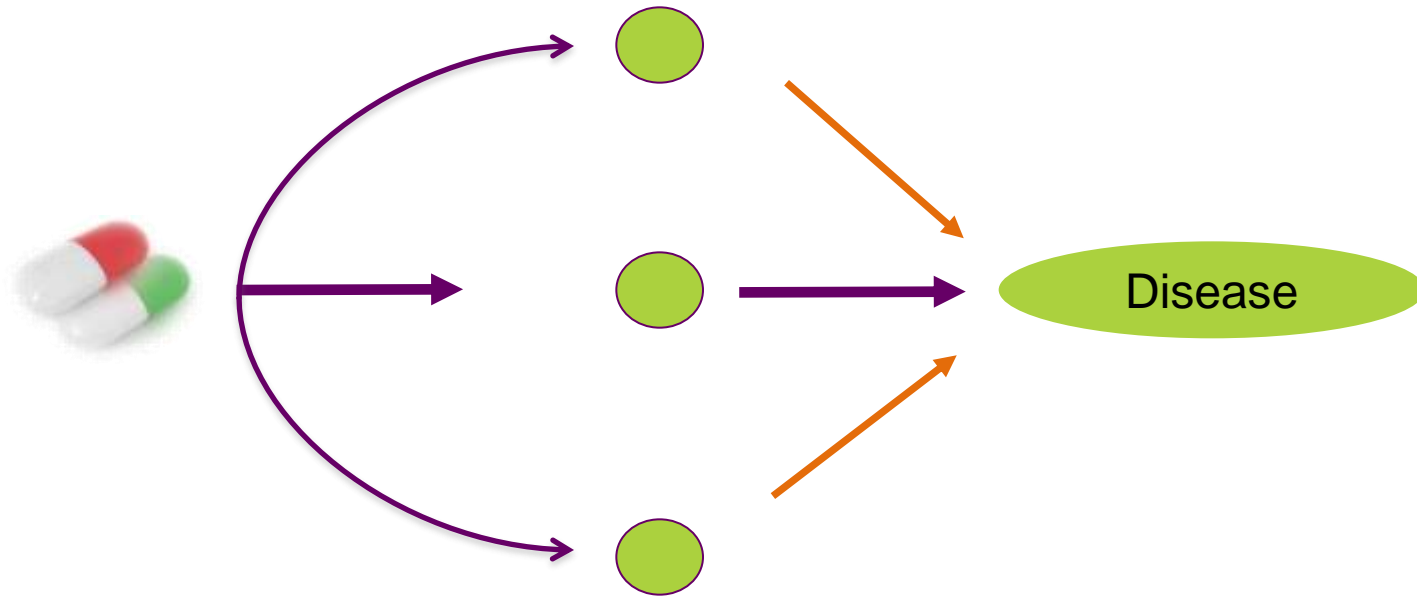


Present: Single-Target Approach





Future: Multi-Target Approach





Future: Multi-Target Approach





May 24, 2013

Woodcock: Redefine studies of personalized drugs

The FDA will have to change the treatment development process to accelerate the entry of personalized, targeted medications into the market, Center for Drug Evaluation and Research Director Dr. Janet Woodcock told an audience at a luncheon hosted by the Personalized Medicine Coalition. A lot of thought needs to go into **how to conduct trials of subsets of patients defined by biomarkers**, she said.

Role for side effect prediction and risk profile analytics?



From:

FDA Sentinel Initiative

... an electronic safety system that tracks drug performance ...

To

Side Effect Prediction Initiative



Undue Burden

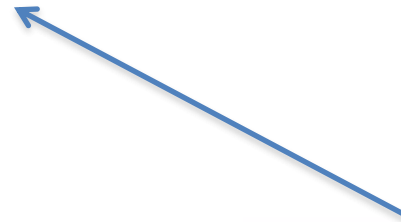
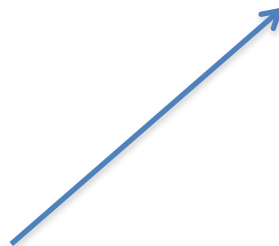
anything creating significant difficulty and/or expense

to meet all aspects of some obligation



Submitted Paper

There is a technology that can predict side effects





Selected 10 Outcomes Relevant to Hypertensive Patients

Biovista Classification	CLAIMS	EMR-Scripts	AERS	Agreement
ADVERSE EVENTS				
Falls				
Major Bleeds				
Seizures				
NEUTRAL/PROTECTIVE				
Cognition				
Depression				
Glaucoma				
Myopathy				
Suicide				
Pulmonary Fibrosis				
VTE				

Note: These outcomes are not on the label, or other known Lisinopril data



COSS™ Agreement with Claims and EMR Data: 80% Analysis of data ongoing

Biovista Classification	CLAIMS*	EMR-Scripts*	AERS*	Agreement
ADVERSE EVENTS				
Falls	1.88			YES
Major Bleeds	1.13			YES
Seizures	2.05			YES
NEUTRAL/PROTECTIVE				
Cognition	0.93		0.39	YES
Depression	0.90	1.12	0.59	YES
Glaucoma	1.23			NO
Myopathy	1.95	0.79		NO
Suicide	0.73			YES
Pulmonary Fibrosis	0.36	0.83	0.65	YES
VTE	0.94	1.11	0.26	YES

* Numbers are Relative Risk. Above 1 is Risk, below 1 is Neutral or Protective



Thank you for your undivided attention!



andreasp @ biovista.com