



ADVANCING SCIENCE, SERVING SOCIETY

# The State of Pharmaceutical **Innovation**

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Chicago

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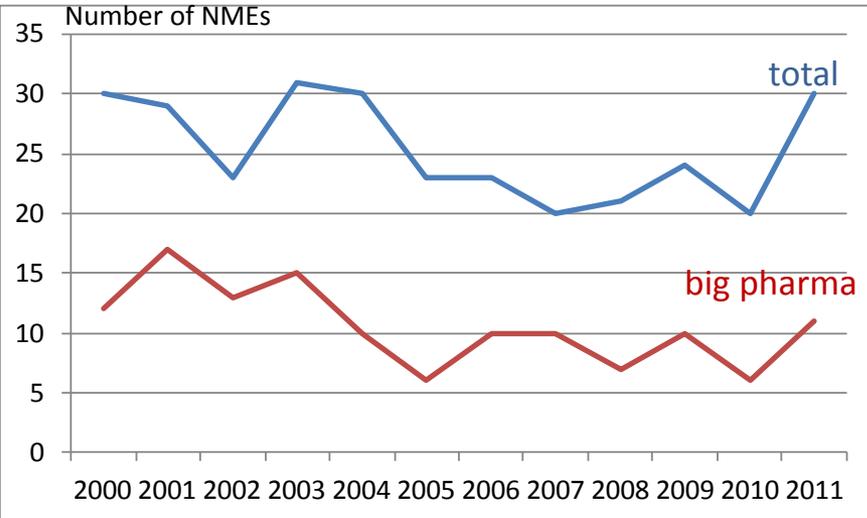


# Outline

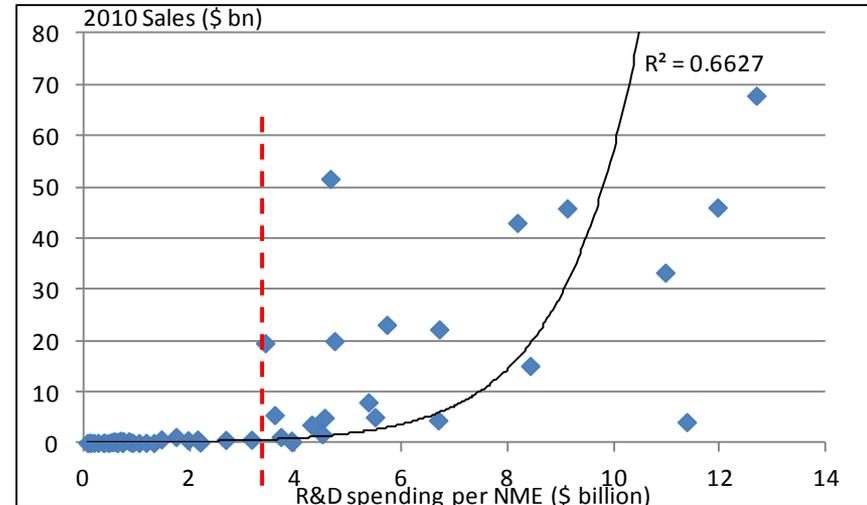
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- **The state of innovation**
- Facts about innovation
- Where does innovation come from?
- Priorities for returning innovation to drug R&D

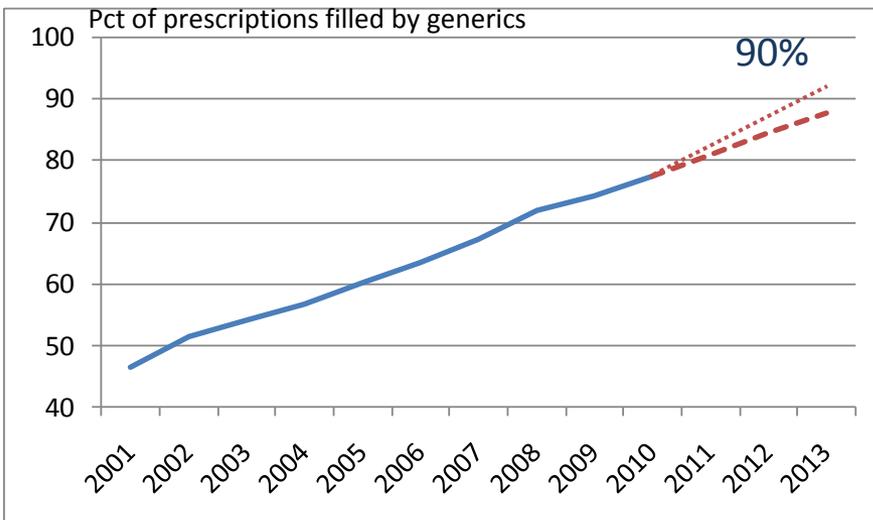
# The pharma industry faces a 'Kodak moment'



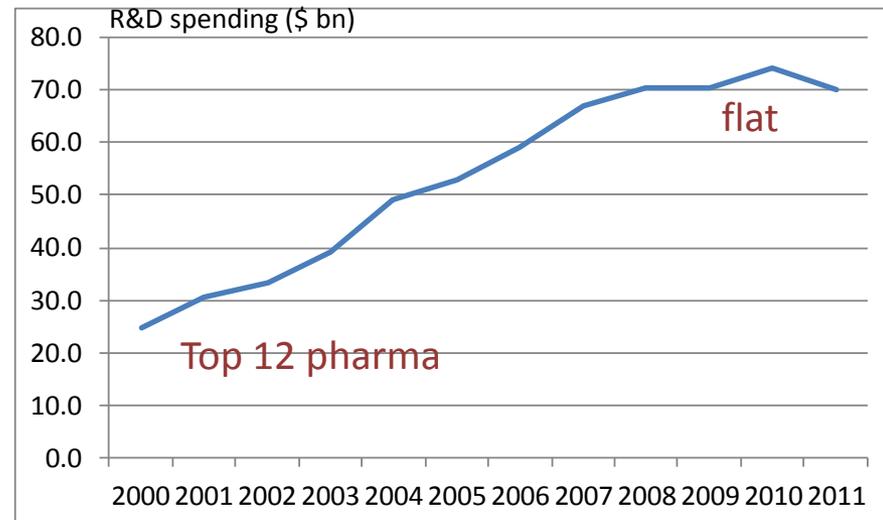
**Not enough innovation**



**Unaffordable innovation**



**Undistinguished innovation**



**Death spiral or transformation?**

# Pharma has **changed** the business model that made it great



The 'old'  
pharma model:

Turning **cutting-edge discoveries**  
into **commercial products**

and creating vast  
new markets and  
value for patients



Pharma now spends much of its time iterating on the same targets/scaffolds



# Pharma **no longer lives** the values that made it great

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- **Ethics:**

- Pharma has paid about **€20 bn** in fines in last 20 years, **75% in last 5 years** (reimbursement fraud, kickbacks, off-label promotion, ghostwriting, falsification...)

- **Innovation:**

- Not enough, marginal, unaffordable

- **Risk-taking:**

- Fear to disrupt
- Lots of breakthroughs waiting to be translated into something useful (synthetic bio, nanomed, tissue engineering, stem cells...)

- **Patient focus:**

- Retrenchment from Rx areas (anti-infectives, neuroscience, cardiovascular)
- Drug shortages
- Pushing patients into bankruptcy

# Pharma's **triple** challenge

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- **More** innovation
- **Better** innovation
- **Affordable** innovation

# Outline

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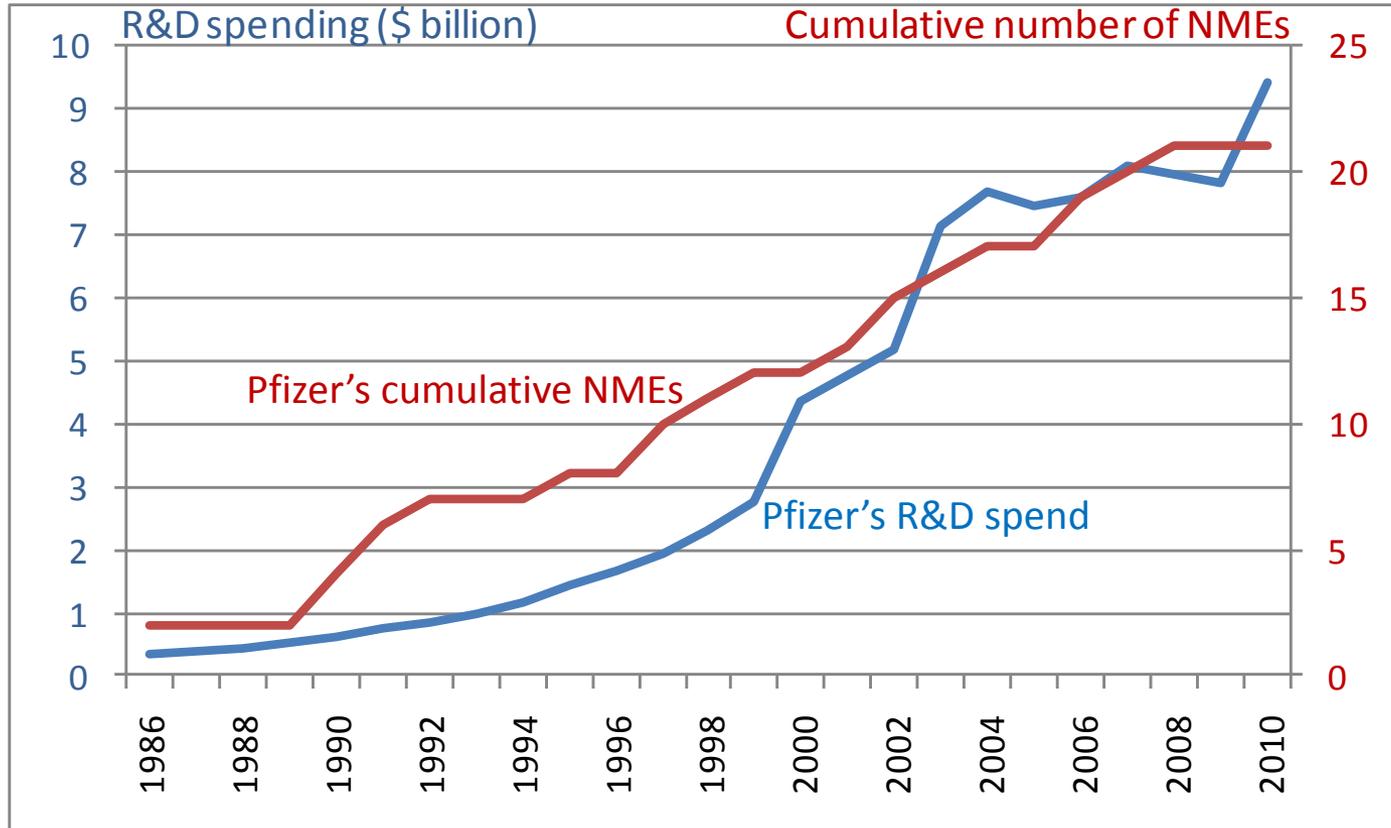
# The innovation **pathways**

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- **High-risk, unconventional** research
- **Patient-oriented** research
- **User-driven** innovation
- **Disruptive** thinking

 **(Assembly-line model)**

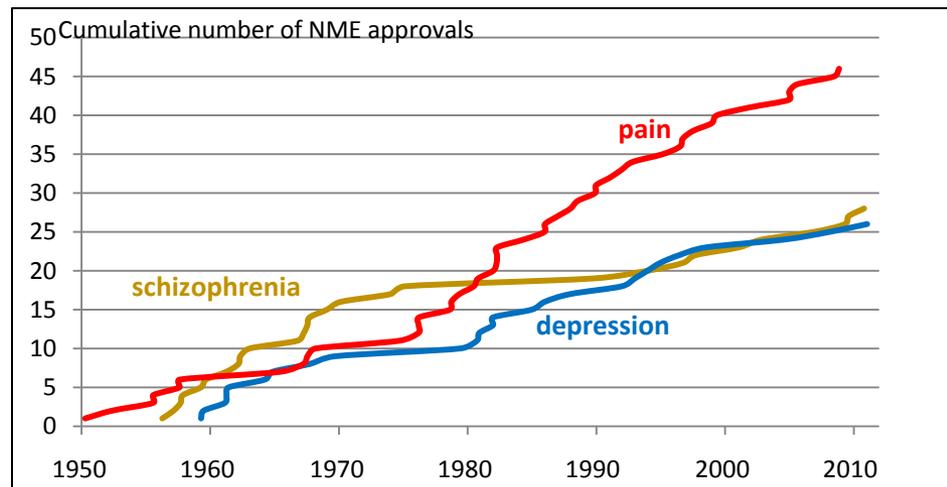
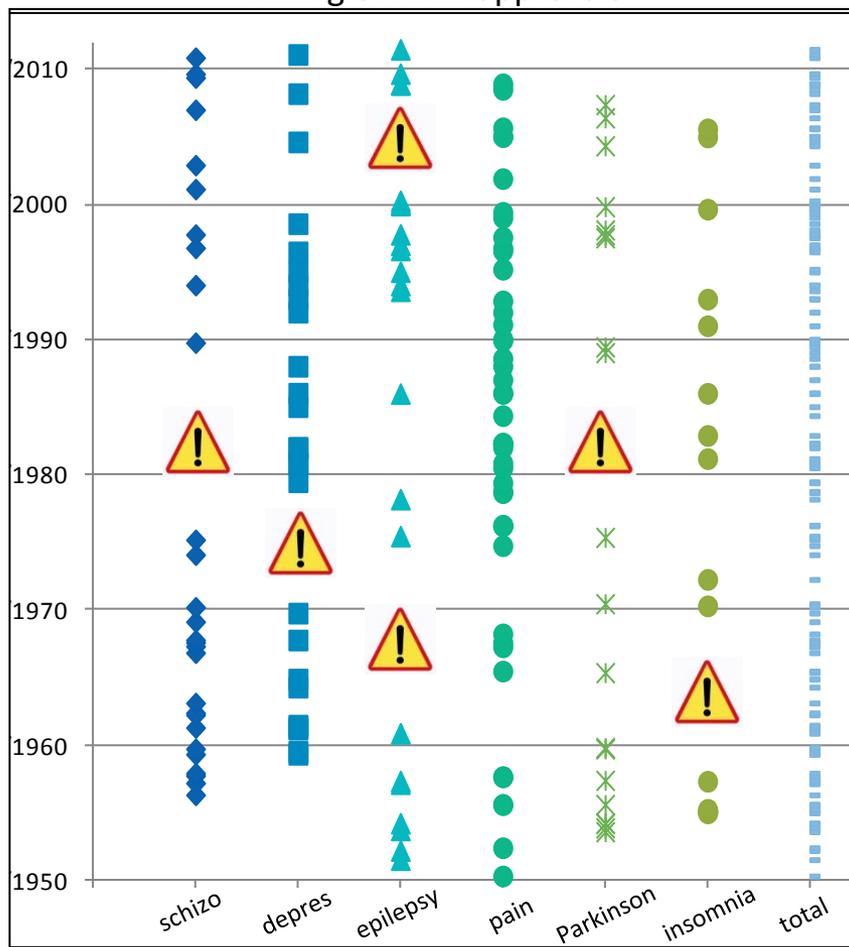
# Innovation **does not scale**



Pfizer's trebling of R&D spending since 1999 has had no detectable impact on its rate of NME production

# Innovation is **highly nonlinear**

Timing of NME approvals



- Innovation comes in **waves**
- **10-year dry spells** are not uncommon
- **Long compound series** are the exception, not the rule
- **34%** of drugs (for CNS) have a poorly understood mode of action

# Outline

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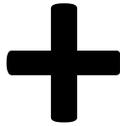
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# Where does **high-value** innovation come from?

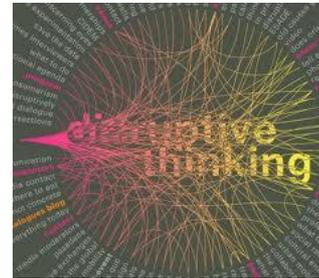
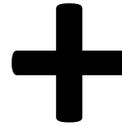
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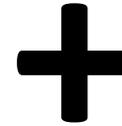
breakthrough  
discoveries



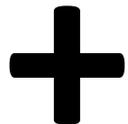
creative scientists



open and  
networked culture



transformational  
leaders



enabling factors

- diversity (cultural, ethnic, academic, age, etc)
- cross-disciplinary, silo-free, equalitarian culture
- few, fuzzy processes (adaptiveness)
- multiple, diversified sources of financing
- supportive authorities (policymakers, regulators)
- intense competition

# Breakthrough discoveries

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- **Breakthrough must be seen through the eye of the patient (user), not the scientist**
  - Gleevec is a breakthrough... so is Augmentin, Zocor, Aranesp, Humulin
  - Lipitor is not a breakthrough
- **Breakthrough discoveries can stem from novel research, shrewd clinical observations or the recombination of existing ideas**
- **Most science funding does not support highly innovative work**
  - Most public and private spending supports 'regular science', not novel original ideas
  - Peer-review and committees foster compromises that do not reward boldness
- **Alternatives?**
  - Need greater focus and selectivity, e.g., DARPA's disruptive focus and milestone-driven approach ("Is this disruptive? Why?"); GSK's Discovery Performance Units

# Creative scientists



The marginal innovator	The disruptive innovator
Wants to grow and nurture existing markets	Wants to obliterate what's there and replace it with something better
Seeks competitive advantage from greater efficiency	Seeks competitive advantage from changing the game
Improves and optimizes	Disrupts
Aligned with the organization's goals	Orthogonal to the organization's goals
Analytical, cautious	Intuitive, bold
Sticks to process and job description	Knows no boundaries
fits in	sticks out
Risk-averse, change-wary	Risk-taking, change-friendly
Seeks consensus	Never minds being alone

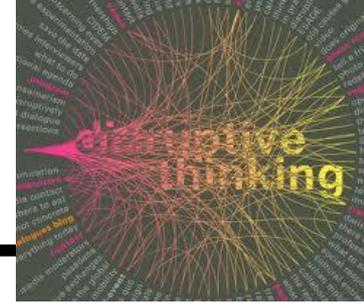
Source: adapted from Munos, [Clin Pharmacol Ther.](#) 2010 May;87(5):534-6

***Disruptive and marginal innovators  
are different species separated by a  
chasm that must be bridged***

The crazies, the misfits, the  
rebels, the troublemakers,  
the square pegs...

# Open culture

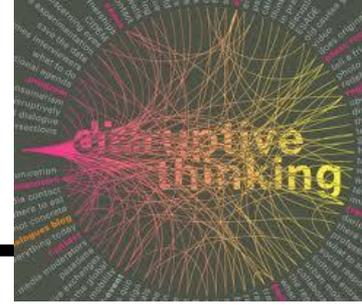
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- Innovation is a **by-product of culture**, not a by-product of organization, six-sigma, or anything else
- **Principles and values**, not processes, define a corporate culture
  - A few powerful principles are worth more than many standard-operating-procedures
- Principles must value **diversity** and **openness**

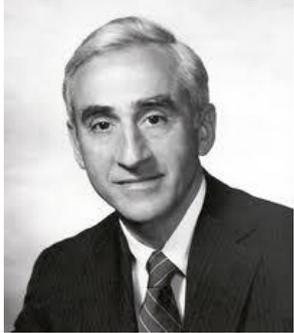
# Networked culture

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- Networks are a **powerful** but underappreciated ingredient of innovation
- **Local networks** help get things done but can reinforce orthodoxies
- **Global networks** bring novel ideas into the fray
- **Both** are necessary

# Transformational leaders



Roy Vagelos, Merck



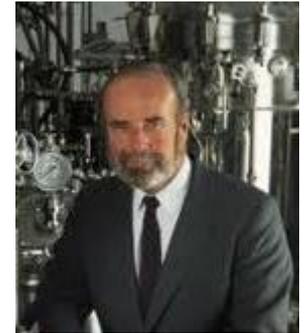
Paul Janssen, Janssen



Art Levinson,  
Genentech

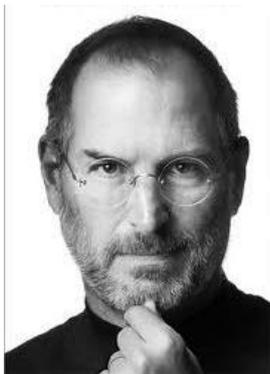


Dan Vasella, Novartis



George Rathmann,  
Amgen

Corporate leaders who left the **most admired legacy**  
were also passionate de-facto **Chief Innovation Officers**



Steve Jobs



Jeff Bezos



Bill Gates



Bill Hewlett,  
Dave Packard

When it comes to innovation, bolder is better, and it starts at the top

# Enabling factors

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- **diversity (cultural, ethnic, academic, age, etc)**
- **cross-disciplinary, silo-free, equalitarian culture**
- **few, fuzzy processes (adaptiveness)**
- **multiple, diversified sources of financing**
- **(supportive authorities (policymakers, regulators))**
- **(intense competition)**

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# Priorities for returning innovation to drug R&D

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- **Foster an innovation culture:** welcome the curious, passionate scientist; let boldness and vision drive decision-making; make it safe to be bold
- **Pick an innovation model that works.** Stop doing what doesn't.
- **Forget blockbusters, chase breakthroughs:** don't let sales forecast, NPVs and ROI steer you toward the **trap** of marginal innovation and commoditization
- **Build broad innovation networks:** no matter how big you are, most great ideas come from elsewhere
- **Focus on translating breakthrough science** that has the potential for creating vast new markets
- **Restrict clinical research to candidates that have the hallmarks of breakthroughs,** backed by compelling evidence
- **Speed innovation and save money:** embrace precompetitive collaboration; leverage open innovation models

**Thank you!**

Questions?

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