The Value of Medical Innovation

Council of State Governments
September 20, 2013

Rich Bagger, Senior Vice President
Celgene Corporation
The Paradox of Medical Innovation: The Promise of Medical Science Has Never Been Greater ...
...Yet There is Great Concern About Whether Innovation is Affordable and Sustainable

"Spiralling" drug prices are unsustainable

The New York Times
Doctors Denounce Cancer Drug Prices of $100,000 a Year

Editorial
Exorbitant Prices for Leukemia Drugs
By THE EDITORIAL BOARD
Published: May 1, 2013
A MAJOR PARADOX

The potential of science is greater than ever ...

But the outlook for investment has never been more uncertain

R&D Investment = Longer, Better, Healthier Lives

The Value of Medical Innovation: Living Longer, Better & Healthier Lives

Medical Innovation Involves High Risks and Long Time Horizons

Track Record of Success

The Promise of Medical Science

Medical Innovation Drives Economic Growth and Societal Benefit

Delivering on the Promise for Patients
It Takes 12 Years or Longer to Bring a New Treatment to Patients

The Drug Development Pyramid

<table>
<thead>
<tr>
<th>Years</th>
<th>Phase I</th>
<th>Phase II</th>
<th>Phase III</th>
<th>Phase IV</th>
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The average cost to develop one new approved drug – including the cost of failures – increased approximately **50%** between the late 1990s and early 2000s.

Higher Overall Success by Disease

- Infectious Disease: 15% Lead, 3% Secondary
- Endocrine: 14% Lead, 2% Secondary
- Autoimmune: 12% Lead, 7% Secondary
- Respiratory: 13% Lead, 2% Secondary
- Neurology: 12% Lead, 4% Secondary
- Cardiovascular: 7% Lead, 3% Secondary
- Oncology: 11% Lead, 2% Secondary

**New Cancer Therapies Face High Clinical Hurdles**

Even After Approval, Few Medicines Recover Their R&D Costs

Just 2 in 10 Approved Medicines Produce Revenues that Exceed Average R&D Costs

New Medicines Introduced Between 1990 and 1994, Grouped by Tenths, by Lifetime Sales

Source: Vernon JA, Golec JH and DiMasi JA. Drug development costs when financial risk is measured using the Fama-French three-factor model. Health Economics. 2009; 002-5.
Limited Time for Innovators to Recover R & D Investment

Developing a new medicine takes an average of 10 – 15 years; the Congressional Budget Office reports that “relatively few drugs survive the clinical trial process.”

Majority of Biotechnology Investors Fail to Recoup Their Investment

In a study of 180 biotechnology companies, less than half of the investors recouped the money they had invested.

Source: Biotech M&A Review. Windhover Information 2008
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Longer Life Through Better Medicines 1900-2010

1900 – First large-scale adoption of water chlorination

1908 – First large-scale adoption of water chlorination

1908 – Yellow Fever vaccine

1912 – Diphtheria and TB vaccines

1913 – Sulfa drugs (first antibiotic)

1918 – Penicillin first used as a treatment

1921 – Diphtheria and TB vaccines

1921 – Pertussis vaccine

1930s – Pertussis vaccine

1936 – Yellow Fever vaccine

1936 – Polio vaccine

1935 – Sulfa drugs (first antibiotic)

1940s – Penicillin first used as a treatment

1943 – Polio vaccine

1955 – Polio vaccine

1963 – Measles vaccine

1955 – Polio vaccine

1974 – Meningococcal disease vaccine

1987 – Azidothymidine (first HIV treatment)

1985 – Influenza vaccine

1995 – Hepatitis A vaccine

Deaths per 100,000 people

>96% Decrease

New Therapies are the Greatest Contributor to Increased Life Expectancy

45%  
1960 - 1997  
New drugs account for 45% in the increase in life expectancy

73%  
2000 - 2009  
New therapies account for 73% in the increase in life expectancy

Impact of New Therapies on Death Rates

Decline in Death Rates from Leading Causes 1960-2011

Deaths Per 100,000

- Diabetes: 22 (2011), 23 (1960)
- Pneumonia & Influenza: 54 (2011), 10 (1960)

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Today, it takes 6 hours and $900 to read 150 million bases of genetic code.

Medical Innovation is Increasing Patient Survival

Cancer-Related Death Rates Have Declined Since 1990

As Cancer Patients Live Longer

Death Rate from Cancer Has Been on the Decline for Over 30 Years

Case Study: Survival Rate for Multiple Myeloma Patients Soar with New Innovative Therapies

5-year relative survival rate, myeloma

50% INCREASE 1992-2008

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Increasing Life Expectancy Sustains Economic Growth

U.S. Life Expectancy vs. Real GDP per Capita 1929 to 2010

Over the past 50 years, medical innovation has been the source of more than $\frac{1}{2}$ of all economic growth.

A 1% REDUCTION In CANCER-related DEATHS in the U.S.

$500 Billion In Societal Value

- Improved quality of life
- Stimulates economy*
- Maximized life expectancy

*Extended survival contributes to economic stimulus by affording people more time to purchase and enjoy leisure activities

Spending on Biopharmaceuticals in Perspective: US Spending on Medicines Declined 3.5% Per Capita in 2012

Source: CMS National Health Expenditures Jul 2012; IMS Health, National Sales Perspectives, Dec 2012; U.S. Census Bureau Jan 2013; Economic Intelligence Unit Nov 2012; IMS Market Prognosis Apr 2013

Chart Notes: Measures total value of pharmaceutical spending, including generics, branded products biologics, small-molecules, retail and non-retail channels. Value measured at Trade Price – the price paid to wholesalers or manufacturers by retail and non-retail channels and excluding off-invoice discounts and rebates that lower net prices received by the manufacturers. Real Per capita adjustments based on data from U.S. Census Bureau and U.S. Bureau of Economic Analysis.
U.S. Prescription Drug Spending in 2011 and 2012

<table>
<thead>
<tr>
<th>Year</th>
<th>Spending (Billion)</th>
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<tr>
<td>2011</td>
<td>$328.1</td>
</tr>
<tr>
<td>2012</td>
<td>$299.2</td>
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Savings in 2012 due to loss of exclusivity:
- Total 2012 spending on oncology drugs: $28.9 Billion
- Savings due to loss of exclusivity: $25.9 Billion

Cost of Treating Cancer Remains a Small and Stable Portion of Total Health Care Expenditures

Spending on Cancer Care within this stable portion of health care expenditures shifting from inpatient treatment to outpatient treatments, including medicines taken orally

New Cancer Therapies: Small Cost, Large Benefit for Patients and Society

Only 9% of U.S. healthcare spending is dedicated to new therapies, with cancer treatments accounting for ~1%.

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Maximizing the Promise of Science: 5,000+ Medicines in Development

932 Cancer
- 140 Lung Cancer
- 129 Breast Cancer
- 119 Leukemia
- 84 Colorectal Cancer
- 82 Skin Cancer

460 Rare Diseases

383 Respiratory Disorders

250 Mental and Behavioral Disorders

200 Diabetes Mellitus

198 Arthritis and Related Conditions

88 HIV/AIDS and Related Conditions

98 Alzheimer’s and Other Dementias

36 Parkinson’s and Related Conditions


Reflects number of compounds in clinical trials or under review by the FDA for approval through New Drug Application (NDA) or Biological License Application (BLA) pathways. Medicines with multiple indications may appear in more than one category but are counted only once for total (3,091).
More People are Surviving Cancer as More New Therapies are Developed

In 2005, a man diagnosed with multiple myeloma asked me if he would be alive to watch his daughter graduate from high school in a few months. In 2009, bound to a wheelchair, he watched his daughter graduate from college. The wheelchair had nothing to do with his cancer. The man had fallen down while coaching his youngest son's baseball team.

*The Emperor of All Maladies* Author
Dr. Siddhartha Mukherjee