How to Realize “Affordable” Drugs—
Panel Discussion

Feb. 3, 2017

"The whole business case from the patient’s view”

The Inspire2Live 2017 Annual Congress

Panel:

Lou Garrison (Chair, University of Washington, USA)
Marcel van Raaij, Ministry of Health
Ad Antonisse, AstraZeneca
Huig Schipper (Inspire2Live)
Susan Noyon (Zilveren Kruis)
Casper van Eijck (Erasmus Univ.)

The Price of Medicines: Conventional Economics of Innovative Medicines

February 3, 2017

Lou Garrison, PhD

Professor Pharmaceutical Outcomes Research & Policy Program
Department of Pharmacy

Adjunct Professor, Departments of Global Health and Health Services

University of Washington

Seattle, Washington, USA

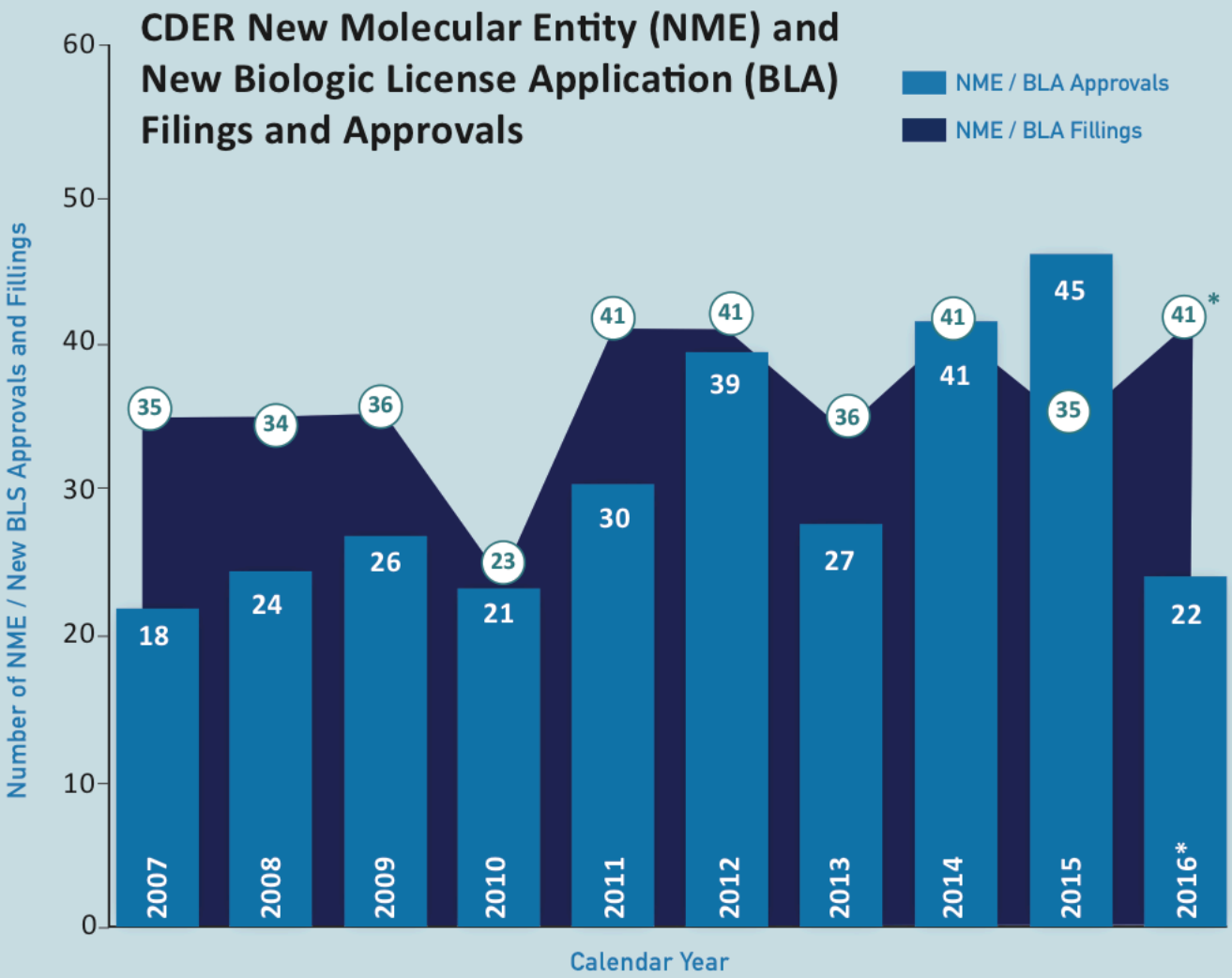
22

novel drug approvals in CY 2016 is less than the average number approved annually during the past decade

From 2007 through 2015 CDER averaged about

30

novel drug approvals per year



FDA, 2017

Key Facts 2016—From PhRMA

R&D SPENDING

Year	PhRMA members[3]
2015	$58.8 billion (*est.*)
2014	$53.3 billion
2013	$51.6 billion
2012	$49.6 billion
2011	$48.6 billion
2010	$50.7 billion
2009	$46.4 billion
2008	$47.4 billion
2007	$47.9 billion
2006	$43.0 billion
2005	$39.9 billion
2000	$26.0 billion
1990	$8.4 billion
1980	$2.0 billion

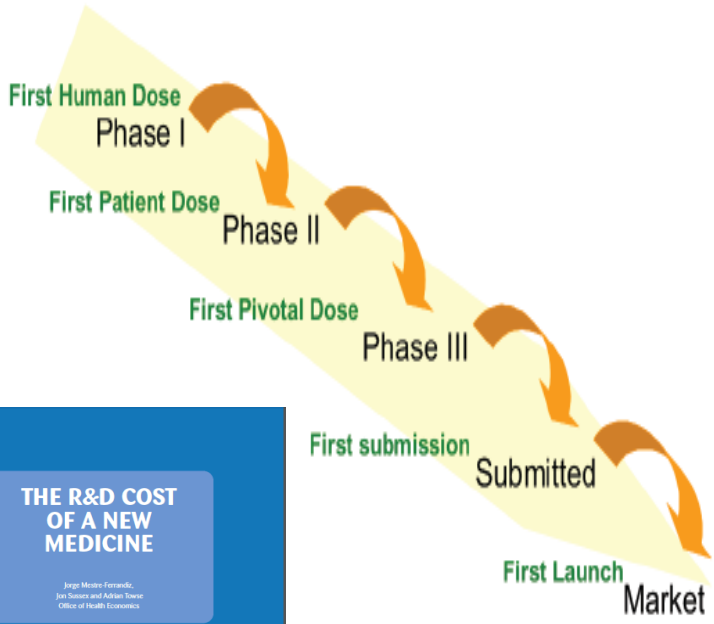
SALES

Generic share of prescriptions filled:[4]

2000 = **49%**

2015 = **91%**

Drug Development: Complex, Risky, and Costly



Only about 20-25 percent of drugs tested in humans make it to the market

New Tufts Estimate--$2.6 Billion Per New Medicine

Tufts Center for the Study of Drug Development

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News

November 18, 2014

Cost to Develop and Win Marketing Approval for a New Drug Is $2.6 Billion

BOSTON – Nov. 18, 2014 – Developing a new prescription medicine that gains marketing approval, a process often lasting longer than a decade, is estimated to cost $2,558 million, according to a new study by the Tufts Center for the Study of Drug Development.

". . . the cost to develop and win marketing approval for a new drug has increased by 145% between the two study periods, or at a compound annual growth rate of 8.5%."

What is a "medicine" from an economic perspective?

- One input in a "health production function":
  - H = H(physician visits, hospital care, medicines, own time, **OTHER**)
  - "OTHER"—the social determinants of population health

- What about an "innovative" drug?
  - Represents new information or knowledge.

- What is unique about new information or knowledge from an economic perspective?
  - It's a NOT a private good: it's a "public good."
  - It's NOT ONLY a public good, it's a **GLOBAL public good**.

- Free markets will tend to **undersupply public goods** (below what is socially optimal).
  - Therefore, intervene, but how?
  - Patents (intellectual property) and subsidies.

Patents (Intellectual Property) for Medicines

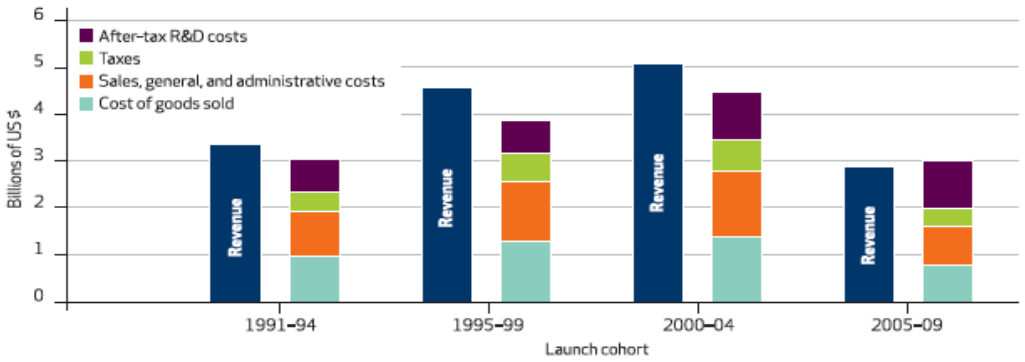
- Statutory patent life is 20 years.

- For medicines:
  - Takes 8-12 years to launch product.
  - Implies 8-12 years remaining after approval for marketing

- Provides strong (but limited) protection against competition
  - Generic copies are blocked during patent life
  - But follow-on competition is common

EXHIBIT 3

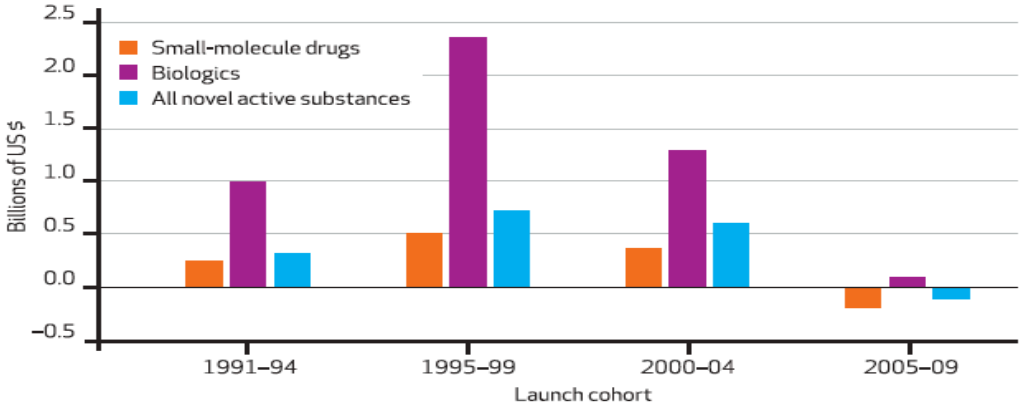
Average Present Value Of Lifetime Global Net Sales And Total Costs Of Novel Active Substances, By Launch Cohort, 1991–2009



SOURCE Authors' analysis of 1991–2012 data from IMS Health Inc.'s MIDAS database. **NOTES** Revenue is lifetime global net sales. R&D is research and development.

EXHIBIT 4

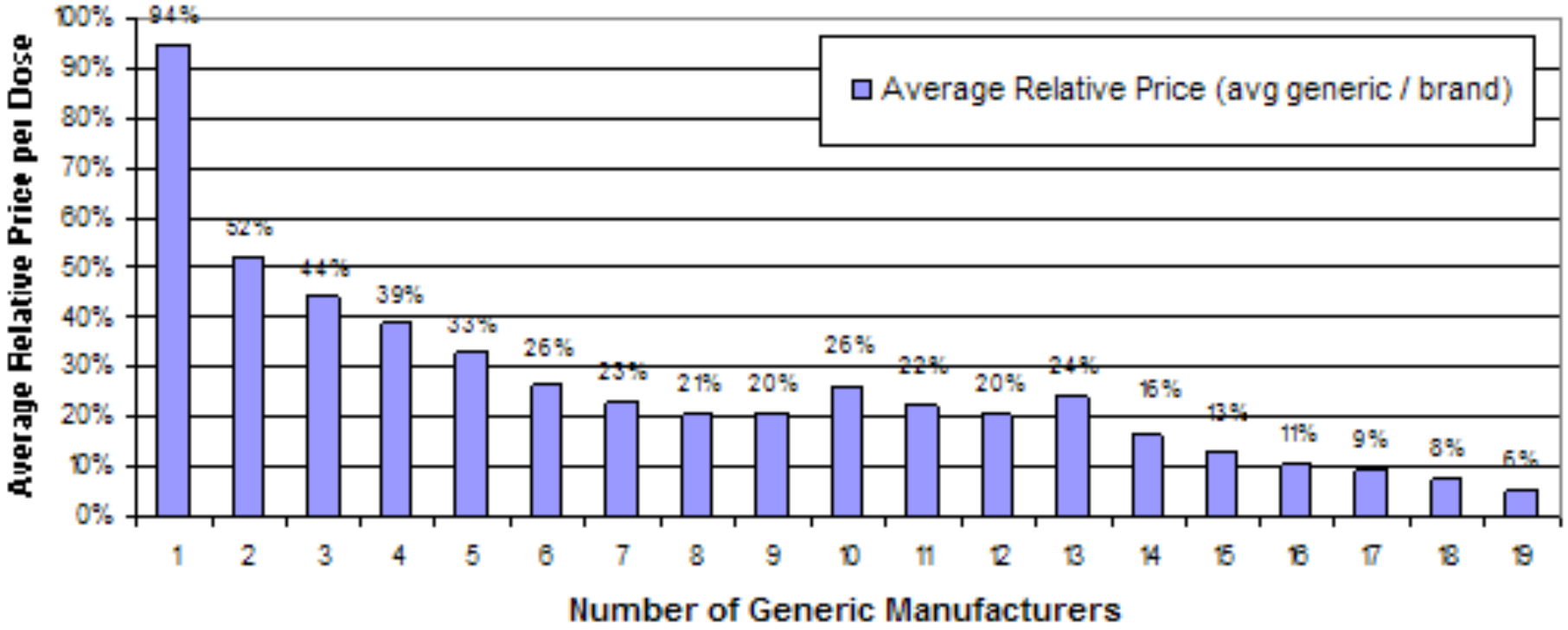
Average Lifetime After-Tax Net Returns Of Novel Active Substances, By Launch Cohort, 1991–2009



SOURCE Authors' analysis of 1991–2012 data from IMS Health Inc.'s MIDAS database.

Source:
Berndt et al.,
2015

Generic Competition and Drug Prices



Source: FDA analysis of retail sales data from IMS Health, IMS National Sales Perspective (TM), 1999-2004, extracted February 2005

Table 12.6 Comparison of Pharmaceutical Prices Across Selected Countries
EXHIBIT 6

Pharmaceutical Price Indexes, Relative to US Prices (US = 100), 2005

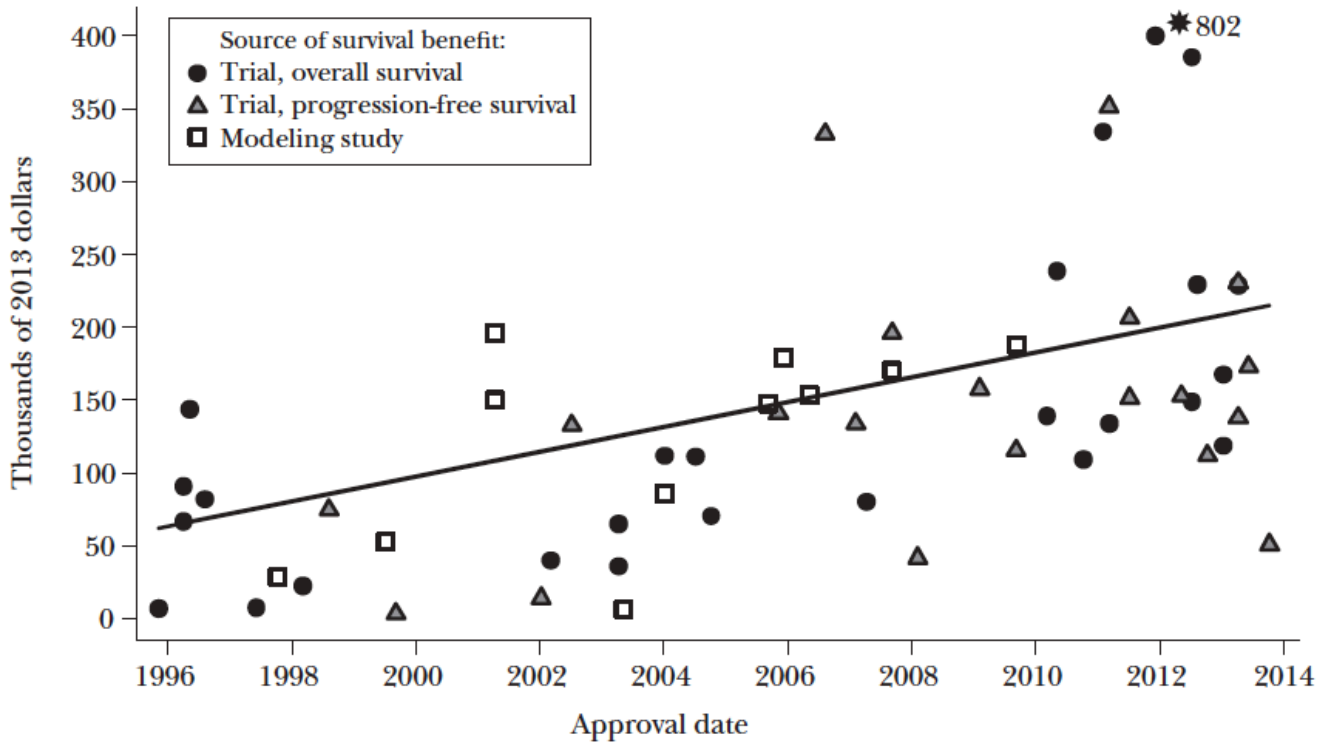
Country	Comprehensive Indexes[a]				Originator versus Generic[b,c,d]				
					Originator		Generic	Rx versus OTC[b,c,d]	
	Manuf.[d] at Exch. Rates[c]	Public[e] at Exch. Rates[c]	Public[e] at GDP PPPs[f]	Manuf.[d] Normalized by Income[g]	Single-source	Multi-source	Branded and Unbranded	Rx	OTC
US	100	100	100	100	100	100	100	100	100
Canada	81	81	79	103	74	60	133	79	189
France	74	91	78	100	64	37	108	69	262
Germany	75	90	95	106	74	65	151	77	192
Italy	67	87	82	94	55	68	150	63	527
Spain	59	69	71	93	62	40	109	57	377
UK	72	81	68	93	76	61	131	77	202
Japan	111	99	50	151	81	99	211	101	362
Australia	69	70	66	90	63	62	138	70	195
Brazil	69	80	68	336	62	109	128	64	186
Chile	56	65	119	206	56	55	138	58	312
Mexico	102	107	157	414	90	87	216	110	218

Note: ATC3 is Anatomical Therapeutic Classification.
[a]Bilateral matching with US by molecule-atc3.
[b]Bilateral matching with US by molecule-atc3-form-strength.
[c]Price converted to US dollars at exchange rates.
[d]Manufacturer prices.
[e]Public prices.
[f]Prices converted to US dollars at gross domestic product (GDP) purchasing power parities (PPPs).
[g]Price index normalized by GDP per capita.
Source: World Development Indicators, 2005; and authors calculations based on data from IMS Health MIDAS database, 2005. Source: Danzon, P. M. & Furukawa, M. F. (2008). International prices and availability of pharmaceuticals in 2005. *Health Affairs*, 27(1), 221–233.

Scott Morton-Kyle 2012

Figure 2

Drug Price per Life Year Gained versus Drug Approval Date



Journal of Economic Perspectives—Volume 29, Number 1—Winter 2015—Pages 139–162

Pricing in the Market for Anticancer Drugs†

David H. Howard, Peter B. Bach, Ernst R. Berndt, and Rena M. Conti

Conclusion: Final Comments

1. Long-term sustainability of the current industry "blockbuster" business model is questionable.
2. Access to innovative medicines remains a significant problem in this system
3. This is a global problem: global differential pricing is needed—likely to be helpful, but not a "solution."

Thanks—lgarrisn@uw.edu

Speaker:

Marcel van Raaij, Ministry of Health

Speaker:

Ad Antonisse

Speaker: Ad Antonisse (AstraZeneca)

Key Points/Issues:

1. Basic science and pharmaceutical science get closer and closer

2. Personalised medicine = Drug + Diagnostics + Funding + Process

3. We do not sell the product. We sell the knowledge.

Speaker:

Huig Schipper

Speaker: Huig Schipper (Inspire2Live)

Key Points/Issues:

1. Pay for Value , cap prices to €100k per QALY
2. Restore power balance by sharing IP with trial patient (organizations), Patients demand their 33% share of IP when signing there informed consent
3. Increase tax by 10% on tobacco, alcohol and sugar. Use the revenue for better accessability for medicines

Speaker:

Susan Noyon (Zilveren Kruis)

Speaker:

Casper van Eijck (Erasmus Univ.).

Thanks for your attention.

Discussion: Q&A