

Myths and Realities About Why US Drugs Cost So Much

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Conflict of Interest

- No conflicts to declare

Learning Objectives

- Be aware of how US drug prices compare to prices in other countries
- Be able to debate the reasons for high US prices
 - Cost of research/value of drugs
 - Profit levels
 - Uptake of new drugs/cost of promotion
 - Market forces
- Understand the consequences of high prices
- Know how other countries control prices & what can the US do

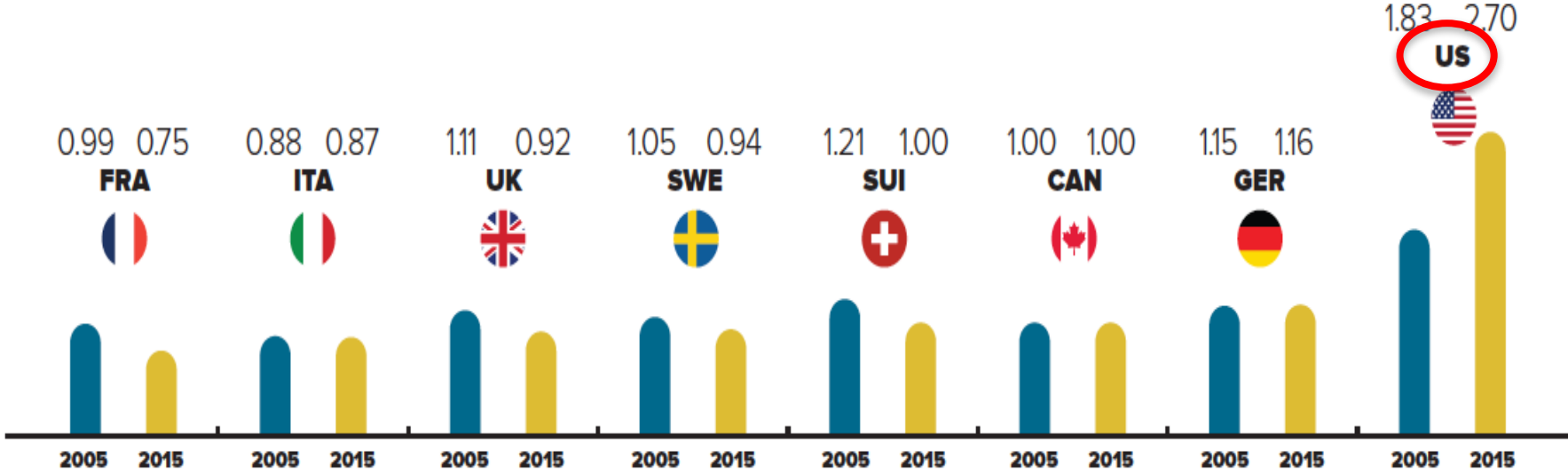
Comparison of Drug Prices (US \$/month)

Drug	Dose	Country								
		US (list)	US (discount)	Australia	Canada	France	Germany	Japan	Norway	United Kingdom
Crestor	10mg OD	216.00	86.40	8.70	32.10	19.80	40.50	28.80	20.09	25.80
Lantus	3 ml pen device – 50 units OD	372.75	186.38	54.05	67.00	46.40	60.90	64.40	45.25	63.65
Advair	one inhalation BID – 250 micrograms/50 micrograms	309.60	154.80	29.28	74.12	34.52	37.71	51.05	24.28	46.99
Januvia	100 mg OD	330.60	168.61	33.60	68.10	35.40	39.00	47.40	34.20	48.00
Sovaldi	400 mg OD x 12 weeks	30,000	17,700.00	NA	14,943.30	16,088.40	17,093.70	13,020.00	13,462.20	16,770
Humira	40 mg one injection q2weeks	3,430.82	2,504.50	1,242.75	1,164.32	981.79	1,749.26	980.34	918.41	1,157.53
Gleevec	400 mg OD	10,122.30	10,122.30	2,585.10	2,420.70	2,303.10	3,003.30	2,205.60	2,093.10	2,645.10

Source: <https://www.bloomberg.com/graphics/2015-drug-prices/>

US Prices Are Increasing Faster Than Those in Other Countries

FIGURE 9. Average Foreign-to-Canadian Price Ratios: 2005, 2015



Source: PMPRB

Why Are US Prices So High?

- Industry's reasons
 - High cost of research
 - US subsidizes the low cost in other countries
- Other peoples' reasons
 - High profits
 - Rapid uptake of new more expensive drugs that offer little advantage
 - Promotion
 - Price is what market will pay & no controls on costs

Cost of Bringing a New Drug to Market

- PhRMA's claim
 - Over \$2.6 billion dollars
- But the research used for that figure
 - Is based on confidential data that isn't released
 - Comes from a self-selected sample of companies willing to release information on some drugs
 - Excludes drugs licensed in or co-developed

Growth in Cost of Research - PhRMA

(dollar figures in millions)

Year	Domestic R&D	Annual Percentage Change	R&D Abroad*	Annual Percentage Change	Total R&D	Annual Percentage Change
2014**	\$41,104.4	1.7%	\$10,121.8	-9.8%	\$51,223.2	-0.8%
2013	\$40,396.0	7.7%	11,217.6	-7.1%	\$51,613.6	4.1%
2012	37,510.2	3.1	12,077.4	-1.6	49,587.6	1.9
2011	36,373.6	-10.6	12,271.4	22.4	48,645.0	-4.1
2010	40,688.1	15.1	10,021.7	-9.6	50,709.8	9.2
2009	35,356.0	-0.6	11,085.6	-6.1	46,441.6	-2.0
2008	35,571.1	-2.8	11,812.0	4.6	47,383.1	-1.1
2007	36,608.4	7.8	11,294.8	25.4	47,903.1	11.5
2006	33,967.9	9.7	9,005.6	1.3	42,973.5	7.8
2005	30,969.0	4.8	8,888.9	19.1	39,857.9	7.7
2004	29,555.5	9.2	7,462.6	1.0	37,018.1	7.4
2003	27,064.9	5.5	7,388.4	37.9	34,453.3	11.1
2002	25,655.1	9.2	5,357.2	-13.9	31,012.2	4.2
2001	23,502.0	10.0	6,220.6	33.3	29,722.7	14.4
2000	21,363.7	15.7	4,667.1	10.6	26,030.8	14.7
1999	18,471.1	7.4	4,219.6	9.9	22,690.7	8.2
1998	17,127.9	11.0	3,839.0	9.9	20,966.9	10.8
1997	15,466.0	13.9	3,492.1	6.5	18,958.1	12.4
1996	13,627.1	14.8	3,278.5	-1.6	16,905.6	11.2
1995	11,874.0	7.0	3,333.5	***	15,207.4	***

Growth in Sales versus Growth in R&D Spending

- R&D (domestic & foreign): 1995-2014
 - From \$15.2 billion to \$51.2 billion
 - Increase of **\$36 billion**
- Sales (domestic & foreign): 1995-2014
 - From \$91 billion to \$286 billion
 - Increase of **\$195 billion**

Even Drug Company Executives Admit R&D Has Nothing To Do With Price

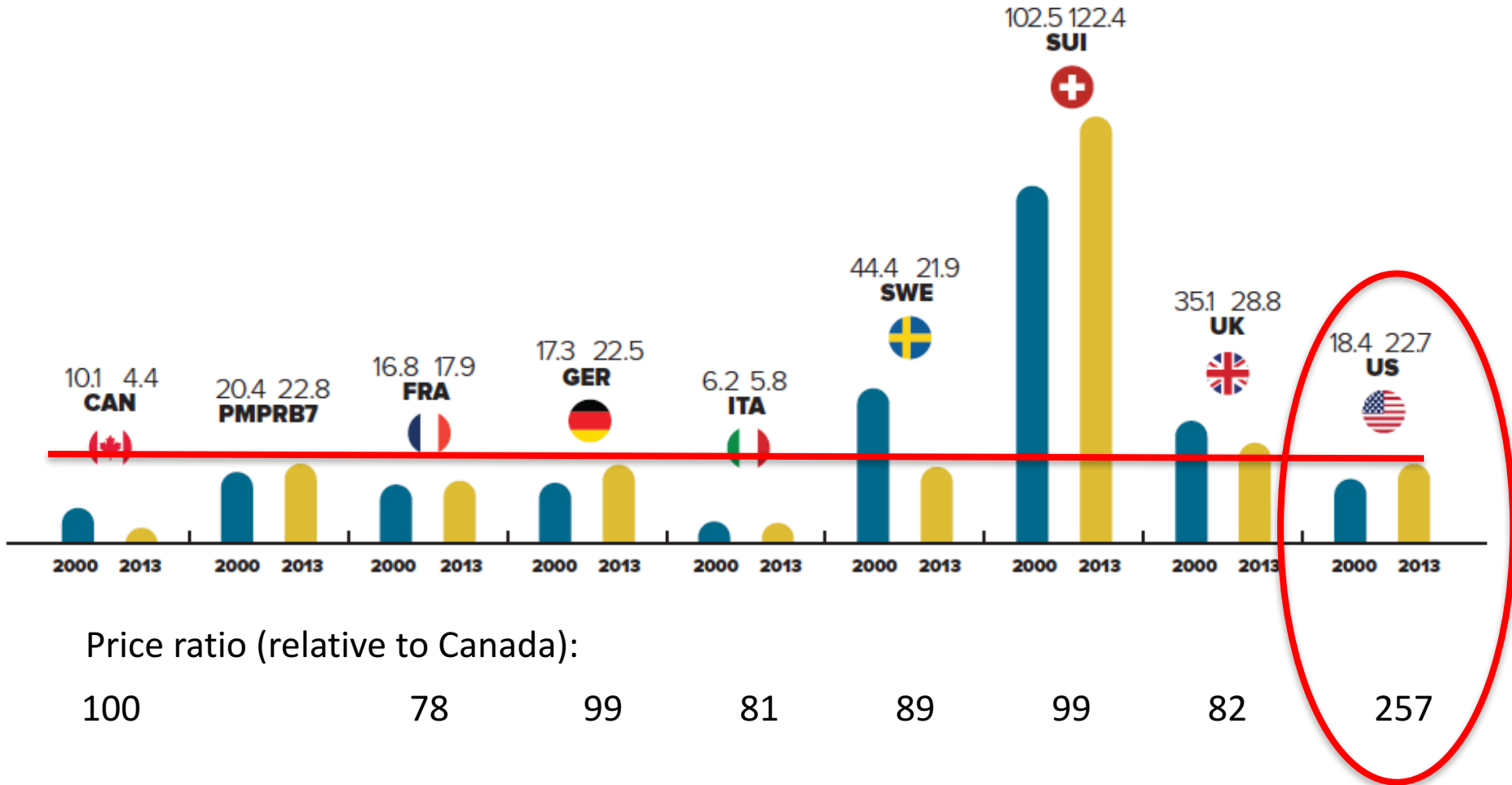
“It’s a fallacy to suggest that our industry, or any industry, prices a product to recapture the R&D budget”

Hank McKinnell, former CEO of Pfizer

Does the US Subsidize Foreign Prices?

- United Kingdom
 - Profits are about 17% of sales
 - Only slightly below profit levels in the US

R&D to Sales Ratio and Drug Prices



Ongoing Profitability

Industry	Net Margin in 2016
Pharma: Generic	30%
Investment Managers	29.1%
Tobacco	27.2%
Pharma:major	25.5%
Internet Software/Services	25%
Biotechnology	24.6%
Savings Banks	24%
IT Services	23%
Regional Banks	23%
Major Banks	22.9%

<http://www.forbes.com/sites/liyanchen/2015/12/21/the-most-profitable-industries-in-2016/#58c3e0485716>

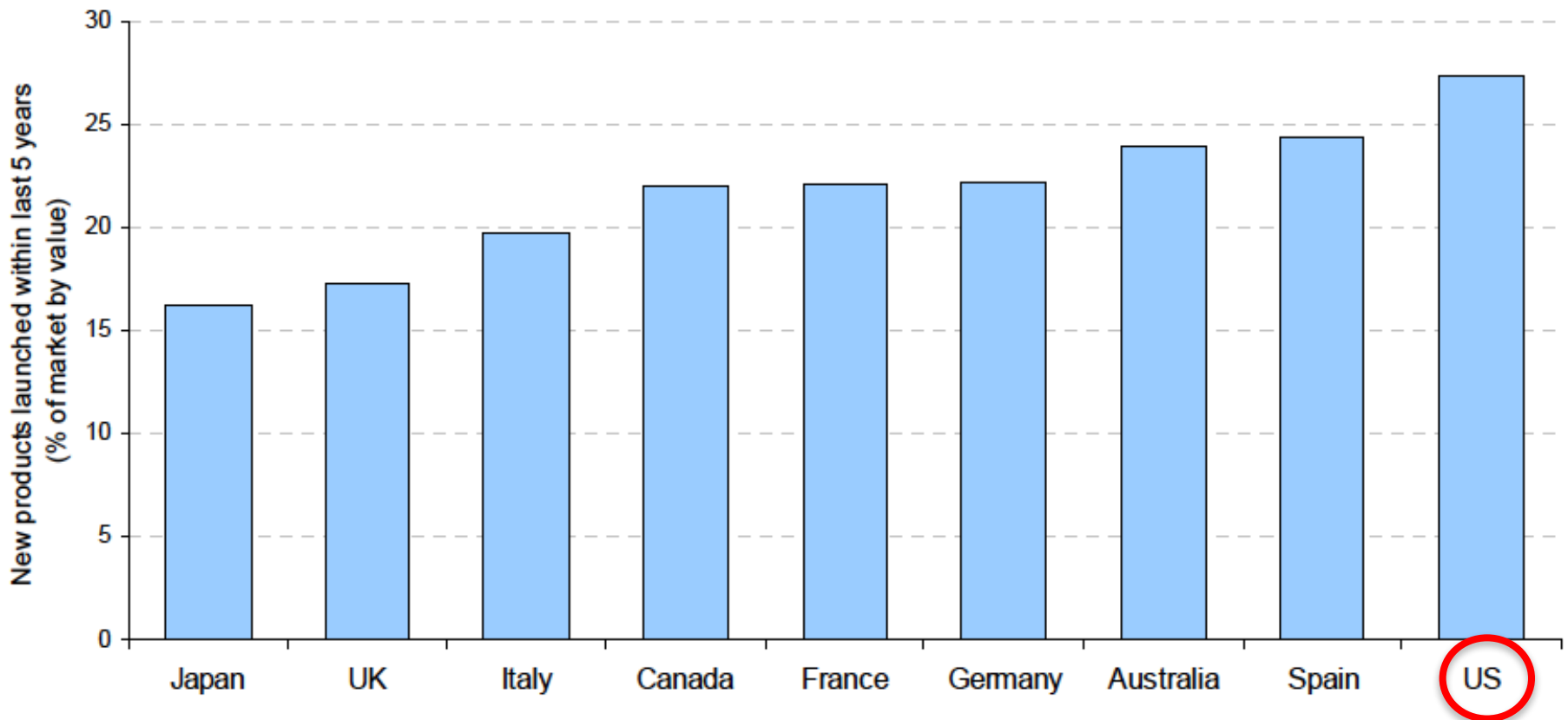
What Are Profits Used For, 2005-2014?

Company	Stock buybacks (\$ billions)	Cash dividends (\$ billions)	Research & development (\$ billion)
Johnson & Johnson	38.8	56.7	78.2
Pfizer	60.8	66.6	84.0
Merck	26.5	41.3	66.5
Abbott	9.0	24.1	30.4
Eli Lilly	3.7	20.3	43.3
Bristol-Myers Squibb	4.6	23.0	36.1
Amgen	34.7	4.9	34.5
Gilead	17.0	0.0	14.4
Allergan	4.1	0.6	8.6
Total	199.2	237.5	396.0

Lazonick et al. Submission to UN Secretary-General's High-Level Panel on Access to Medicines, Feb. 28, 2016

Rate of Adoption of New Drugs

Figure 4.1: Proportion of national markets in 2004 accounted for by products launched in 1999-2004 (% of 2004 market by value)



Note: The data used captures all new products including new generic products.

Source: PICTF, 'Competitiveness and Performance Indicators 2005'.

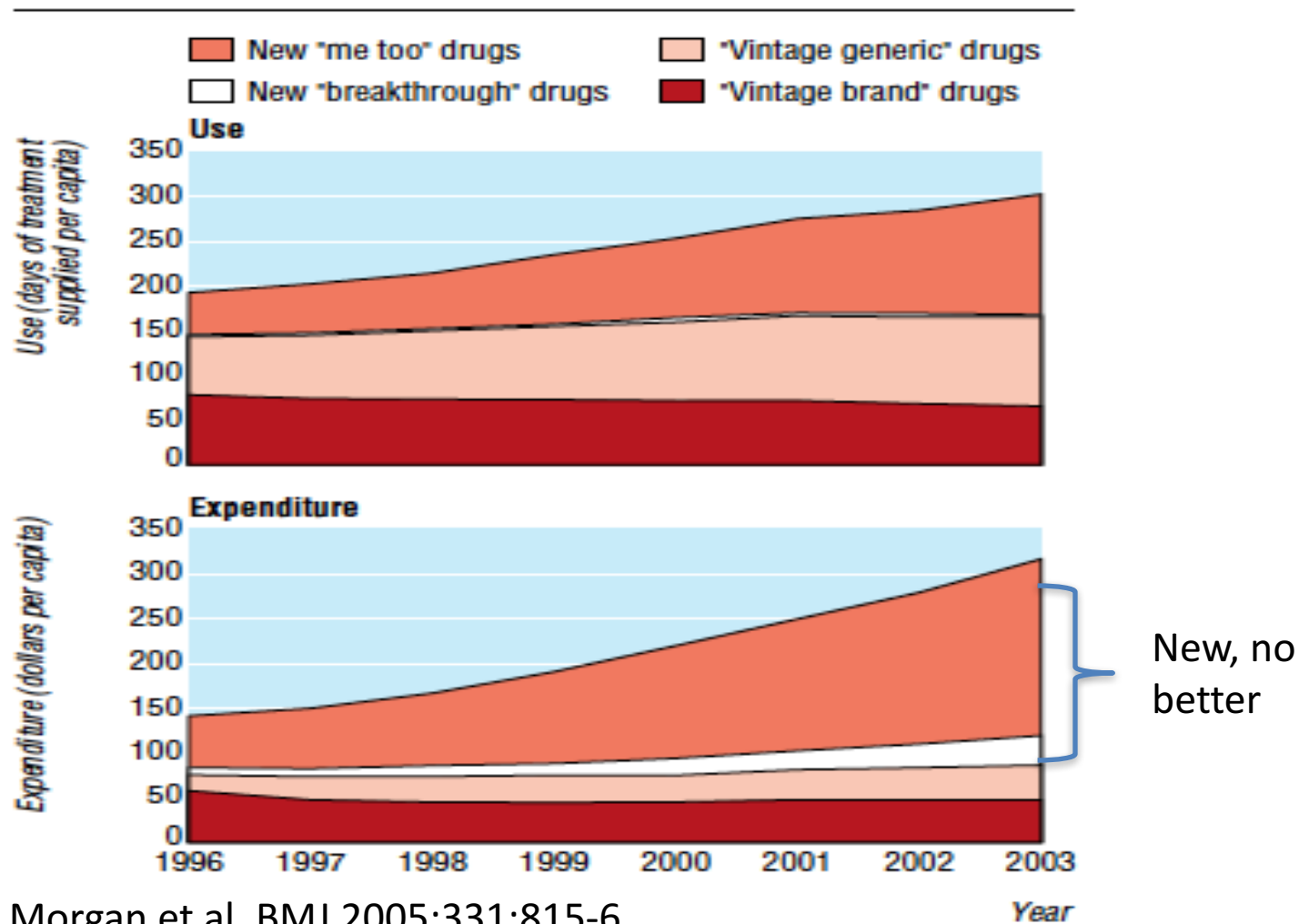
Is Faster Use of Drugs Better?

Therapeutic Innovation 2006-2015

Category	Number	Percent
Major therapeutic innovation in an area where previously no treatment was available	3	0.3
Important therapeutic innovation but has limitations	10	1.0
Some value but does not fundamentally change the present therapeutic practice	56	5.4
Minimal additional value and should not change prescribing habits except in rare circumstances	198	18.9
May be new molecule but is superfluous because does not add to clinical possibilities offered by previously available products	537	51.4
Without evident benefit but with potential or real disadvantages	173	16.6
Decision postponed until better data and more thorough evaluation	68	6.5
Total	1045	100.0

Prescrire Editorial Staff. New drugs and indications in 2015. Prescrire International 2015;25:136-9.

Most New Spending Is For Drugs With Little Additional Value (Canada)



Morgan et al. BMJ 2005;331:815-6

Cost of Promotion

Category	2004 (billions)	2010 (billions)
Samples	15.9	13.9
Detailing	20.4	5.8
DTCA	4.0	4.4
Meetings	2.0	2.8
E-promotion, mailings, clinical trials	0.3	0.5
Journal advertising	0.5	0.3
Unmonitored promotion (estimate)	14.4	NA
Total	57.5	27.7
Percent of sales	24.4	9.0

Gagnon et al. PLoS Medicine 2008;5:e1; Korenfield et al. PLoS One 2013;8:e55504

No Relationship Between R&D Costs and Canadian Prices of Drugs

Therapeutic class	Average R&D Cost for a drug in the class (\$ millions)*	Drug Price/year (example of drug in class) (\$)	Year approved
Rheumatoid arthritis	1,203	~17,330 (infliximab)	2001
Alzheimer's disease	1,161	~1,710 (memantine)	2004
Asthma	951	~560 (montelukast)	1998
Breast Cancer	784	~49,920 (trastuzumab)	1999
HIV/AIDS	616	~7,930 (darunavir)	2006

2 fold difference in R&D cost 89 fold difference in price

*Mestre-Ferrandiz et al. Office of Health Economics, December 2012

Cost Related Nonadherence

Table 4 National prevalence and adjusted odds of cost-related non-adherence among respondents to the 2014 Commonwealth Fund International Health Policy Survey of Older Adults, stratified by income

Country	All incomes		Below-average income		Average income or above	
	CRNA %	Adjusted OR (95% CI)	CRNA %	Adjusted OR (95% CI)	CRNA %	Adjusted OR (95% CI)
Australia	6.8	2.17 (1.28 to 3.67)	7.6	3.61 (1.57 to 8.26)	5.5	1.48 (0.74 to 2.98)
Canada	8.3	2.76 (1.66 to 4.59)	11.7	5.43 (2.40 to 12.35)	4.5	1.23 (0.64 to 2.40)
France	1.6	0.47 (0.23 to 0.94)	0.7	0.22 (0.05 to 0.95)	2.5	0.57 (0.25 to 1.30)
Germany	3.7	0.99 (0.52 to 1.91)	5.3	1.80 (0.70 to 4.65)	2.0	0.52 (0.19 to 1.44)
Netherlands	4.0	1.18 (0.62 to 2.23)	5.8	1.99 (0.76 to 5.21)	2.9	0.73 (0.31 to 1.75)
New Zealand	4.8	1.68 (0.87 to 3.23)	5.3	2.43 (0.91 to 6.49)	4.3	1.32 (0.54 to 3.23)
Norway	2.4	0.66 (0.33 to 1.31)	2.7	0.99 (0.36 to 2.72)	2.2	0.52 (0.19 to 1.39)
Sweden	2.4	0.80 (0.47 to 1.37)	3.6	1.53 (0.66 to 3.53)	1.5	0.41 (0.20 to 0.81)
Switzerland	2.9	0.86 (0.48 to 1.56)	3.4	1.46 (0.60 to 3.56)	2.2	0.59 (0.24 to 1.44)
UK	3.1	Reference	2.3	Reference	3.4	Reference
USA	16.8	6.09 (3.60 to 10.20)	24.9	10.87 (4.76 to 25.00)	9.7	3.30 (1.68 to 6.49)

Morgan et al. BMJ Open 2017;7:e014287

Kaiser Survey in US, Aug. 2015

- Cost related problems:
 - 24% did not fill a prescription
 - 19% cut pills in half or skipped doses of medicine

Off-loading Costs and Health Care Utilization

	Changes in		
	Hospitalization	Physician visits	ED visits
Elderly	+35%	+13%	+50%
Welfare recipients	+194%	+22%	+106%

How Do Other Countries Control Prices? (Circa 2006)

Country	Before Drugs Are Marketed (clinical trial data only)				After Drugs Are Marketed (clinical trial data and clinical practice)			
	Free pricing	Pricing relative to substitute	International reference pricing	Price volume rebate agreement/rebates	Price cuts	Profit controls	Pricing relative to substitute	International reference pricing
Australia		✓		✓			✓	
Canada		✓	✓					✓
Finland		✓	✓		✓		✓	✓
France		✓	✓	✓	✓		✓	
Germany	✓			✓			✓	
Netherlands		✓	✓				✓	✓
Spain		✓	✓	✓	✓		✓	
Sweden		✓					✓	
Switzerland		✓	✓				✓	✓
UK	✓				✓	✓		

Office of Fair Trading (UK), February 2007

What Can the US Do?

- What the US federal government is already doing
- Companies required to report to VA their average and lowest prices charged to nonfederal buyers
- VA then negotiates a price (Federal Supply Schedule) available to all government agencies that buy drugs
 - FSS can be no more than 76% of non-federal average manufacturer price (price paid by wholesalers to manufacturers)

What's the Result?

- For all drugs:
 - US prices for patented drugs are about **200% higher** than Australian prices
- For therapeutically important drugs that are subject to FSS prices:
 - Australian prices are **4.2% higher** than US Federal Supply Schedule prices

Conclusions

- US prices are high by international standards
- There is no additional value that comes from those high prices
- High prices hurt vulnerable people
- Government action can lower prices



CURRENT OPINION

Myths and Realities About Why Prescription Drug Prices in the United States Are So High

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