

UNPACKING THE CONCEPT OF FAIR PRICING AND PUTTING IT INTO PRACTICE

**PLENARY SESSION: FAIR PRICING IN PRACTICE
2ND GLOBAL FORUM ON FAIR PRICING
WORLD HEALTH ORGANIZATION**

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Photo Source: James Love, 11 April 2019, Johannesburg, South Africa

WHAT IS A FAIR PRICE FOR A MEDICINE?

FAIRNESS TO SELLERS AND BUYERS

A **SIMPLIFIED** MODEL

Sellers:

Small and large developers, manufacturers, distributors

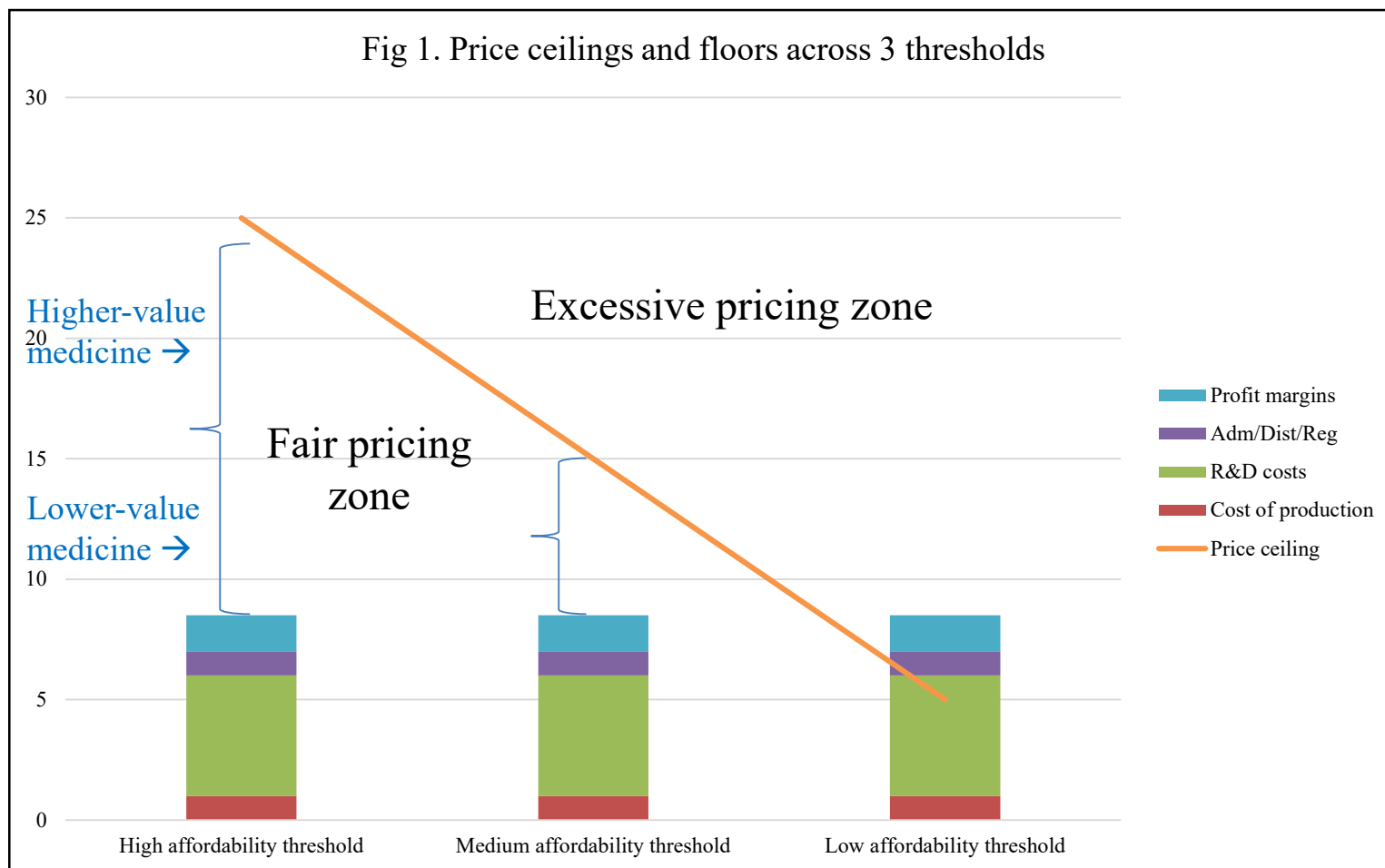
- Cost of R&D
- Cost of manufacturing and distribution
- Other related costs (e.g. registration, administration, pharmacovigilance)
- Fair profit

Buyers:

Payers, insurers, households, patients

- Present and future affordability (binding constraint)
- Value to the individual and health system
- Security of supply

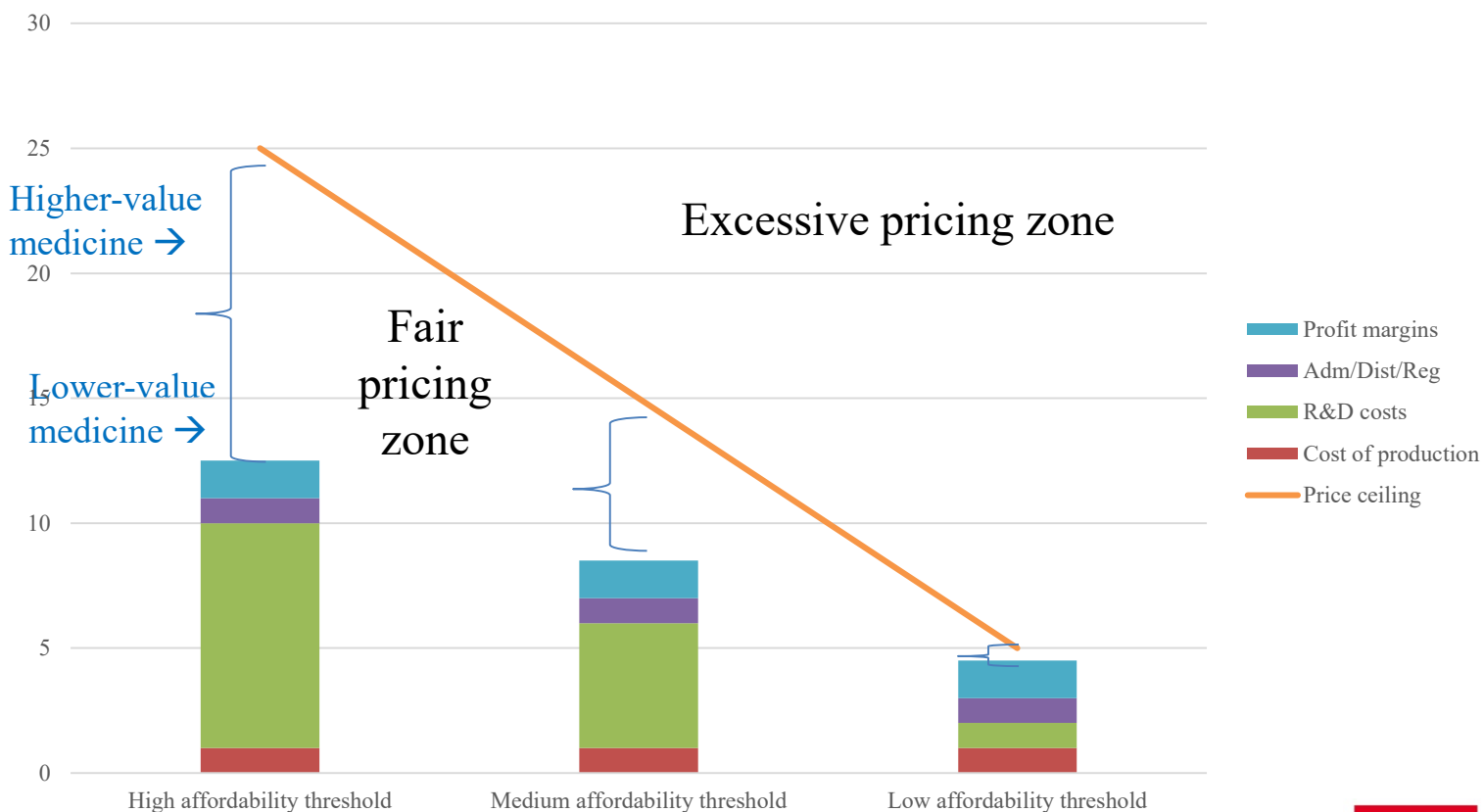
A ZONE OF FAIR PRICING: EQUALLY DISTRIBUTED R&D COSTS



Source: Moon et al. Achieving Fair Pricing of Medicines: Defining the concept of a fair price. Manuscript under review.

A ZONE OF FAIR PRICING: PROGRESSIVELY DISTRIBUTED R&D COSTS

Fig 2. Price ceilings and progressive price floors across 3 affordability thresholds

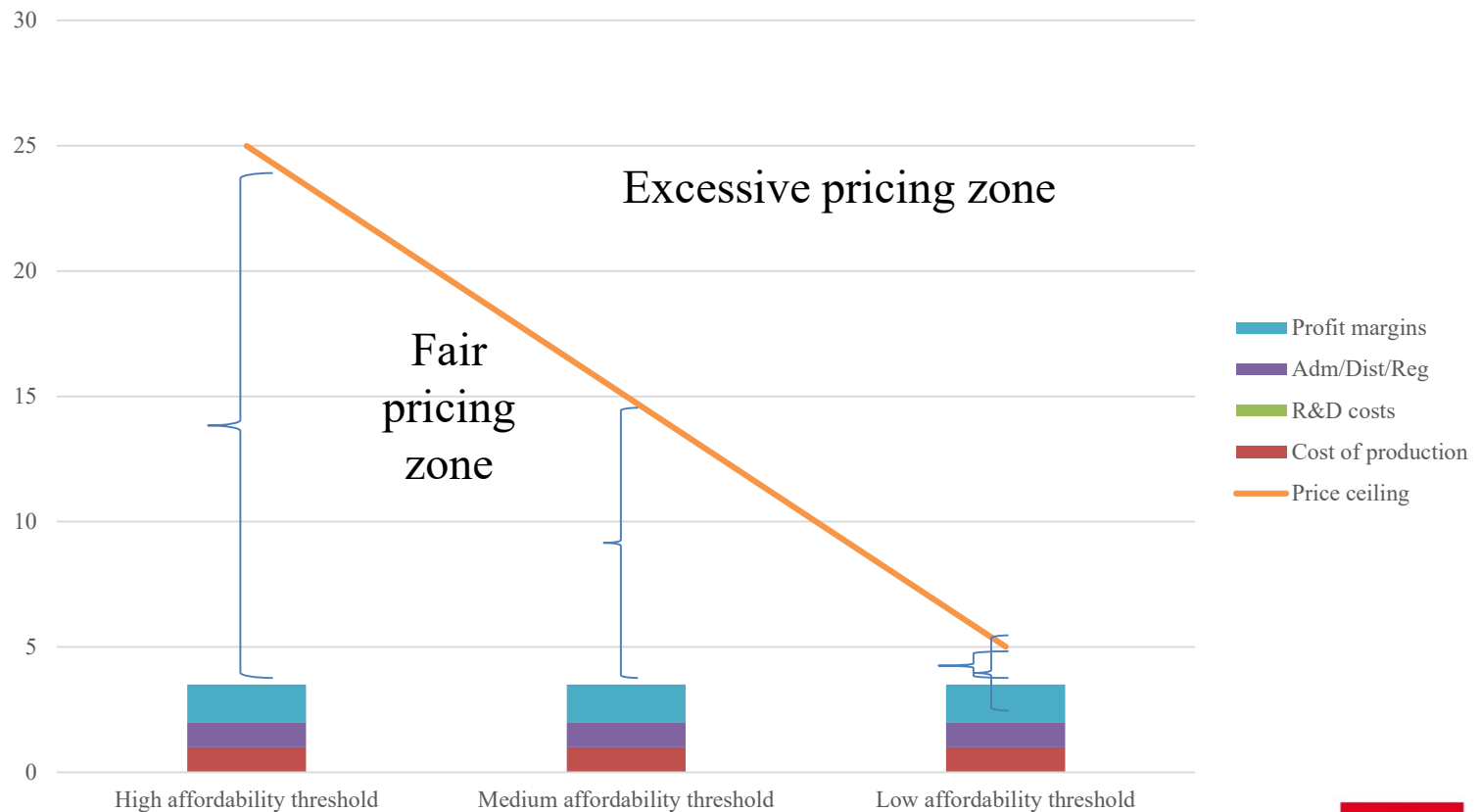


Source: Moon et al. Achieving Fair Pricing of Medicines: Defining the concept of a fair price. Manuscript under review.

A ZONE OF FAIR PRICING

GENERIC MEDICINE

Fig 2. Price ceilings and progressive price floors across 3 affordability thresholds



ILLUSTRATIVE EXAMPLE

SOFOSBUVIR (HEPATITIS C)

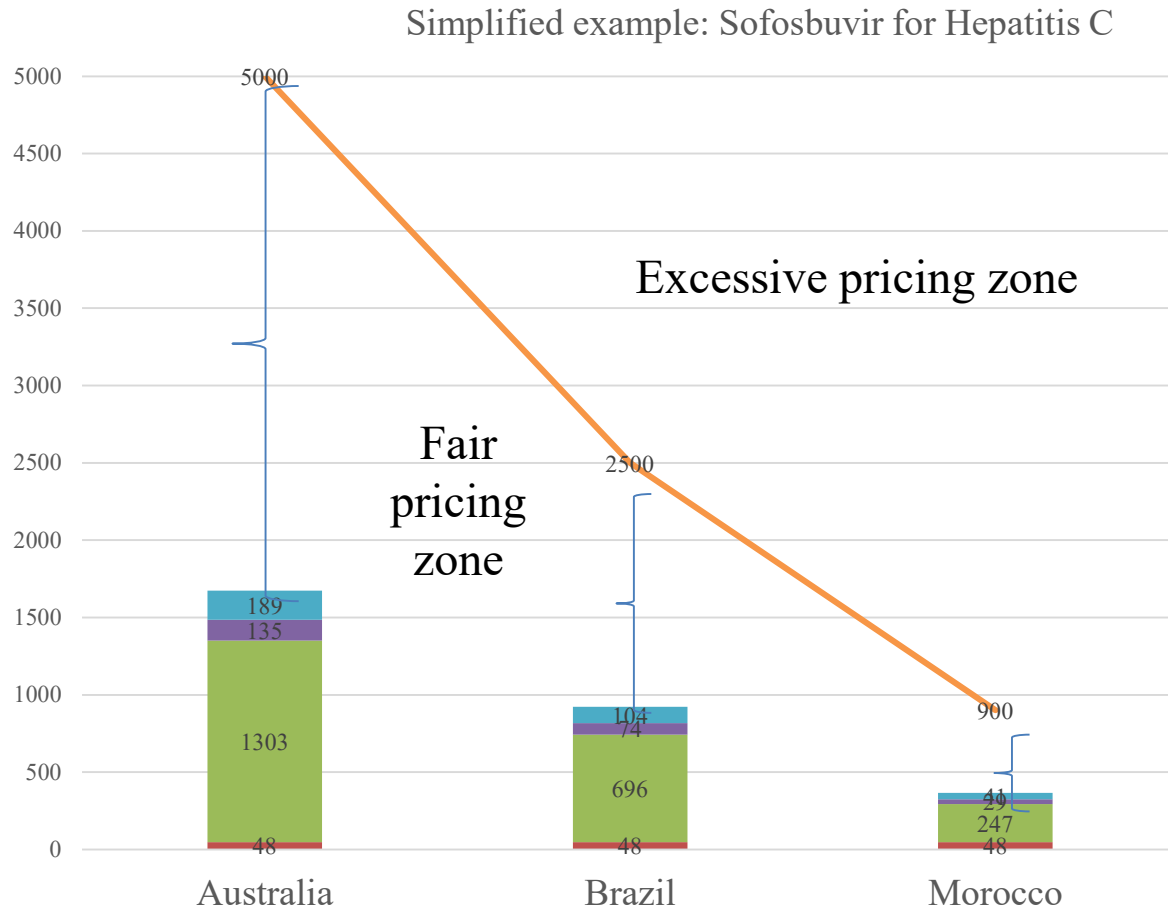
- R&D costs:
 - Pharmasset (\$62 M) + Gilead (\$880 M) = \$943 M
- Gilead acquires Pharmasset: \$11,000 M
- Gilead outlay: \$11,880 M (R&D + acquisition cost)
- Recouped over 10 years (minimum) patent term
- Cost of production: \$47 per treatment course
- Administration, distribution, registration: 10%
- Profit: 14%

Capacity to pay	Country	% of global economy	GNI per capita	# patients treated/year
High	Australia	1.65	51,360	15,000
Medium	Brazil	2.35	8600	40,000
Low	Morocco	0.14	2860	6500

Data Sources: US Senate Finance Committee (2015), WHO Progress Report on Access to Hepatitis C Treatment (2018), World Bank, MedsPAL, Hill, Barber, Gotham (2018)

A ZONE OF FAIR PRICING

SIMPLIFIED EXAMPLE: SOFOSBUVIR FOR HEP C



IS:
 -Conceptual
 -Judgment tool

IS NOT:
 -Fixing a price
 -International agreement

- Profit margins
- Adm/Dist/Reg
- R&D costs
- Cost of production
- Price ceiling

HOW DO WE THINK ABOUT MEDICINES PRICES?

Old

- How much do we pay, compared to others (like us)?
- How does it compare to prices of competing products?
- At that price, how many people can we afford to treat?
- How to achieve fairness in my country?
- What is the price per patient?

New

- What price is affordable & allows for universal access?
- How much did it cost? (to develop, produce and distribute)
- How much profit has been earned? What's a fair profit?
- How to achieve fairness in my country, in a global context?
- How to pay for innovation, delinked from setting a price per person treated?

Need some combination of old and new, but probably more new

Reference Pricing

Licensing - compulsory or voluntary

Patentability criteria

Negotiation

Competition Law

Pooled procurement

Alternate R&D models



Mandate Information Disclosure

Conditions on public R&D funding & incentives

“Netflix” model

Publicly-mandated production

Health Technology Assessment

Address regulatory barriers to competition

Import for Personal Use

Medical Tourism

Pharmacist compounding

AUSTRALIA'S “NETFLIX” MODEL HEPATITIS C

- 2015: estimated 230,000 with HepC but high drug prices
- Fixed lump-sum fee – or “prize” of ~AU\$ 1 billion (\$766m)
- 5 years of unlimited supply = universal access offered

- Our estimate 2016-21: 104,000 patients
 - Effective per-patient price: AU\$ 9600 (\$ 7352) vs ~\$54,000
- Savings: AU\$ 6.4 billion or 93,000 patients
- Australia: 1.65% global GDP vs 1.32% global DAA market

- Public benefit: budget certainty; each person = no marginal cost; incentive to treat early
- Seller benefits: sizeable reward; revenue certainty; production cost ~1% revenue

Source: Moon and Erickson (2019)

3 CONCLUSIONS

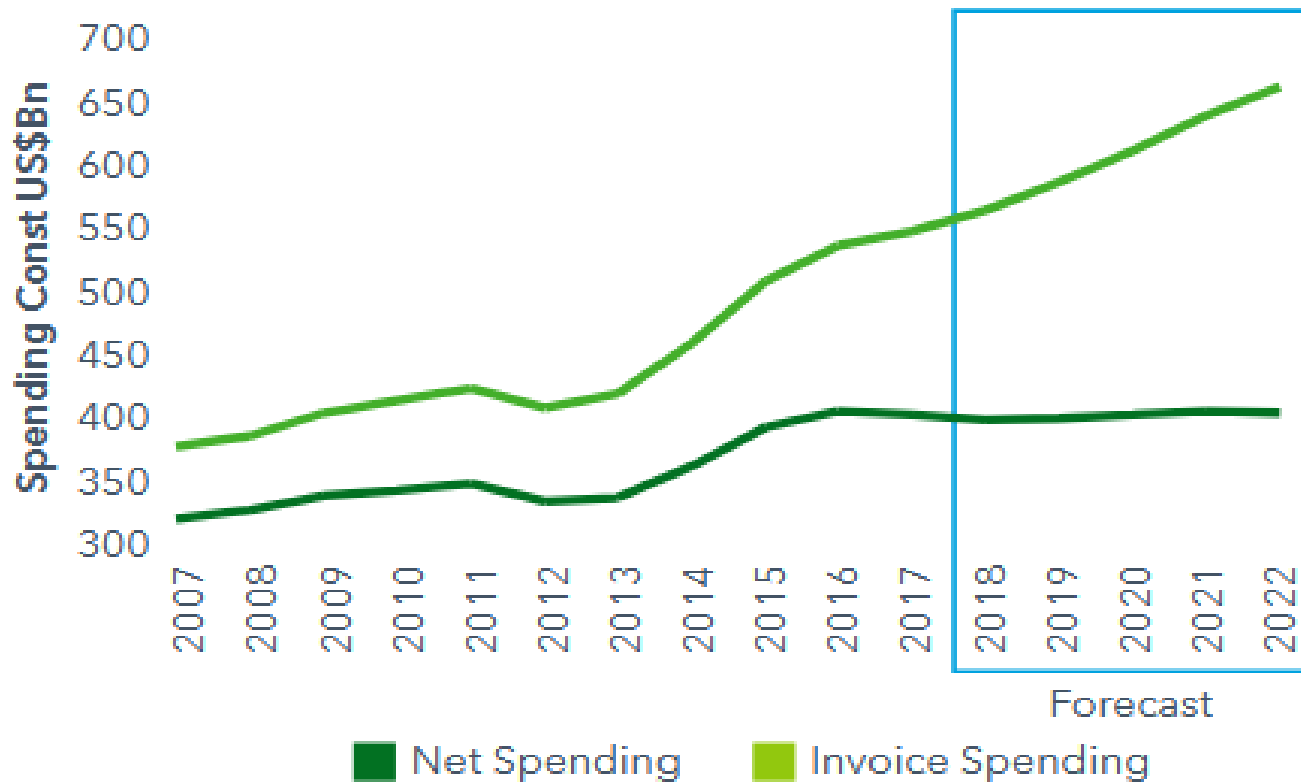
1. A clear idea of “fairness” can help
 - To achieve it in practice
 - To justify it to publicly
2. More information transparency needed to assess fairness more objectively
3. Many tools available to make prices fair(er) in practice
 - Key question: political willingness to use these tools

Thank you, Ke a leboha

Comments to: Suerie.moon@graduateinstitute.ch

EXTRA SLIDES

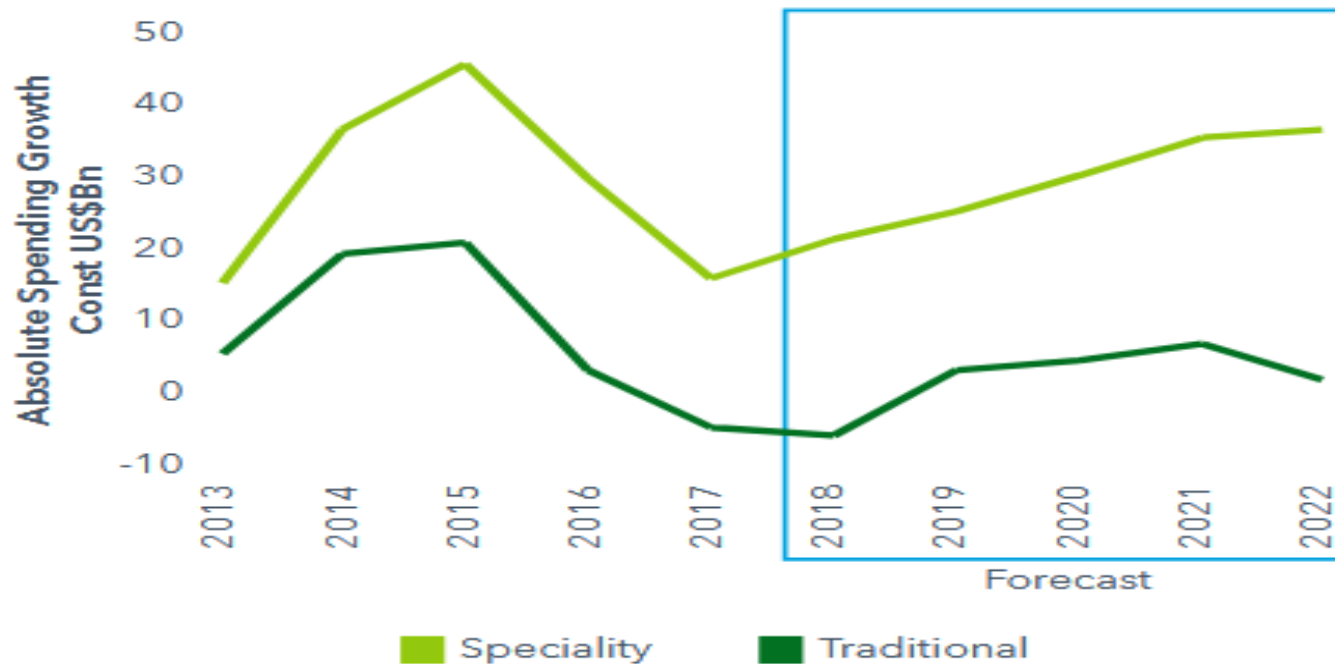
Exhibit 8: Developed Market Brand Invoice and Net Spending 2007-2022



Source: IQVIA 2018. 2018 and Beyond: Outlook and Turning Points. Available : [https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/2018-and-beyond-outlook-and-turning-points.pdf?_ =1540209266492](https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/2018-and-beyond-outlook-and-turning-points.pdf?_=1540209266492).

PRICE TRENDS

Exhibit 10: Brand Spending Growth of Specialty and Traditional Drugs 2013-2022 in the Developed Markets



Source : IQVIA 2018. 2018 and Beyond: Outlook and Turning Points. Available : https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/2018-and-beyond-outlook-and-turning-points.pdf?_=1540209266492

- Specialty: ~40% total spending (2018) → ~50% by 2022
- Includes cancer, HIV, Hepatitis C, autoimmune, others

STICKER SHOCK

€ 48,000
(2014)



€ 133,000
(2015)



€ 320,000
(2018)



\$850,000
(2018)



TRANSPARENCY

REMOVING THE BLINDFOLD ON MEDICINES PRICING

Information needed on:

- Prices
- R&D costs
- Public R&D funds
- Tax breaks
- Patent status
- Data on safety, efficacy, health system effects



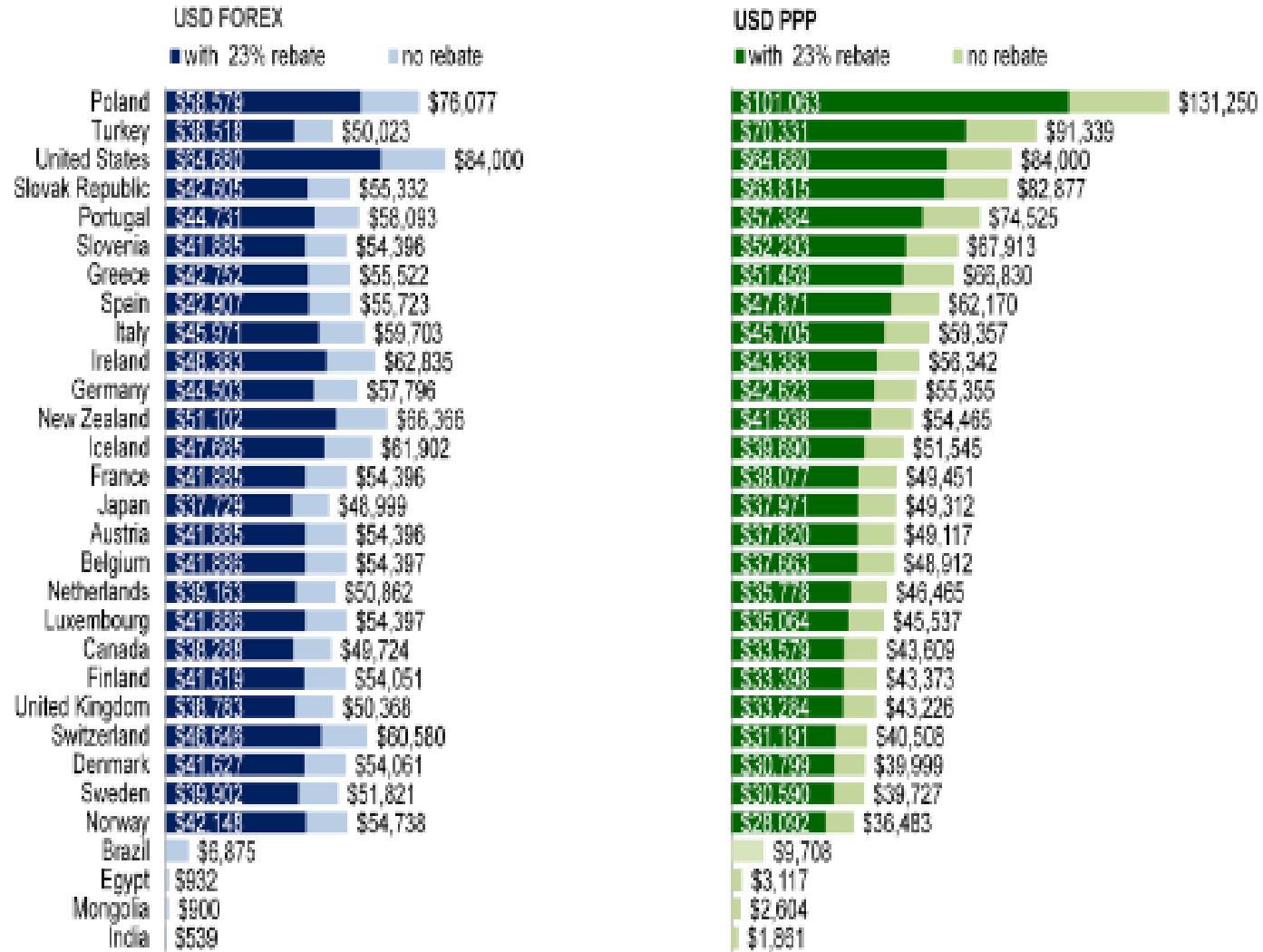
PUBLIC RETURN ON PUBLIC INVESTMENT: CASE STUDY DAA FOR HEPATITIS C

- 1974: Non-A, Non-B Hepatitis identified by US NIH scientists
- 1989: Hepatitis C virus identified (US CDC, US NIH, Chiron)
- 1999: Replicon isolated by R. Bartenschlager (Heidelberg University, funded by German Ministry for Research & Technology, German Society for Research)
- 2002: Replicon improved by C. Rice (Rockefeller University, funded by US NIH)
- 1999-2008: Apath (SME) distributes replicon to drug developers (funded by US Small Business Innovation Research program)
- 2001-11: Pharmasset (SME) develops sofosbuvir
 - 2004-8: PS-6130 adapted with McGuigan method (UK Medical Research Council, European Commission, Belgium)
- 2011: Gilead acquires Pharmasset for \$11 billion
- 2012-5: Merck, Bristol Myers Squibb, J&J acquire Hep C SMEs
- 2013: US FDA approves Gilead's sofosbuvir
- 2013-7: Gilead HepC revenues >\$50 billion

- Sampat & Lichtenberg (2011):
 - Patents on 478 FDA-approved medicines 1988-2005
 - About ½ approved medicines benefits from publicly-financed research
 - 2/3 for priority review medicines
- Cleary et al (2018):
 - Publications relating to 210 new molecular entities FDA-approved (2010-6)
 - 100% benefited from US NIH funding
- Areas of market failure:
 - Neglected disease: 84% public (64%) & philanthropic (21%)
 - Antibiotics, Outbreak-prone pathogens?

Sources: Sampat, Bhaven N., and Frank R. Lichtenberg. "What are the respective roles of the public and private sectors in pharmaceutical innovation?." *Health Affairs* 30.2 (2011): 332-339. Cleary, E.G., Beierlein, J.M., Khanuja, N.S., McNamee, L.M. and Ledley, F.D. (2018) 'Contribution of NIH Funding to New Drug Approvals 2010–2016', *Proceedings of the National Academy of Sciences*, 115(10), pp. 2329-2334

(a) sofosbuvir price



Iyengar et al. 2016. Prices, Costs, and Affordability of New Medicines for Hepatitis C in 30 Countries: An Economic Analysis.

Available : <https://journals.plos.org/plosmedicine/article/file?id=10.1371/journal.pmed.1002032&type=printable>

OUTSIDE THE BOX R&D: DNDI'S HEPATITIS C STRATEGY

Traditional pharmaceutical business model



Innovation **“balanced”** against
affordability

New pharmaceutical business model?



Innovation **with** affordability

- Hep C DAA race: Gilead, Merck BMS, J&J, AbbVie
- Slower: Presidio Pharmaceuticals (SME): ravidasvir
- Multiple firms, parallel DAA R&D on public knowledge base

- Drugs for Neglected Diseases initiative (DNDi)
 - 2016 launches ravidasvir+sofosbuvir development
 - Especially relevant for middle-income countries
 - Medicines Patent Pool license: 4% LIC royalty, 7% MICs
 - High-income countries: why not?

OUTSIDE THE BOX R&D: DNDI'S HEPATITIS C STRATEGY

April 2018

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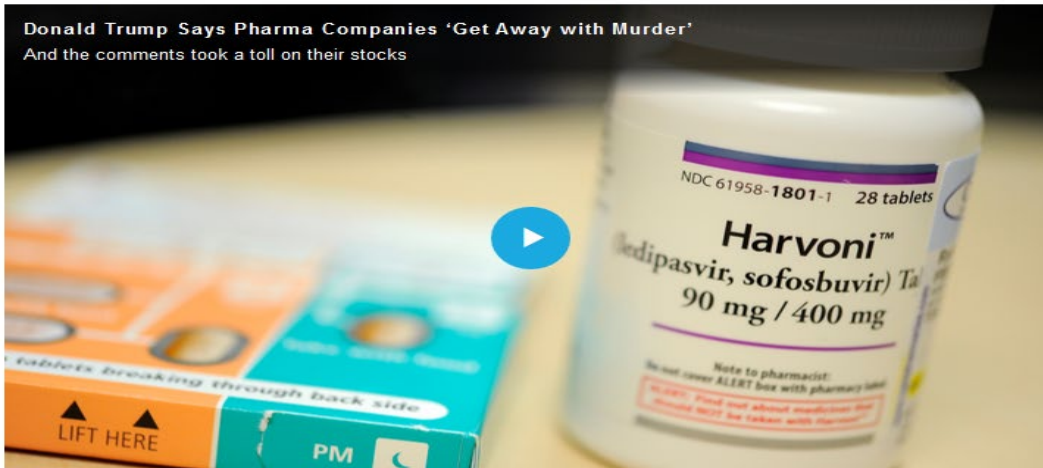
FINNAIR

HEALTH • DRUG PRICES

Hepatitis C Drugs Can Cost \$84,000. This New One May Be Just As Good—But Cost \$300



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And the comments took a toll on their stocks



By SY MUKHERJEE April 12, 2018

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