THE GRADUATE INSTITUTE GENEVA

INSTITUT DE HAUTES ÉTUDES INTERNATIONALES ET DU DÉVELOPPEMENT
GRADUATE INSTITUTE OF INTERNATIONAL AND DEVELOPMENT STUDIES

FAIR PRICING OF MEDICINES: WHAT LESSONS FROM GROWING TRANSPARENCY IN VACCINES MARKETS?

BASED ON: MOON SUERIE, MARIAT STEPHANIE, KAMAE ISAO, PEDERSEN HANNE BAK. DEFINING THE CONCEPT OF FAIR PRICING FOR MEDICINES *BMJ* 2020; 368 :L4726. HTTPS://WWW.BMJ.COM/CONTENT/368/BMJ.L4726

WEBINAR SERIES
KNOWLEDGE NETWORK ON INNOVATION AND ACCESS TO MEDICINES
GLOBAL HEALTH CENTRE, GRADUATE INSTITUTE OF GENEVA

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WHAT IS A FAIR PRICE FOR A MEDICINE?

Does it matter…

- in which country?
- for what kind of payer?
- for what kind of condition?
- at what time in lifecycle?
- what impact on patient?
- what impact on health system?
- what it cost to develop?
- who contributed to the R&D?
- how much profit has been earned?

$311,000 (2019)

WHAT IS A FAIR PRICE?
A GLOBAL PERSPECTIVE

FAIRNESS TO SELLERS AND BUYERS
A SIMPLIFIED MODEL

Sellers:

Small and large developers, manufacturers, distributors

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

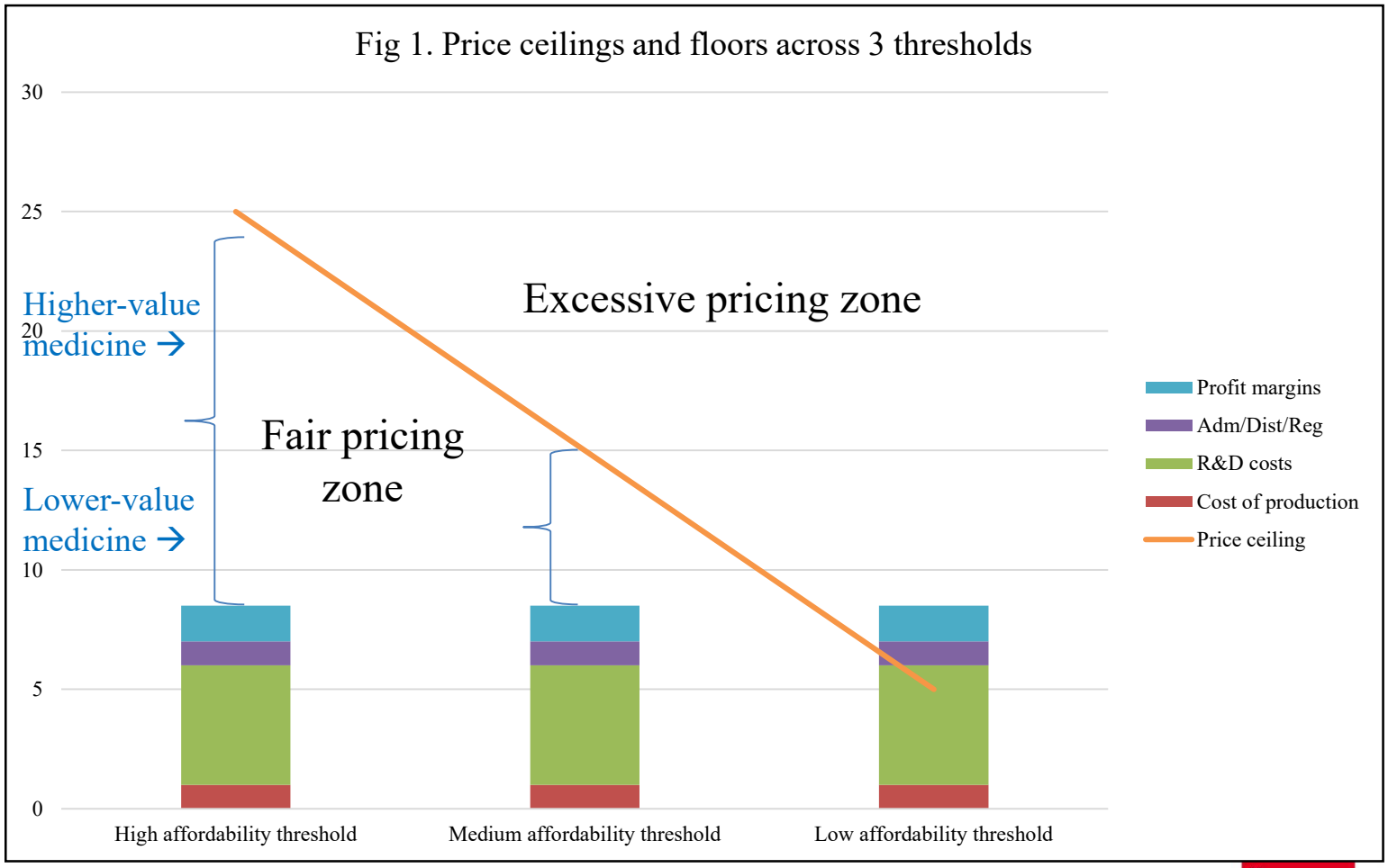
Buyers:

Payers, insurers, households, patients

- Present and future affordability (at individual and health system levels) – binding constraint
- Value (at individual and health system levels)
- Security of supply

Source: Moon et al. 2020. Defining the concept of fair pricing for medicines *BMJ*; 368 :l4726. https://www.bmj.com/content/368/bmj.l4726

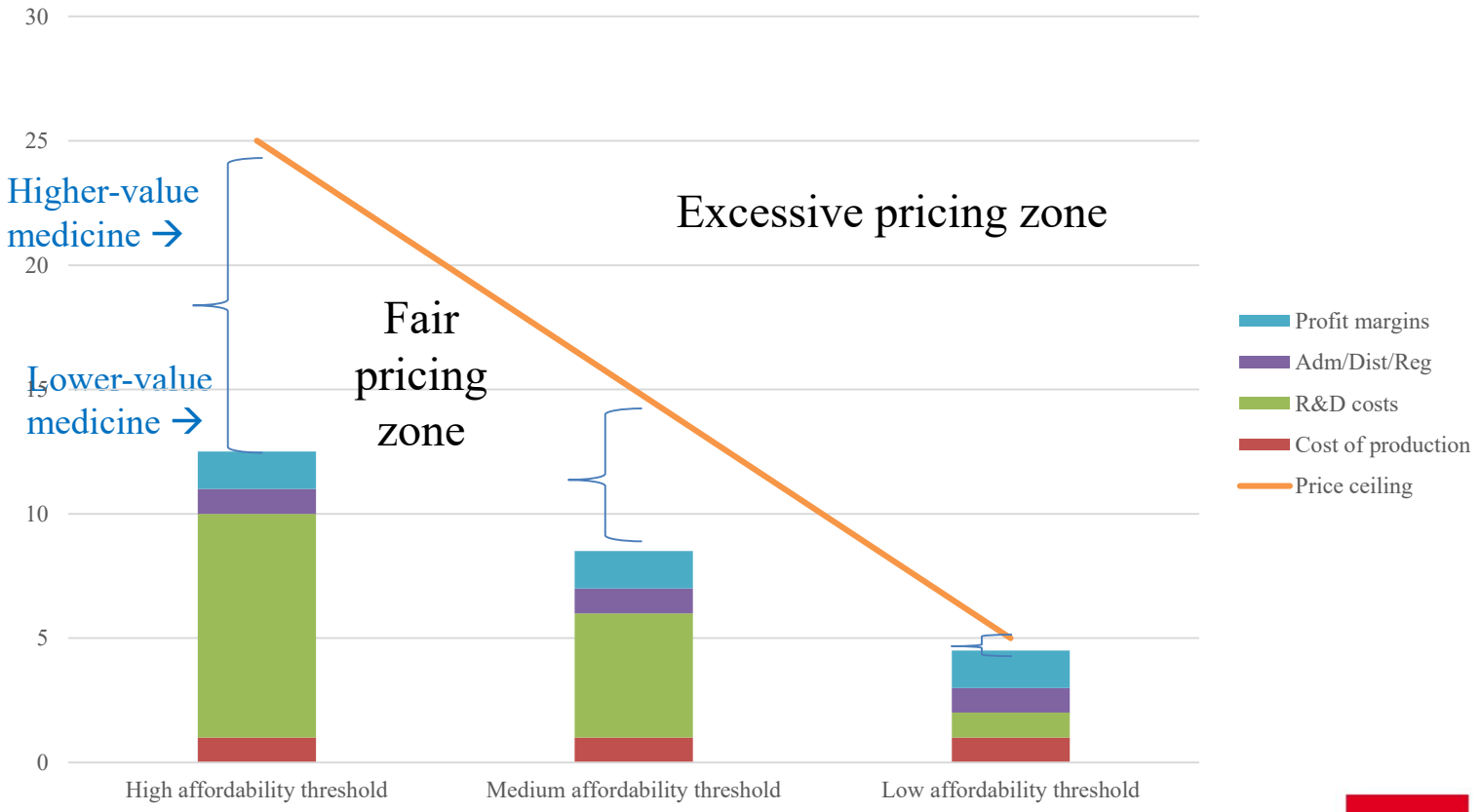
A ZONE OF FAIR PRICING:
EQUALLY DISTRIBUTED R&D COSTS



Source: Moon et al. 2020. Defining the concept of fair pricing for medicines *BMJ*; 368 :l4726. https://www.bmj.com/content/368/bmj.l4726

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

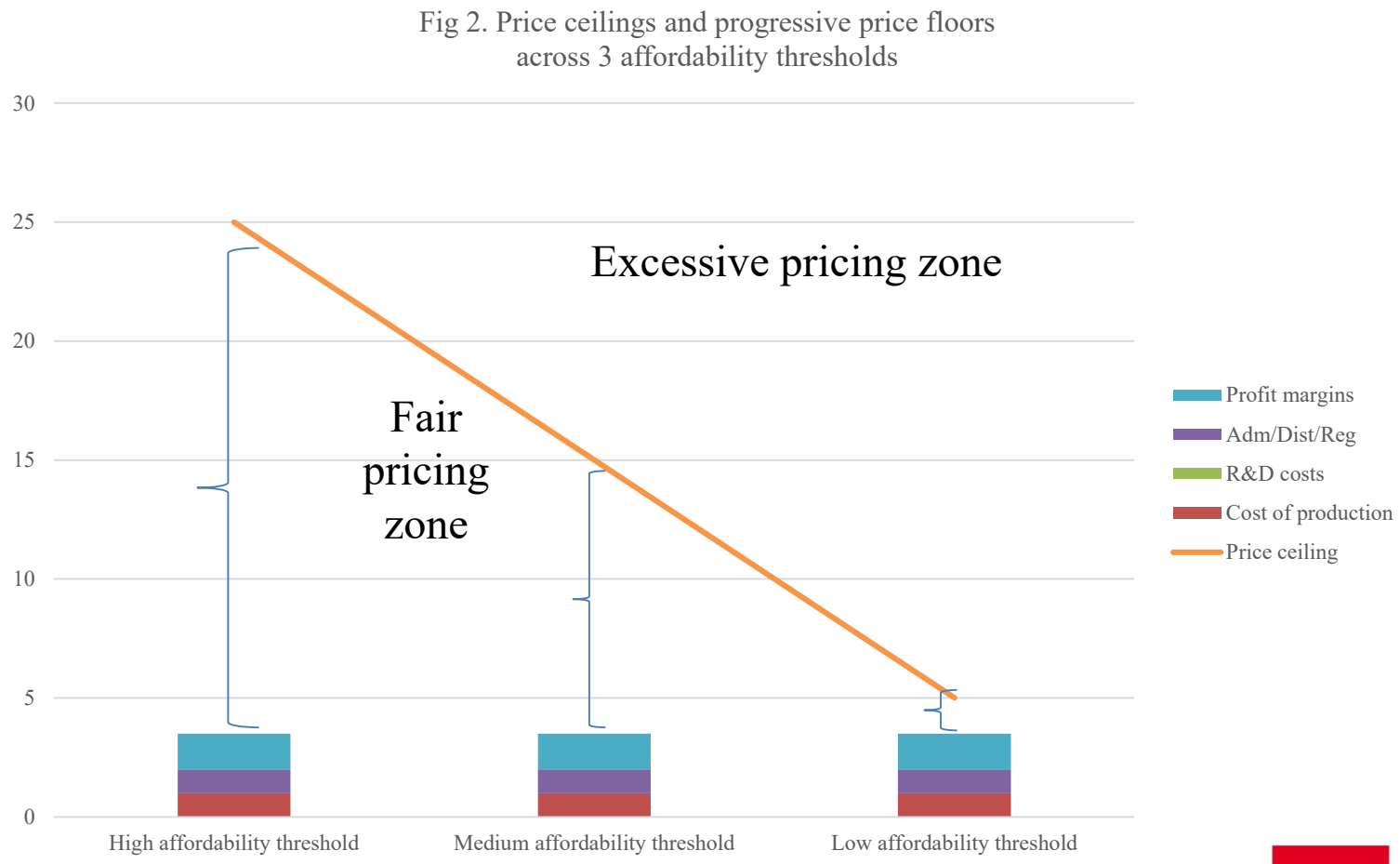
Fig 2. Price ceilings and progressive price floors across 3 affordability thresholds



Source: Moon et al. 2020. Defining the concept of fair pricing for medicines *BMJ*; 368 :l4726. https://www.bmj.com/content/368/bmj.l4726

A ZONE OF FAIR PRICING

GENERIC MEDICINE



Source: Moon et al. 2020. Defining the concept of fair pricing for medicines *BMJ*; 368 :l4726. https://www.bmj.com/content/368/bmj.l4726

ILLUSTRATATION

SOFOSBUVIR (HEPATITIS C)

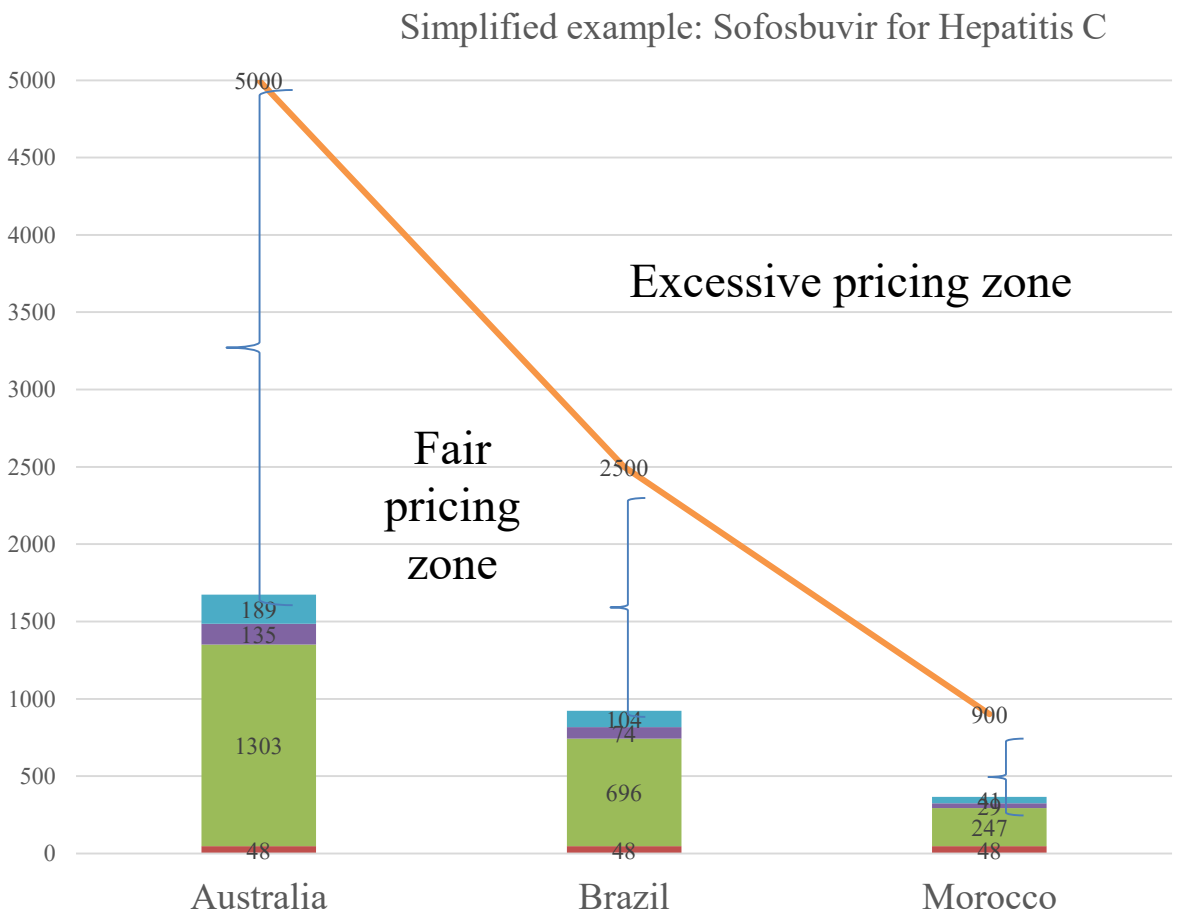
- R&D costs:
  - Pharmasset ($62 M) + Gilead ($880 M) = $943 M
- Gilead acquires Pharm
- Gilead outlay: $11,88
- Recouped over 10 yea
- Cost of production: $4
- Administration, distribu
- Profit: 14%

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
-Cost-plus formula
-International agreement

2 CONCLUSIONS

1. A clear idea of how to assess “fairness” in medicines pricing needed
   - → To assess prices objectively
   - → To achieve fairness in practice

2. More information transparency needed to assess fairness in reasonable, more objective manner

Thank you

Comments welcome: suerie.moon@graduateinstitute.ch

CASE STUDY: CYSTIC FIBROSIS DRUGS

- Cystic fibrosis: rare disease affecting lung function, mean life expectancy in 40s in UK
- US FDA approves Trikafta (Oct 2019)
- Development history:
  - 1989: Cystic Fibrosis (CF) gene mutation identified by publicly-funded research
  - 2000: non-profit Cystic Fibrosis Foundation grants Aurora Biosciences $47m for drug discovery
  - 2001: Vertex Pharmaceuticals acquires Aurora for $592m
    - 2013: ivacaftor (Kalydeco)
    - 2015: ivacaftor + lumacaftor (Orkambi)
    - 2018: ivacaftor + tezacaftor (Symdeko)
    - 2019: ivacaftor + tezacaftor + elexacaftor (Trikafta)
  - Trikafta: 3 years from synthesis to approval
  - 2 clinical trials: 24 & 4 weeks; total 510 patients
  - US FDA designated for Priority Review, Fast Track, Breakthrough Therapy, Orphan Drug credits, Priority Review Voucher

$311,000 (2019)

Sources: Keogh et al. (2018) J Cyst Fibros. 2018 Mar;17(2):218-227. doi: 10.1016/j.jcf.2017.11.019. Epub 2018 Jan 6.https://www.statnews.com/2019/10/23/we-conquered-a-disease-how-vertex-delivered-a-transformative-medicine-for-cystic-fibrosis/, https://www.fda.gov/news-events/press-announcements/fda-approves-new-breakthrough-therapy-cystic-fibrosis, https://www.businesswire.com/news/home/20191021005792/en/ADDING%C2%A0MULTIMEDIA-FDA-Approves-TRIKAFTA-elexacaftortezacaftorivacaftor-ivacaftor-Treat

CASE STUDY: CYSTIC FIBROSIS DRUGS

- Market:
  - 70,000-100,000 globally, mostly North America & Europe
  - From 6% to 90% cystic fibrosis patients now treatment eligible
  - Vertex:
    - 2019 Cystic fibrosis revenue: $3.7 billion
    - 2024: Cystic fibrosis revenue (projected): $8 billion
      - ~50,000 patients @ $160,000/year
  - Vertex monopoly on cystic fibrosis treatment for foreseeable future

$311,000 (2019)

Are these prices fair? excessive?

For which country?

What else do we need to know?

Sources: https://www.statnews.com/2019/10/23/we-conquered-a-disease-how-vertex-delivered-a-transformative-medicine-for-cystic-fibrosis/, https://www.fda.gov/news-events/press-announcements/fda-approves-new-breakthrough-therapy-cystic-fibrosis, https://www.businesswire.com/news/home/20191021005792/en/ADDING%C2%A0MULTIMEDIA-FDA-Approves-TRIKAFTA-elexacaftortezacaftorivacaftor-ivacaftor-Treat