

**R&D policy reform –
From TB to Covid-19:**

**Profit-driven models failing
public health emergencies**

Sharonann Lynch
MSF Access Campaign
TBEC Webinar
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1/ Checklist: Equitable biomedical R&D

1. **Needs-driven:** evidence-based, driven by public health needs and suitable for people and places that need them most
1. **Coordinated:** financial and technical resources are directed towards high priority gaps and needs and reduce duplication
2. **Open and collaborative:** sharing of research knowledge improves efficiency and accelerates progress. Compounds in the public domain
3. **Equitable:** public goods
 - free from IP restrictions/barriers
 - priced as close as possible costs of goods
 - Available through sufficient production capacity, including transfer of technology
4. **Transparent:**
 - Clinical trial protocols, and results
 - Agreements and licenses
 - R&D funding and costs
 - Costs of goods
 - Pricing and regulatory policies

2/ TB R&D: funding

Total TB R&D Funding by Funder Category, 2018

Total: \$906,125,319

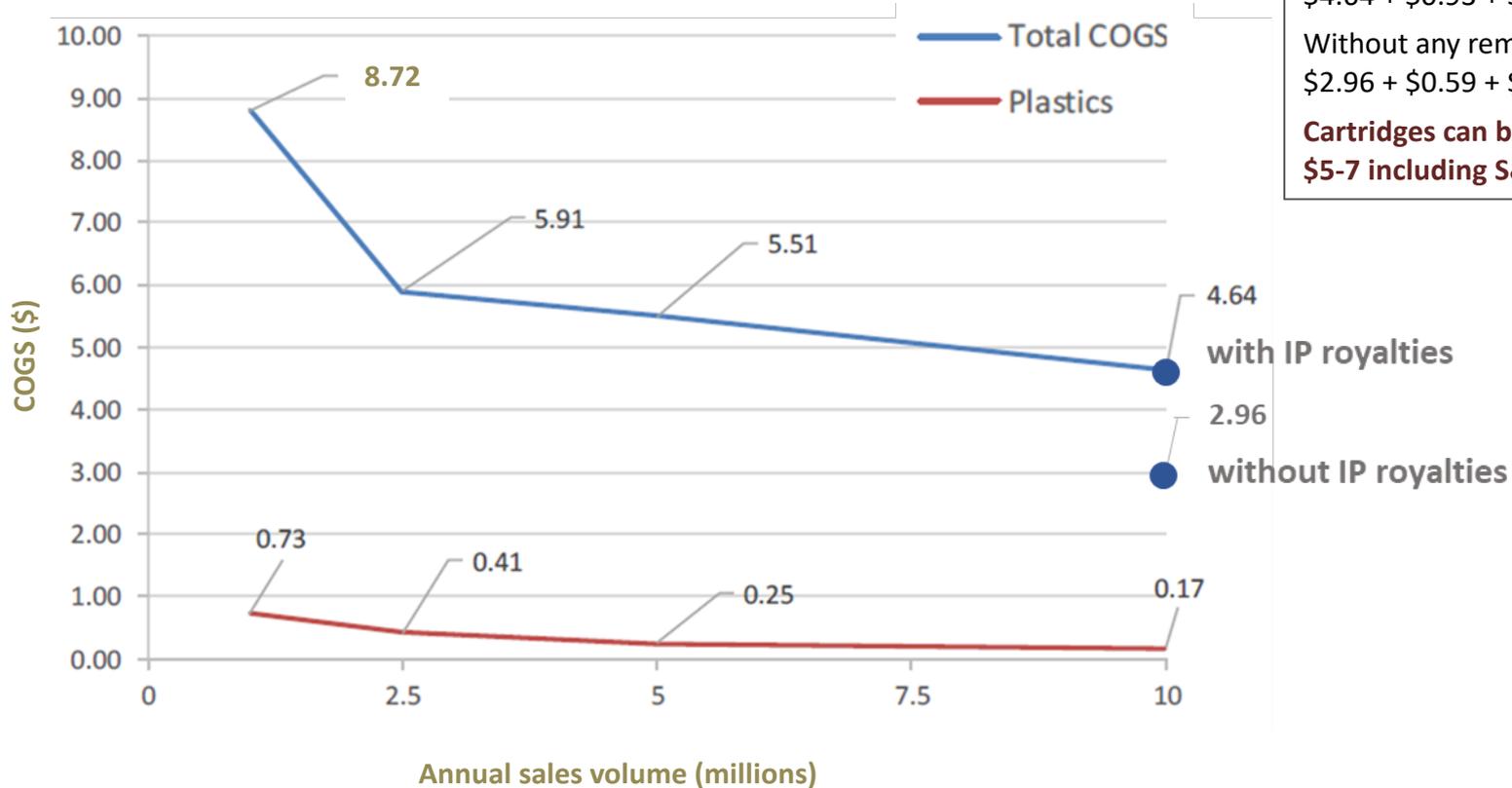


Source: TAG. Tuberculosis Research Funding Trends 2005 – 2018

3/ Case study Cepheid

- **1990s-2000s: Government funding for instrument development**
 - U.S. government \$165 million to develop the GeneXpert instrument
- **2012: Public + BMGF funding for TB tests (MTB/RIF cartridges)**
 - Unitaid, the Bill & Melinda Gates Foundation, and US government subsidy of \$11.1 million to “buy down” TB test price to \$9.98
 - Cepheid, 8 years and millions of tests later, refuse to reduce the price
- **2020: Public funding for Cepheid development of Covid-19 test**
 - U.S. government: \$3.7 million for Xpert SARS-CoV-2 test
- **Cepheid**
 - Pricing, shockingly, at \$19.80 each for LMICs
 - Supply: only 20% of its manufacturing capacity for LMICs

2018: Xpert MTB/RIF Ultra



COGS at 10 M/y + 20% profit + S&M

With remaining royalties:
 $\$4.64 + \$0.93 + \$1 = \6.57

Without any remaining royalties:
 $\$2.96 + \$0.59 + \$1 = \4.55

**Cartridges can be sold with profit at
 \$5-7 including S&M**

4/ TB case study: Bedaquiline

Total public funding for bedaquiline exceeded J&J by almost double to 5 times J&J's pricing

- 2014: \$900 LICs, \$3,000 MICs, \$30,000 HICs per 6 months
- 2020: \$272 per 6 months (\$1.50 a day) – MSF/others called for \$1 a day
- Pharmstandard for Russia and CIS countries+Georgia remains \$1,476 per 6 months

Access

- From 2015 to 2019, only 51,000 people, **11% of those who need it had access**

Patents

- Evergreening patents & secondary patents could extend until 2027 (not mid 2023)

5/ TB case study: Pretomanid

BPaL (bedaquiline, pretomanid, linezolid): first all-oral 6-month treatment for extensively drug-resistant TB (XDR-TB) or treatment-intolerant or non-responsive pulmonary MDR-TB under operational research conditions

Public and philanthropic total funding for pretomanid?

- TB Alliance is non-profit relying on public and philanthropic funding

TBA's pricing policies

- Pretomanid: \$364 for 6 months treatment; BPaL: \$905 for 6 months
- Estimates should be \$11-35 a month (TBA charges double-\$60 a month)
- Developed by TBA, manufactured by Mylan

Patents

- Patent on pretomanid expired in 2016 yet TBA filed for patents on the **BPaL formulation** in many countries

6/ Covid government funding

- Government funding for \$7-9 billion for R&D Covid-19 medical products
- Without life-saving conditions
 - **Affordability** – preferably a small margin over cost of manufacturing
 - **Transparency**
 - R&D funding, cost of manufacturing
 - Clinical trial protocols, details, and results
 - **Accessibility**
 - Manufacturing capacity or tech transfer to supply LMICs
 - Non-exclusive licenses to allow multiple manufacturers

7/ Corporate actions

- **Pfizer**
 - US\$1.95bn funding
 - 0 committed to LMICs to date
 - \$19.50 a dose
- **Moderna**
 - \$2.48 bn US + funding from CEPI
 - 100 mn doses for the US, 0 committed to LMICs to date
 - Est price \$50-60 a dose
- **Novavax**
 - CEPI: \$388m, US \$2.2b
 - 100mn doses US
 - Price – unknown LMICs (pot \$3?) but could be as high as \$32 for HIC like Japan
- **Serum Inst (tech transfer from AZ)**
 - BMGF \$150 mn (at risk for AZ & Novavax manufacture)
 - 1bn doses LMICS
 - Ceiling price \$3/dose
- **J&J**
 - US\$1bn funding;
 - 500 mn for LMICS
 - **\$10 a dose (which claim to be non-profit)**
- **AstraZeneca**
 - US\$1.2bn US funding, \$750 mil Gavi/CEPI funding
 - LMICs commitments (300 mil doses)
 - Price of \$2-\$4 per dose

Thank you

Governments must take 5 steps to transform good intentions into tangible accessible health tools to fight Covid-19

1. Ensure researchers, public health experts, civil society, and political leaders from **LMICs have a seat at the decision-making table**
2. Commit to **open sharing** of research knowledge and data and compound--put in the public domain.
3. Guarantee that health tools are **free of intellectual property restrictions**, which can obstruct research and large-scale production of affordable health technologies.
4. Ensure sufficient production through technology transfer, equitable allocation, and affordable pricing (close as possible to cost of production)
5. Require **full transparency** of the public investments in R&D