Two ideas regarding Innovation and Access

James Love, CPTech

CIPIH Workshop

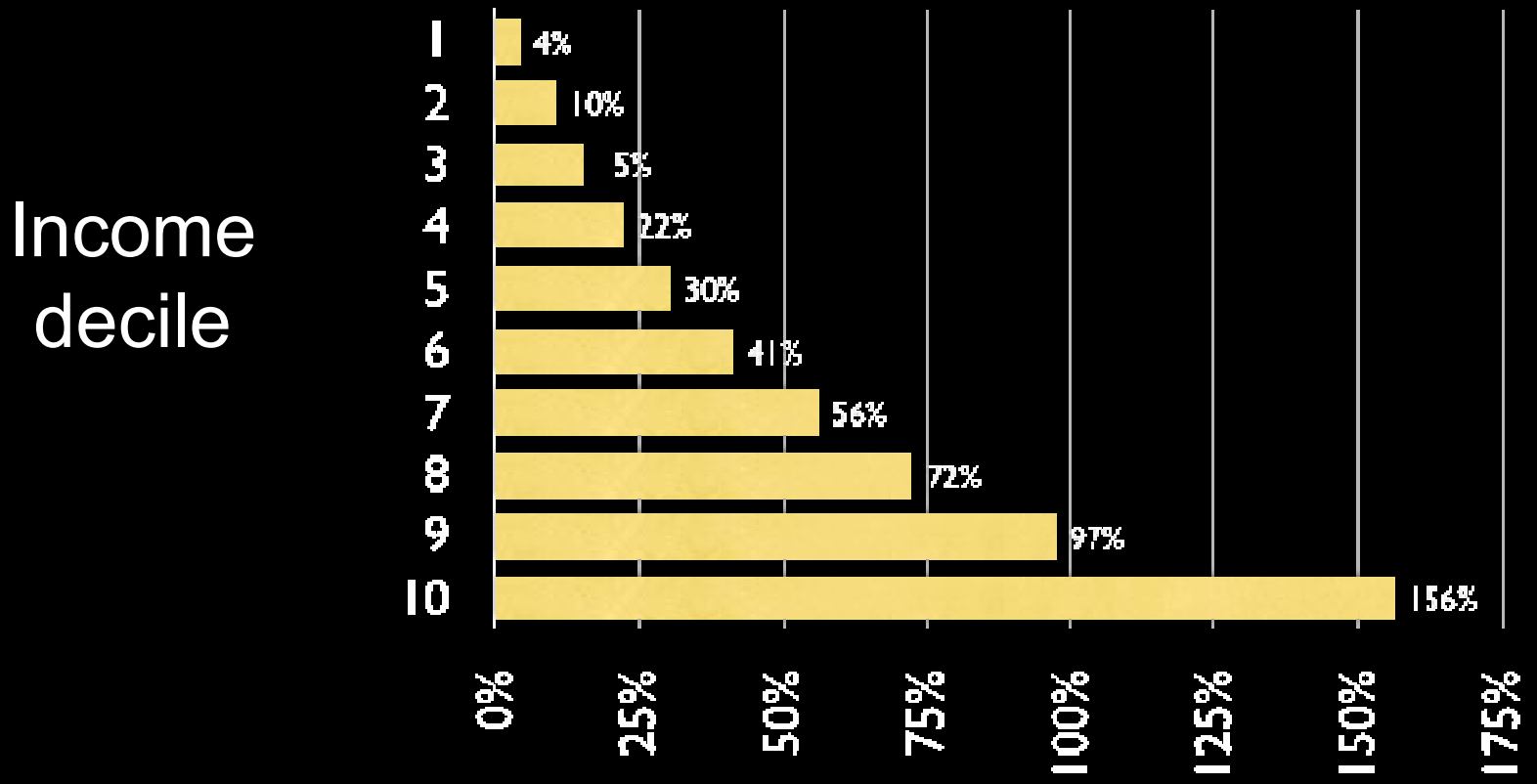
Geneva

1 June 05

1. Separate market for innovation from market for product

Consequences of exclusive marketing rights to finance R&D on Access

Price of Singulair as a share of per capita income in South Africa



Novartis at the World Bank in 2004

- We consider India to be a market of 50 million

US: Cancer Weapons, Out of Reach

Robert Wittes, June 15, 2004, Washington Post

- Third-party payers will not react passively to pricing that increasingly threatens their balance sheets, especially as more drugs like these are commercialized over the next few years. They will carefully scrutinize all proposed uses of expensive new drugs. Historically, an FDA judgment of "safe and effective" -- the statutory criterion for drug approval -- has almost automatically triggered an agreement by payers to reimburse, which is the real gateway to widespread use and market success. We may now see payers deciding, for the first time, that certain novel "safe and effective" medicines are simply not worth paying for. In addition, payers will surely try to limit "off-label" uses of these drugs -- that is, uses other than the FDA-approved ones. Unlike other areas of medicine, physicians have commonly prescribed cancer drugs for a broader array of indications than specifically approved by the FDA, as clinical research routinely reveals additional uses after market introduction. A very high bar to new uses by payers is a virtual certainty.

US FDA Priority and Standard NME Approvals

Calendar Years 1993-2002

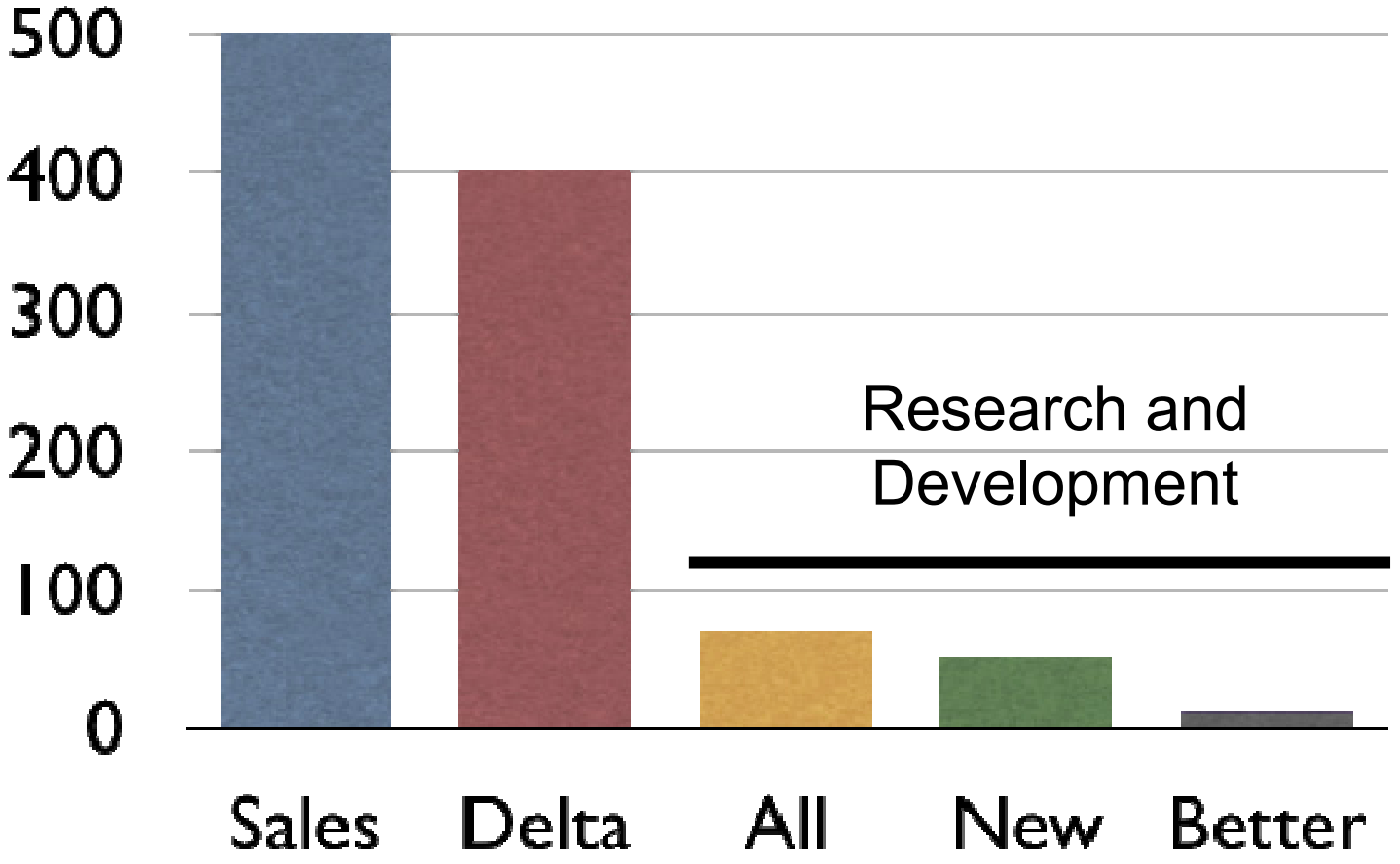
Year	Priority	Standard
1993	13	12
1994	13	9
1995	9	19
1996	18	35
1997	9	30
1998	16	14
1999	19	16
2000	9	18
2001	7	17
2002	7	10
Total	79	180
Percent	31%	69%

Number of patients in clinical trials cited in US FDA approval letters for NCEs 2000 - 2002

	Priority	Standard	All
Average	1,461	2,667	2,253
Median	905	2,238	1,428
Standard Deviation	1,826	2,108	2,083
Coefficient of Variation	1.25	.79	.92

Economics of current pull system

The patent system raises prices and investments in R&D, but it is a costly way to finance R&D, particularly for products that are new and better than existing products



HR 417, the Medical Innovation Prize Fund Approach

1. Patent system intact through product development and market approval

2. No market exclusivity, generic companies can freely compete

3. Medical Innovation Prize Fund provides financial rewards to developers of new products

The Prizes

1. The US MIPF proposes a fund of .5 percent (50 basis points) of US GDP.
   - $60 billion
   - About 5 times the current royalties on patents
   - The sponsors of the legislation are open to consideration of a higher contribution rate.

2. Payments to innovators over 10 year period are based upon incremental health care benefits

3. Organizations that develop new drugs compete against each other, on the basis of the incremental health care benefits their products deliver

Some of the fund is allocated to priority projects

- Global neglected diseases
  - 2 basis points - $2.4 billion
- Orphan drugs
  - 5 basis points - $6 billion
- Research on AIDS, including AIDS vaccines, global infectious diseases, and medicines to treat bio-terrorism
  - 2 basis points - $2.4 billion

MIPF/HR 417 vs. APC

- The MIPF/HR 417 and APC are different versions of a prize fund approach
  - MIPF/HR 417 is compulsory, APC is voluntary,
  - MIPF/HR 417 provides rewards for any new medicine that provides benefits, with set asides for certain broad groups of priority projects
  - The APC proposals are more narrowly focused in particular treatments (i.e. vaccine for malaria, etc)
  - Both approaches reward successful projects that people use
    - The MIPF/HR 417 only rewards products that actually provide benefits
    - The APC only rewards products that are purchased

2. R&D Treaty

Basic obligations

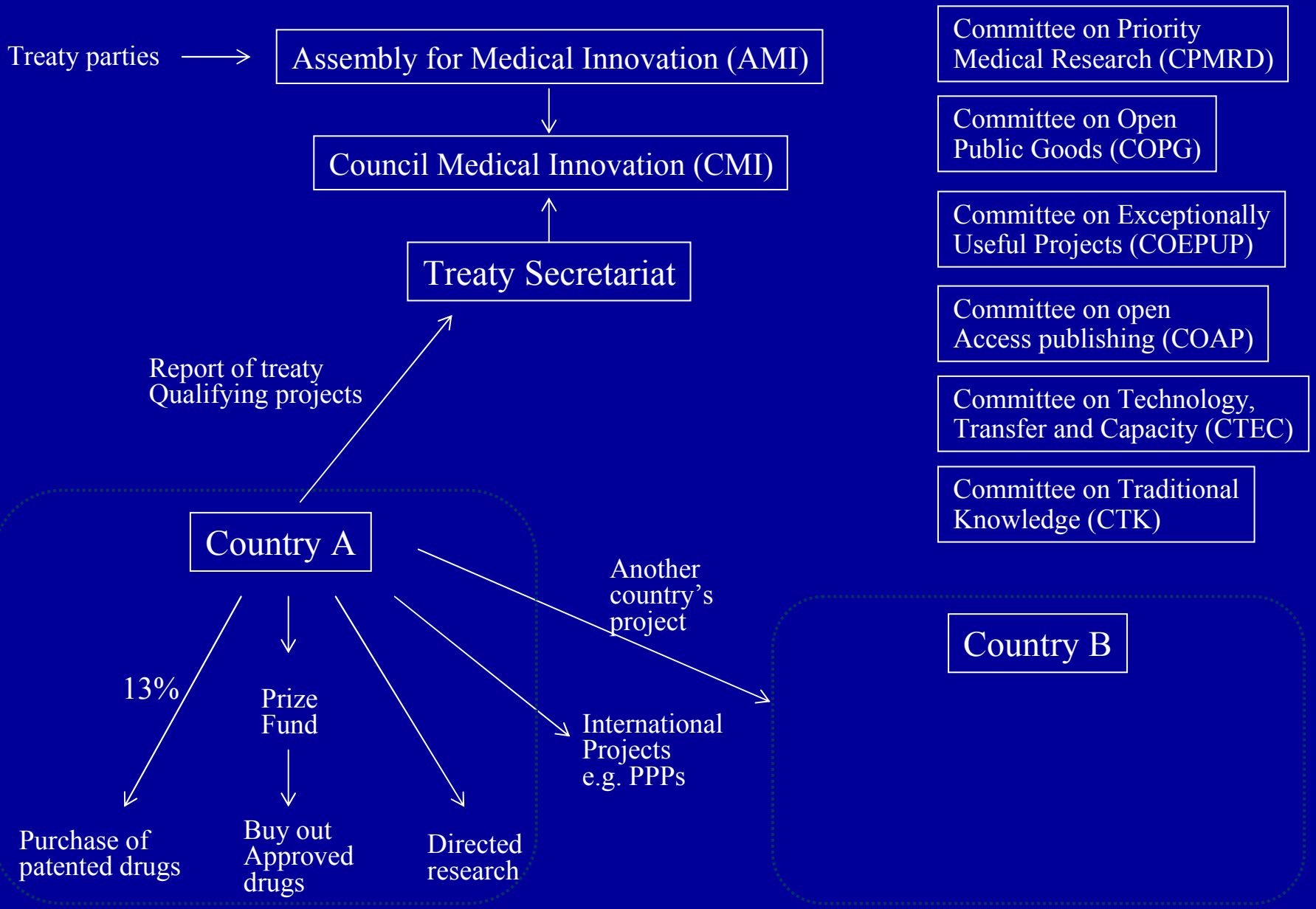
1. Every country is required to support medical R&D
2. The obligation would be a fraction of GDP
3. The fraction would depend upon the level of development
4. Countries would have flexibility in terms of how the R&D was financed and managed
5. Purchases of patented medicines, public sector research, prize funds, etc, would be allowed, to the degree that they stimulate R&D

Investments in some certain projects that are important earn credits. These credits are tradable between countries

- Priority research/neglected diseases
- Open research
- Exceptionally useful projects
- Preservation and dissemination of traditional medical knowledge
- Technology transfer, capacity building

(Subject to some caps)

Treaty mechanisms overview



- Committee on Priority Medical Research (CPMRD)
- Committee on Open Public Goods (COPG)
- Committee on Exceptionally Useful Projects (COEPUP)
- Committee on open Access publishing (COAP)
- Committee on Technology, Transfer and Capacity (CTEC)
- Committee on Traditional Knowledge (CTK)

For more information

CPTech

http://www.cptech.org

james.love@cptech.org