

Health Economics of Hepatitis C

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EUROPEAN HIV HEPATITIS CO-INFECTION (EHHC)
CONFERENCE



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COMPETING INTEREST OF FINANCIAL VALUE \geq £1,000:	
Speaker Name	Statement
Andrew Hill	Andrew Hill has received consultancy payments from Gilead, ViiV, BMS, Janssen and Cipla, not connected with this project. He has also received project funding from the World Health Organization, UNAID, the Clinton Health Access Initiative (CHAI) and the St Stephens AIDS Trust (SSAT)
Date	26 th November 2015



A photograph of a group of people, likely a family, in a small boat on a body of water. The scene is captured at sunset or sunrise, with the water reflecting the golden light of the low sun, creating a shimmering effect. The people are silhouetted against the bright background. One person on the right is holding a long pole or oar. The overall mood is serene and contemplative.

**Africa, 1999: mass treatment
for HIV/AIDS is not feasible**

A key moment in the history of HIV

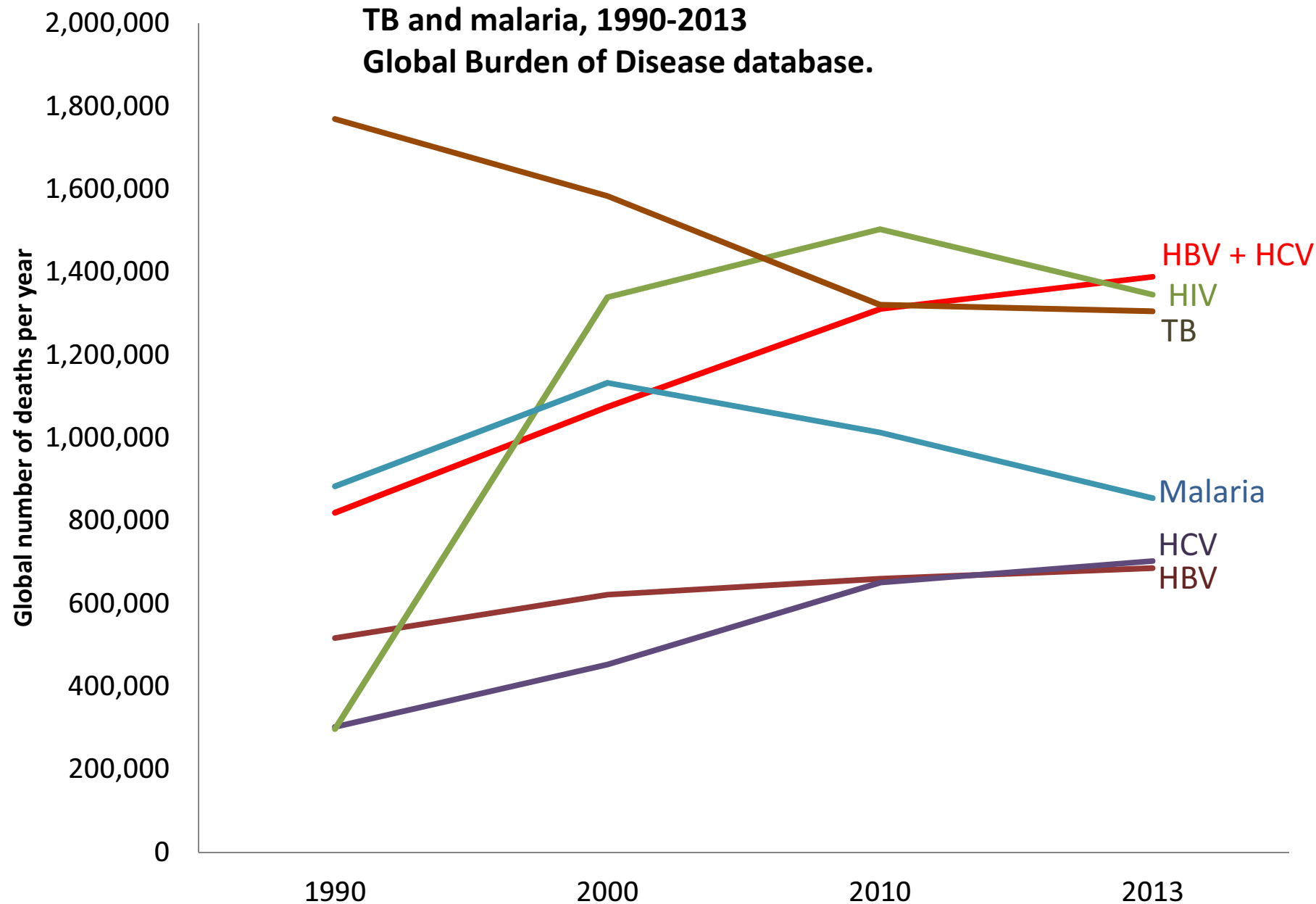
“My generics company
can manufacture
HIV antiretrovirals for
a dollar per day”

Dr Yussef Hamied
Cipla,
G8 summit,
2000



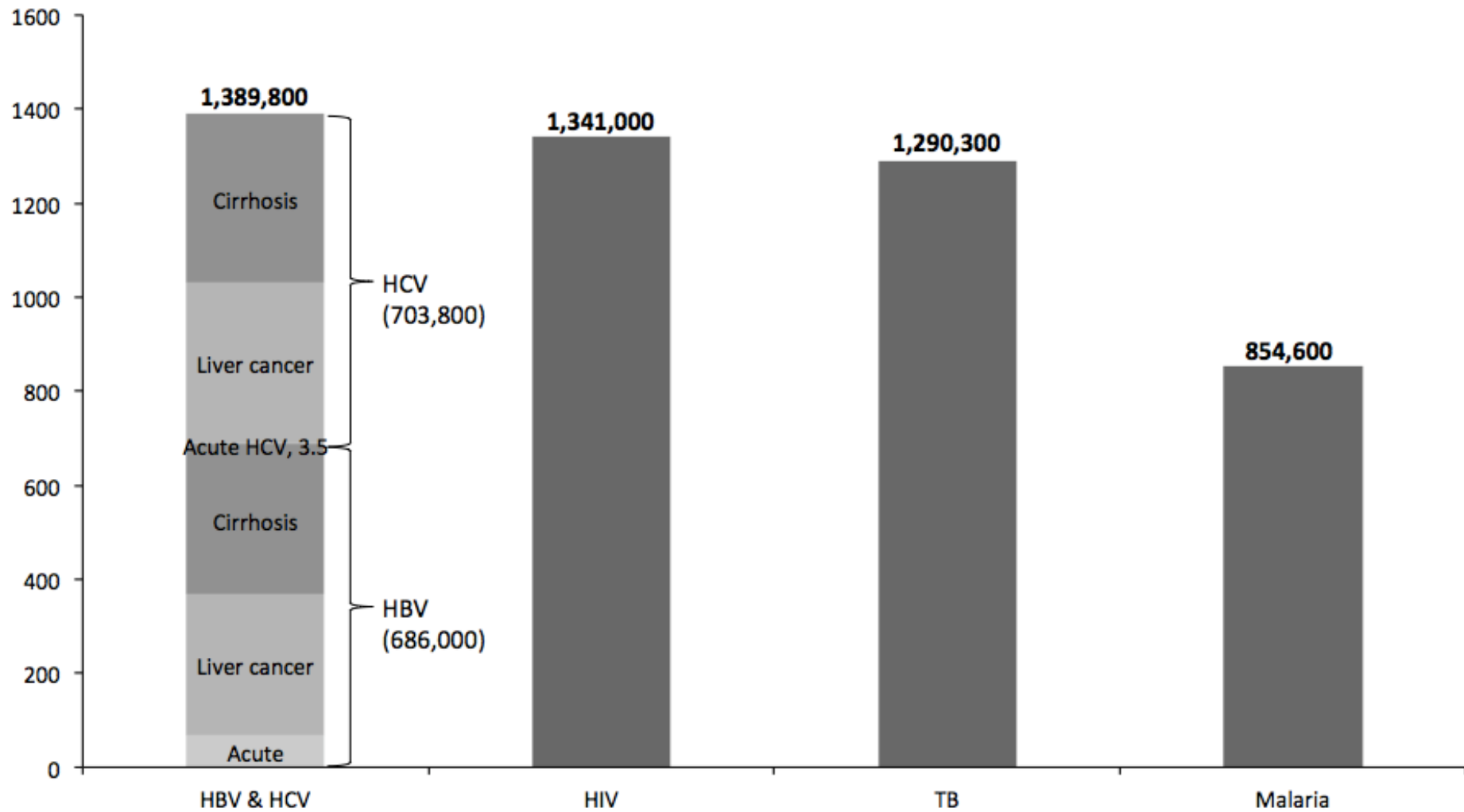
**Could we eliminate
Hepatitis C worldwide
by producing
treatments cheaply?**

**Total deaths worldwide from HIV, Viral Hepatitis,
TB and malaria, 1990-2013**
Global Burden of Disease database.

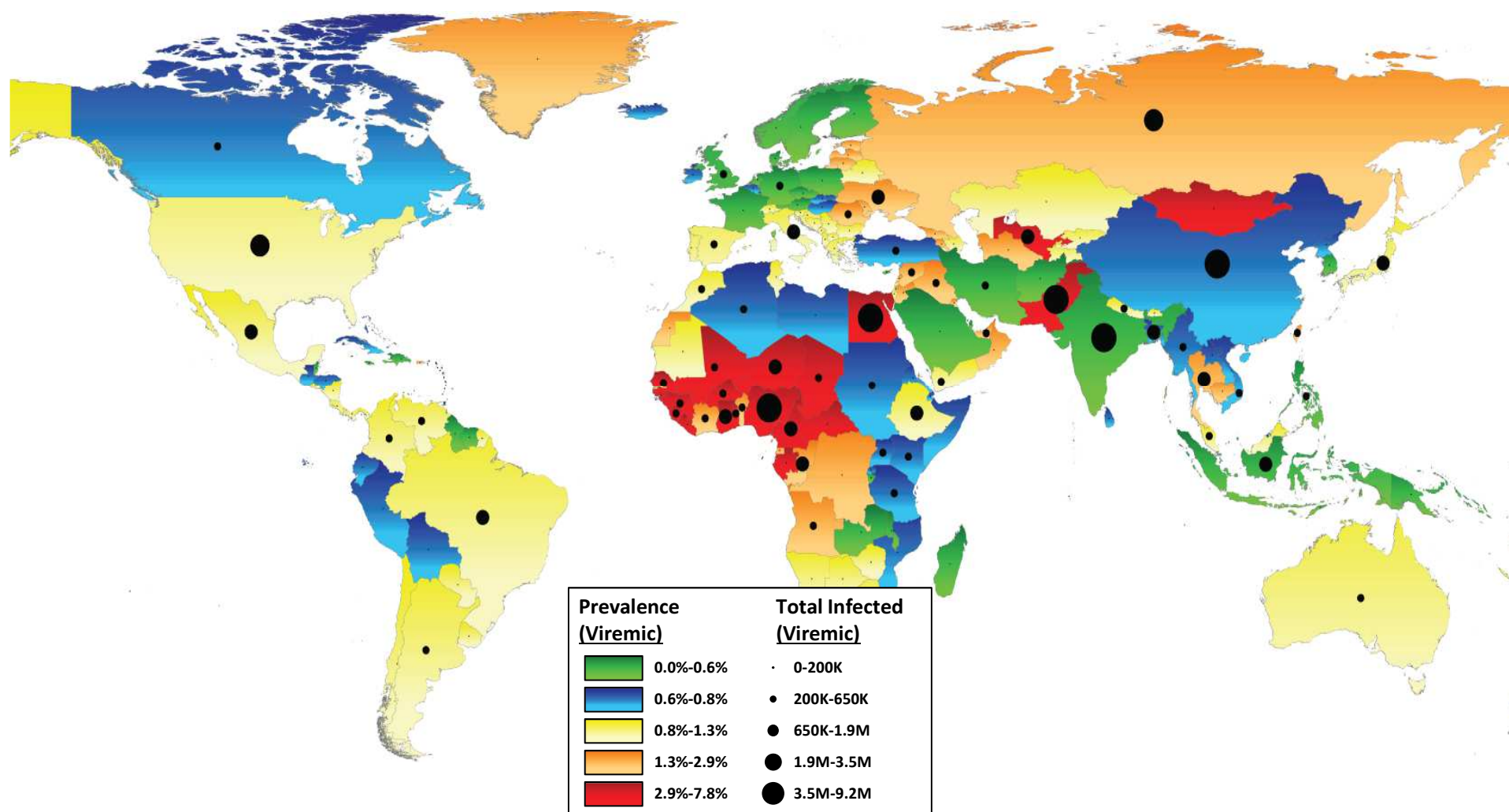


Source: <http://ghdx.healthdata.org/global-burden-disease-study-2013-gbd-2013-data-downloads>

Worldwide deaths from HCV, HBV, HIV, tuberculosis, and malaria in 2013



Global chronic HCV prevalence



HCV genotypes 1-6 worldwide

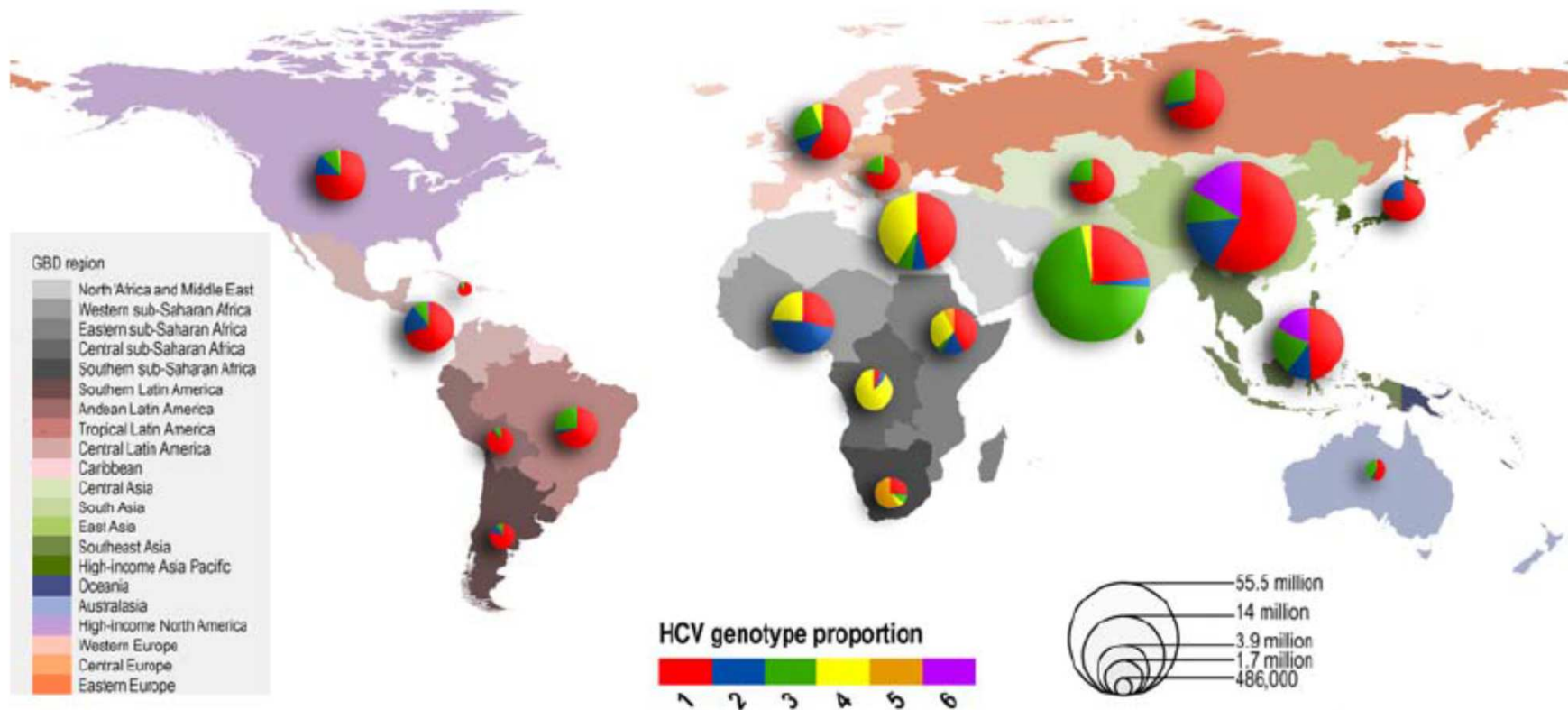
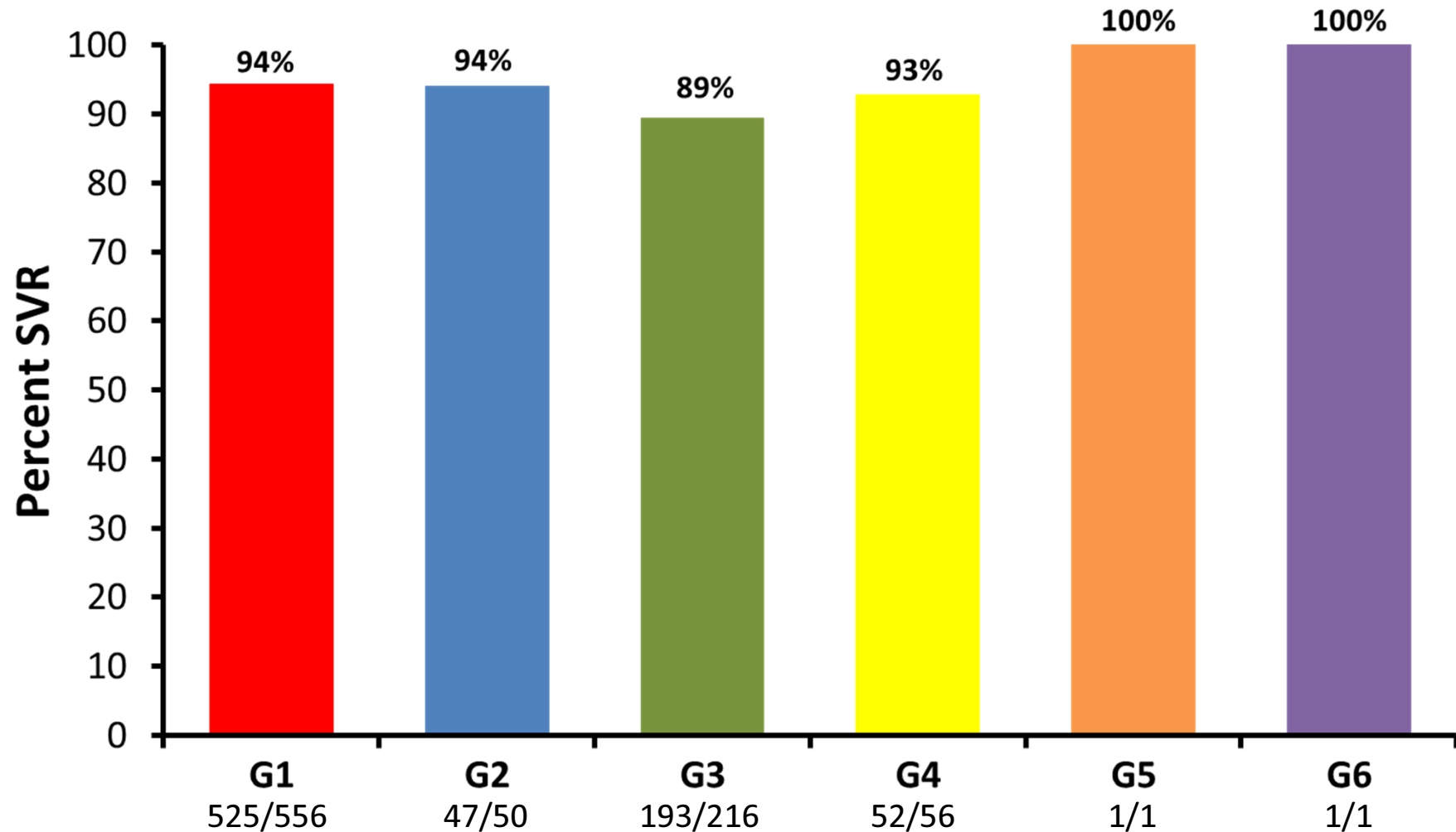


Fig. 1. Relative prevalence of each HCV genotype by GBD region. Size of pie charts is proportional to the number of seroprevalent cas

Sofosbuvir + Daclatasvir \pm RBV (12-24 wks)

Percentage of people cured, by Genotype



Sources: A1444040 trial; ALLY-1; ALLY-2; ALLY-3; 3 French EAPs

Estimating minimum costs of treatment from current export data

Tracking import-export databases to find costs of API (Active Pharmaceutical Ingredient – drug substance before formulation and packaging).

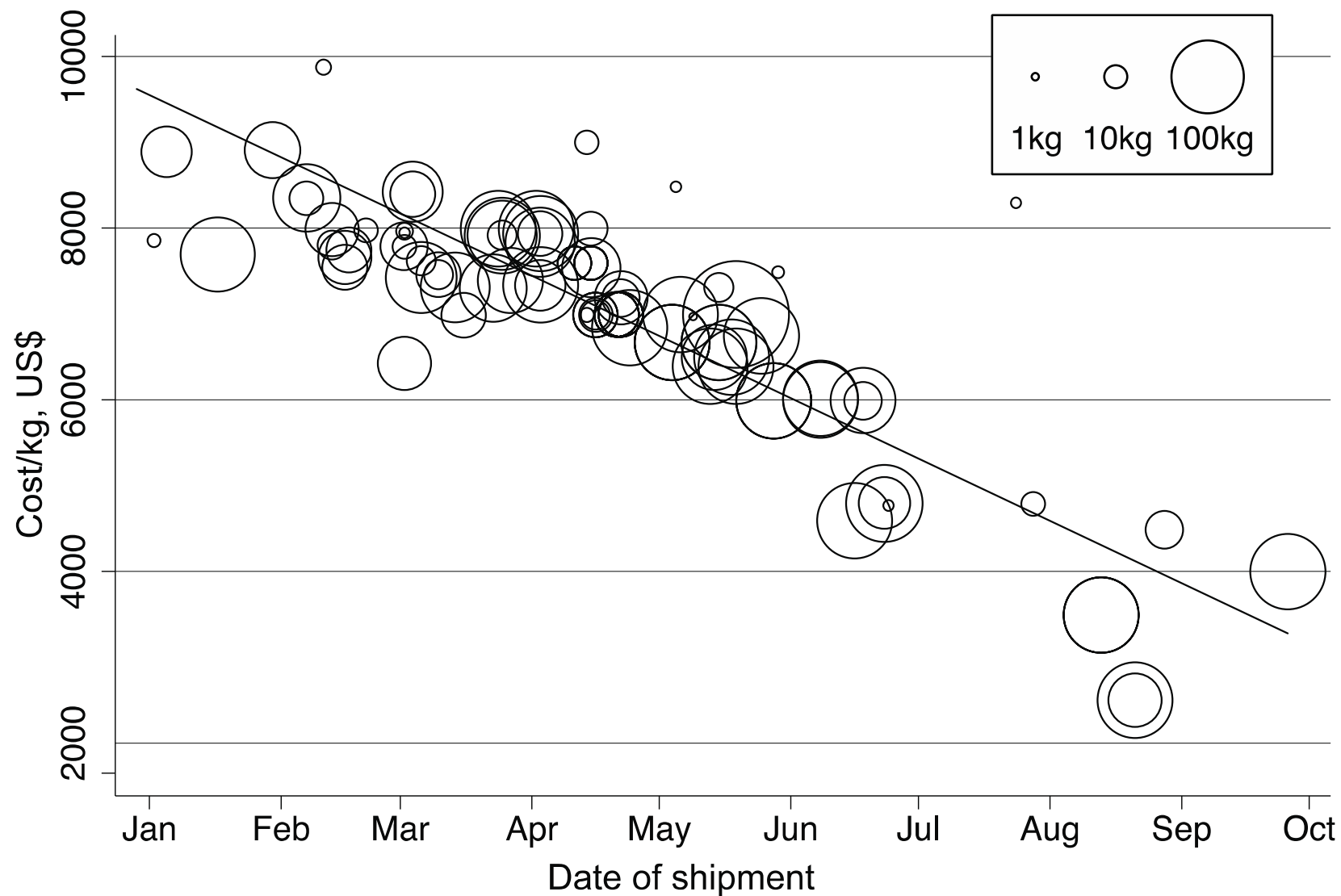
www.indiainfodrive.com

Then add costs of final formulation and profit margin using established methods.

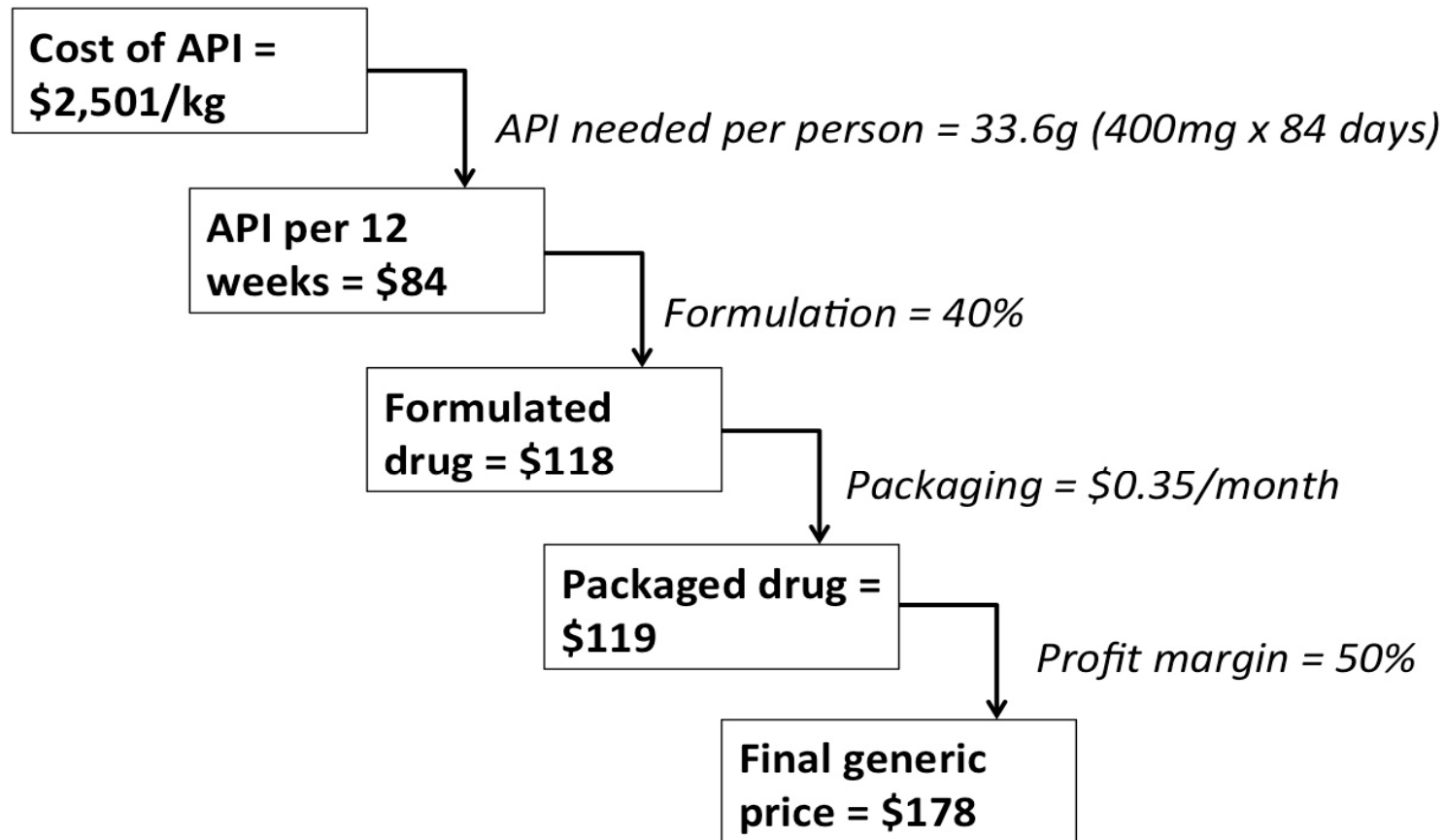
Collaboration with experts in chemical synthesis and mass production of medicines to evaluate prices. Cross-checks using different methods.

Surveys of costs of drugs by country

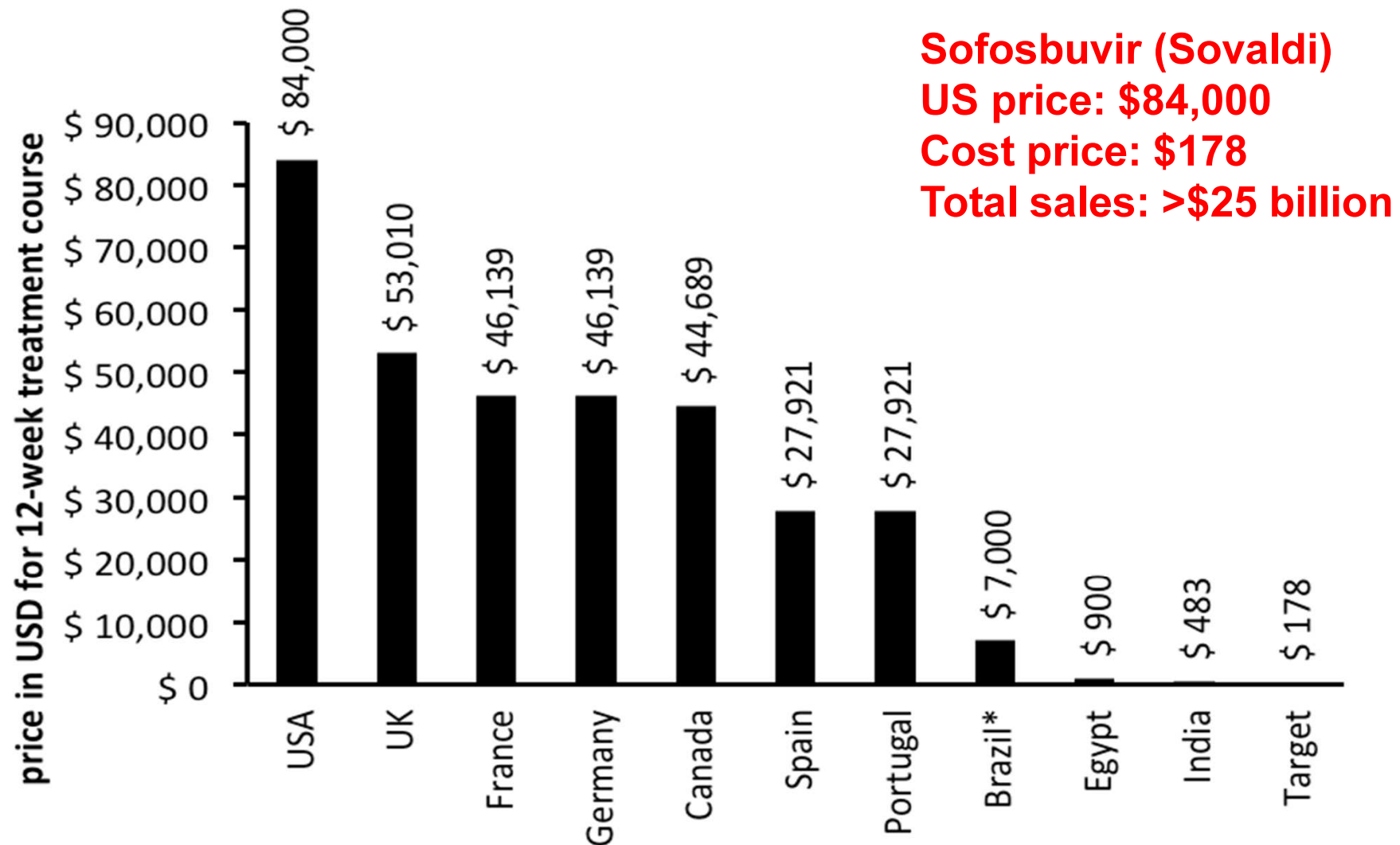
Sofosbuvir API exported from India in 2015, weighted by size of shipment



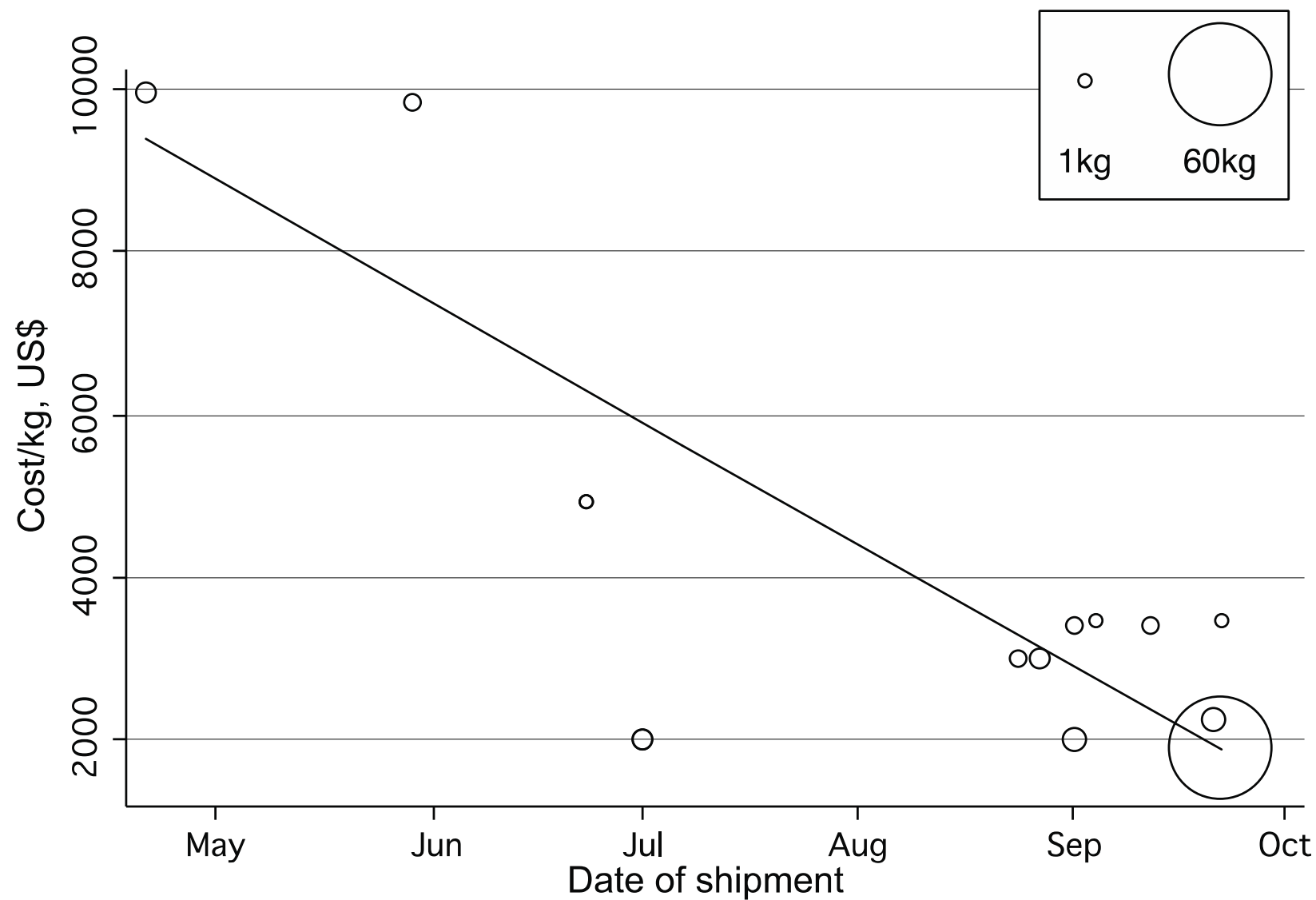
Current Costs of production - sofosbuvir



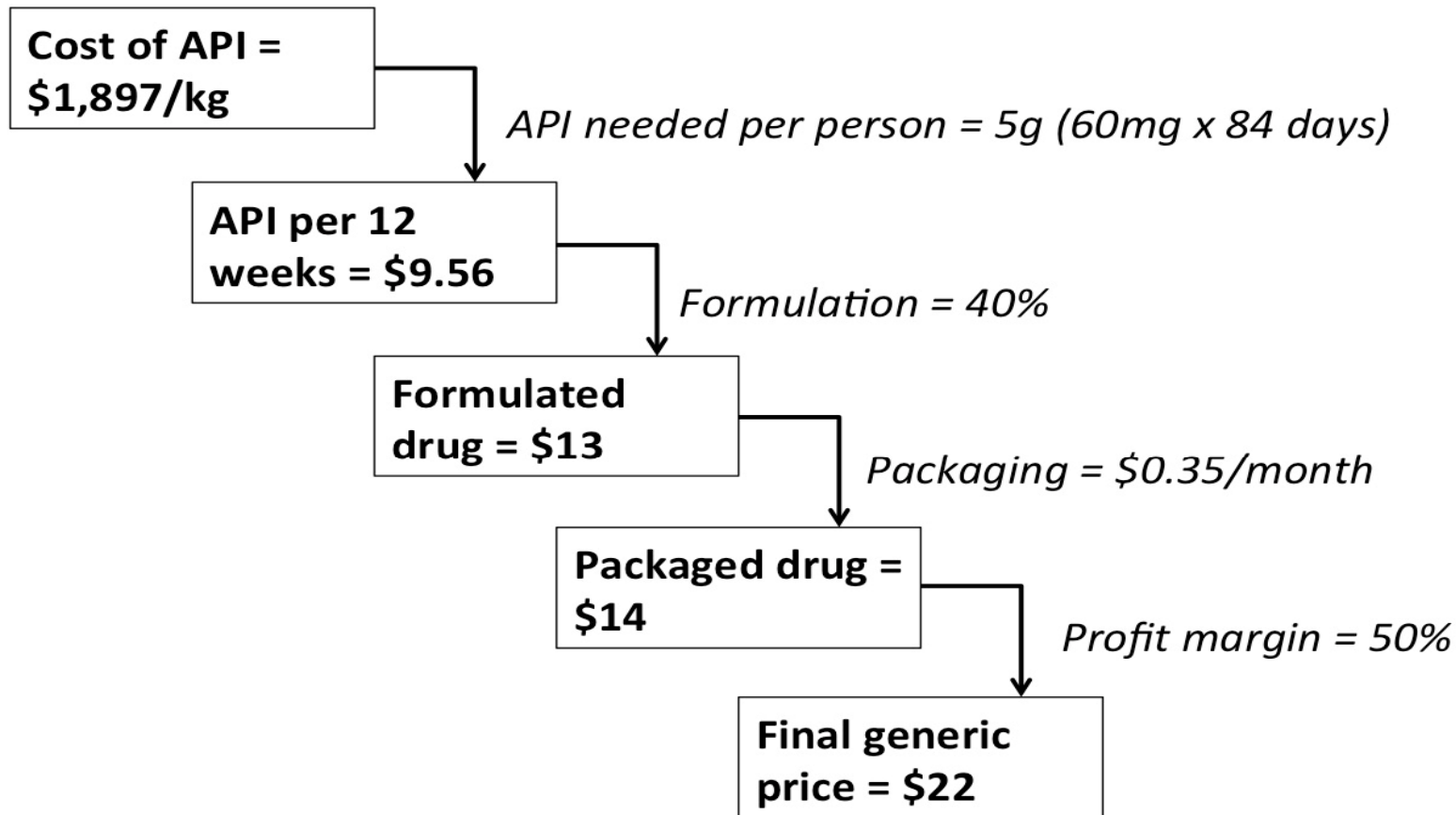
Price of sofosbuvir by country (US dollars per 12 week course)



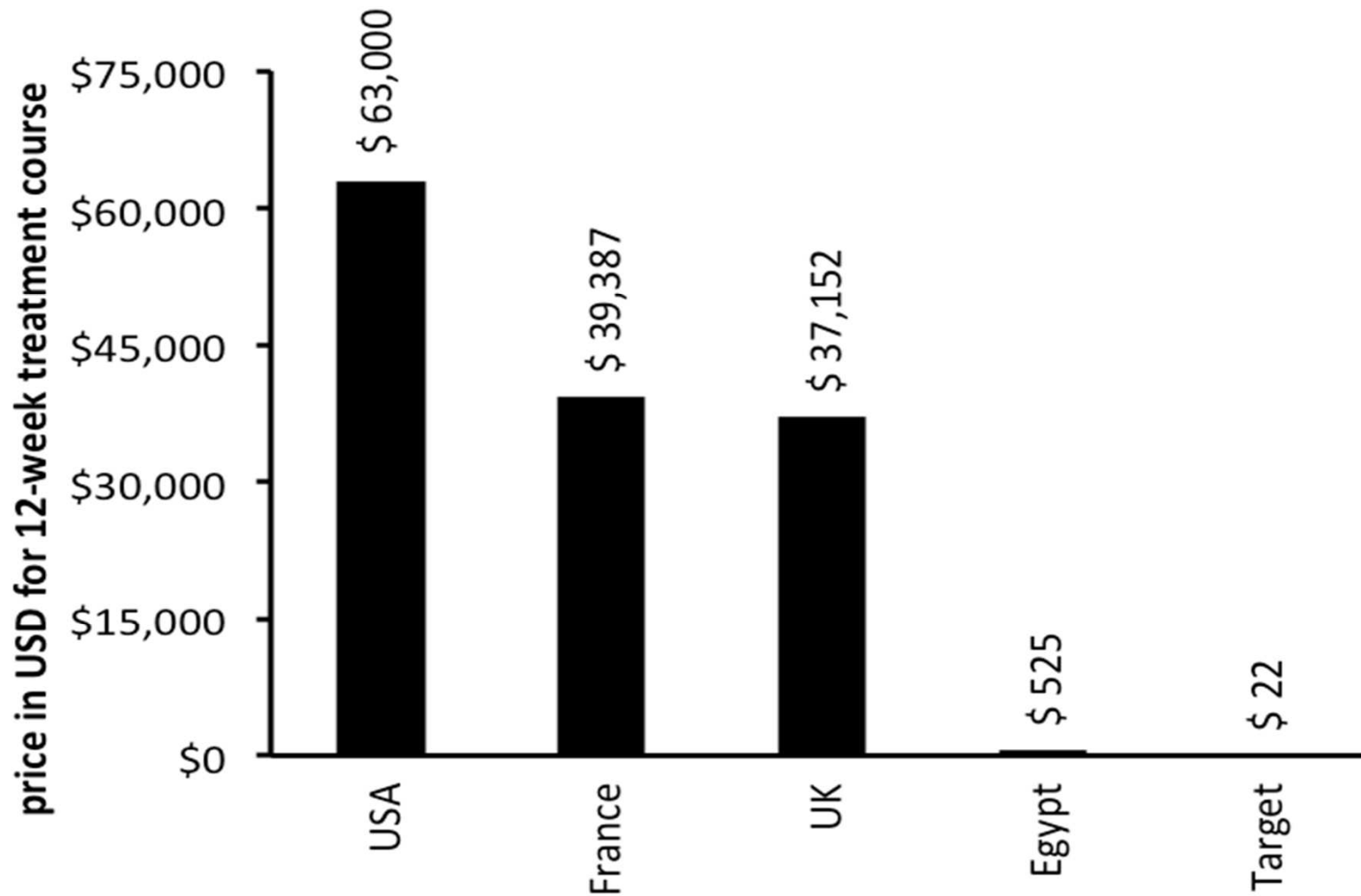
Daclatasvir API exported from India in 2015, weighted by size of shipment



Current Costs of production - daclatasvir



Price of daclatasvir by country (US dollars per 12 week course)



5g of diamonds

25 1-carat (\$1900 each)

Cost = \$48,000



5g of daclatasvir

12 weeks of treatment, 60mg/day

Cost = \$63,000 (US price)



Health Economics

1. Cost-effectiveness

2. Budget Impact

Cost-effectiveness models for HCV DAAs – are they reliable?

1. Treating HCV is not cost-effective over 5 years – shown in several models – only cost-effective over a lifetime
2. However in a lifetime, treatments will become generic and much cheaper.
3. Even in the short-term, treatment costs are falling rapidly.
4. So why pay high prices now, when costs could be 50-80% lower in 1-2 years?
5. In the USA, cost of DAAs per course fell 50% when AbbVie negotiated with Express Scripts

Sofosbuvir is not cost-effective for some Genotype 2 and 3 patients in USA

“At their current cost, sofosbuvir-based regimens for treatment naïve non-cirrhotic patients exceed willingness to pay thresholds in USA”

Linass et al. Ann Intern Med
2015, 162: 619-629

“Budget impact” of treating Hepatitis C in USA (assume 3.4 million infected)

**Unit cost of a cure = \$50,000 per person (discounted)
Cost = \$170 billion, not including medical care,
diagnostics**

**Units cost of a cure = \$200 per person (minimum)
Cost = \$680 million, not including medical care,
diagnostics**

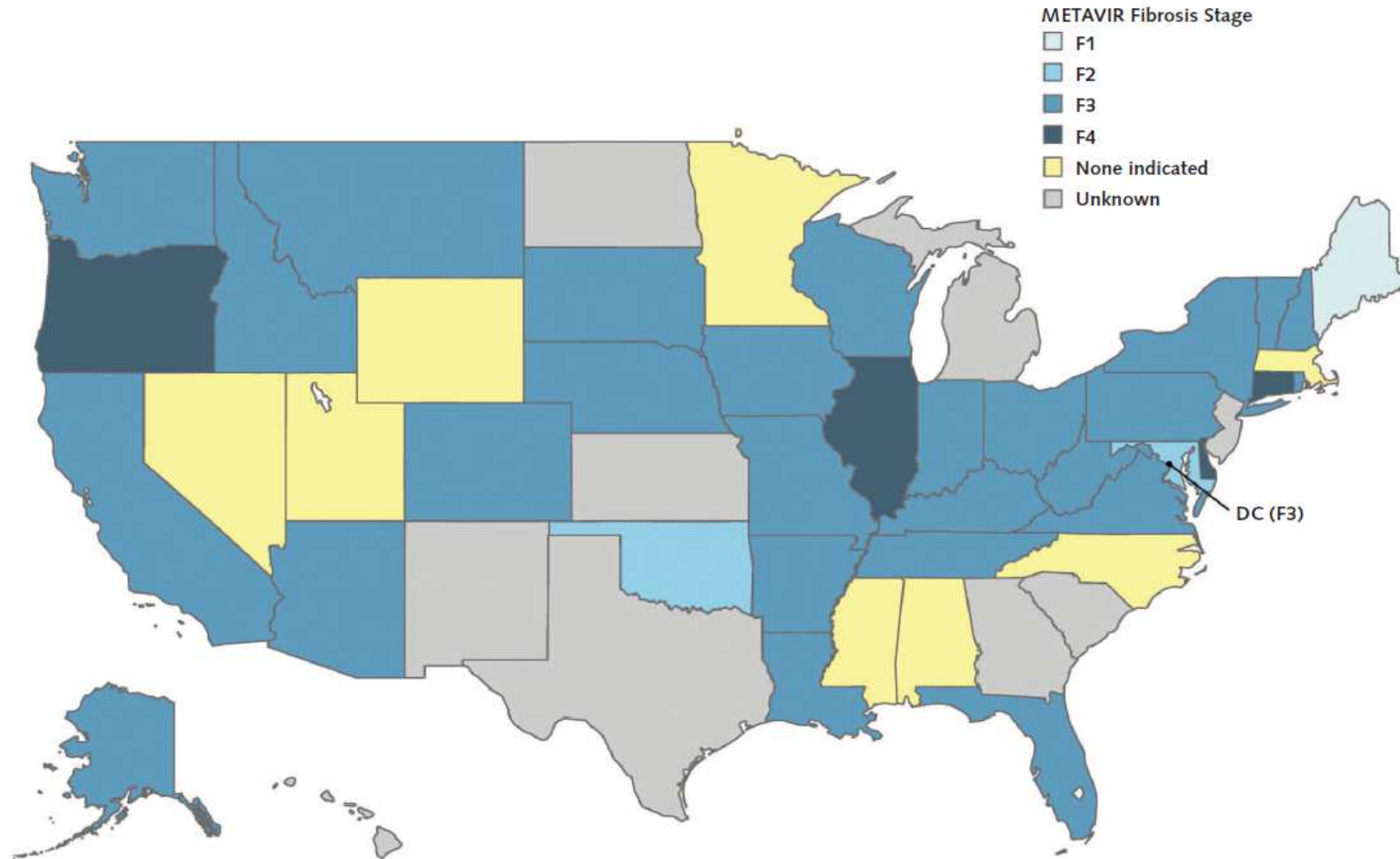
“Budget impact” of treating Hepatitis C in USA – not cost-saving

“Compared with the Standard of Care, treating eligible HCV-infected people in the USA with new DAAs would cost an additional \$65 billion in the next 5 years, whereas the resulting cost offsets would be \$16 billion”

**What happens when
drugs are too
expensive?**

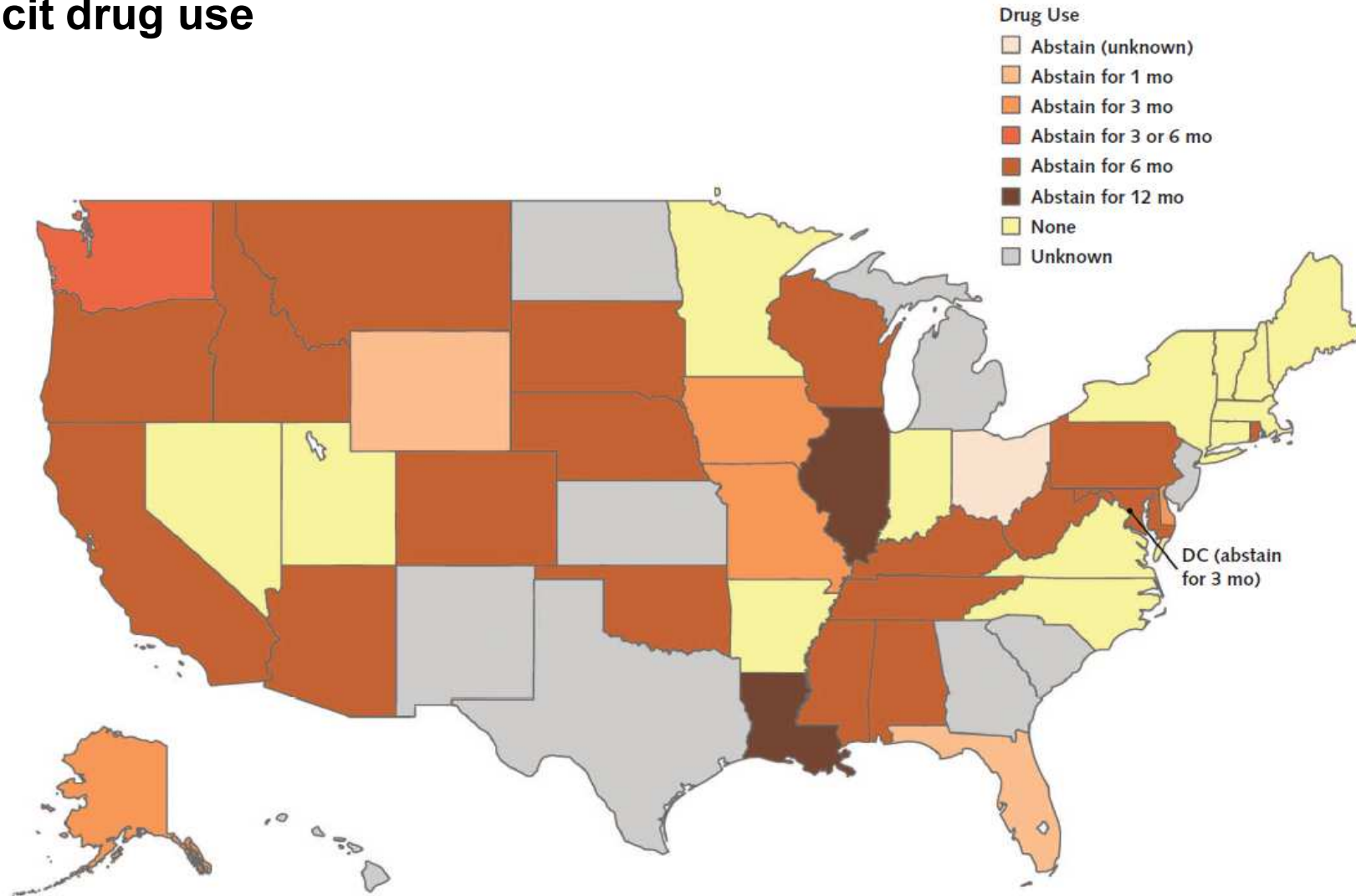
Sofosbuvir Medicaid restrictions in US

Liver disease stage

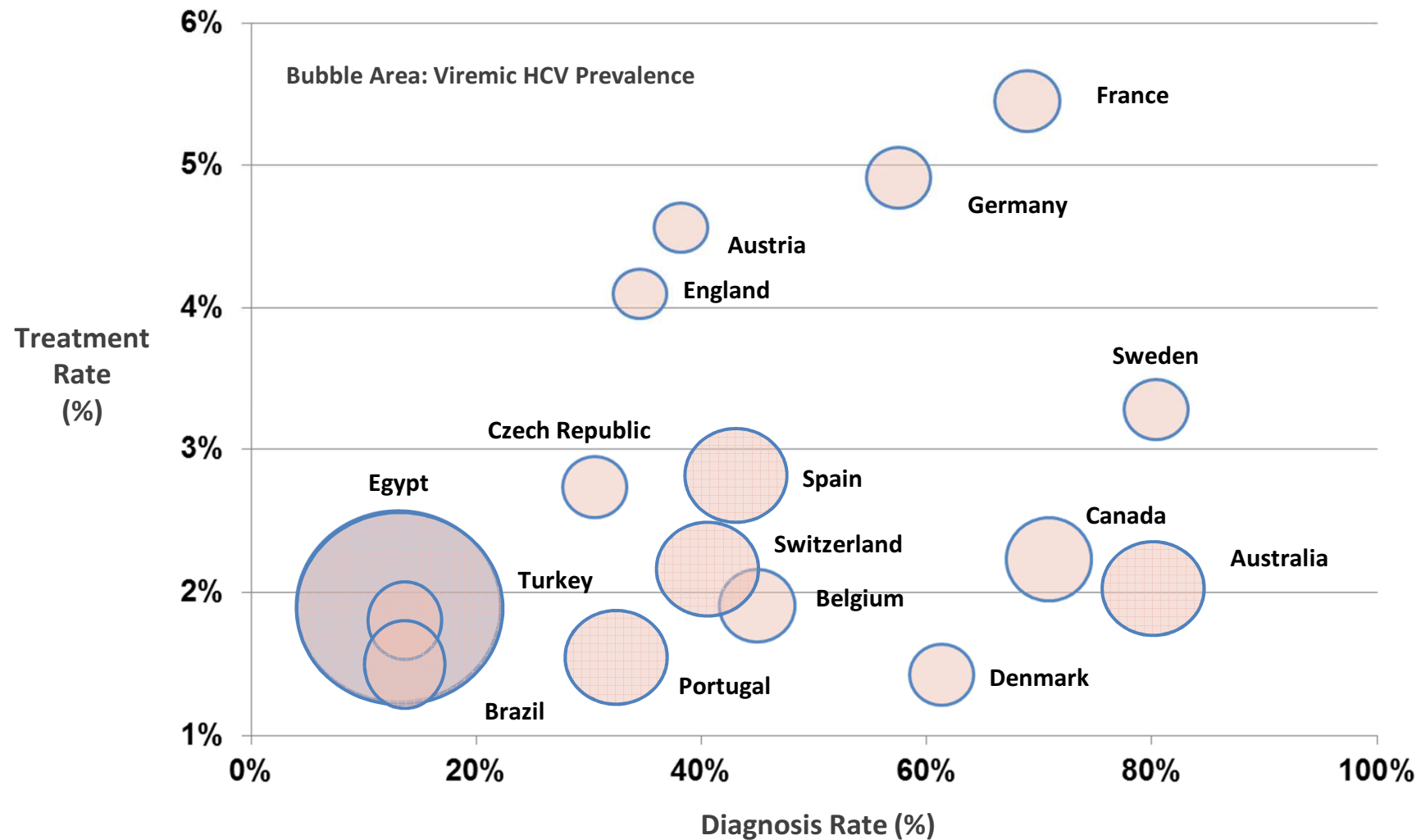


Sofosbuvir Medicaid restrictions in US

Illicit drug use



HCV diagnosis and treatment uptake - worldwide



What about funding R&D from the pharmaceutical industry?

Gilead has already sold over \$25 billion of sofosbuvir and ledipasvir. No sign of sales slowing.

How many billions of dollars in sales will be enough to “repay” the \$11 billion of investment? When can countries access these drugs cheaply?

Gilead made \$12 billion in profits in 2014.

Pharmaceutical companies spend more money on marketing and advertising than research and development.

The pharmaceutical industry has higher profit margins than oil, gas, media, banking or automobiles.

Many pharmaceutical companies use offshore schemes to avoid taxation.

**What can be done, if
medicines are not
locally available?**

Buyers clubs in 2015

High quality generic drugs accessed in low-income countries: India, Bangladesh, Egypt, Thailand.

UK and Australian law allows the legal import of up to 3 months supply of any medicine, provided this is for personal use and supported by a doctors prescription.

Over 1000 people in Australia have been cured of Hepatitis C in this way, plus a few people in UK, USA and other countries.

HIV drugs for pre-exposure prophylaxis are being imported legally into the UK in 2015

Websites: www.fixhepc.com
www.iwantprepnnow.com

Patient
Address
Ref by Dr James A Freeman

DOB
Age
Lab 617647598

Requested 27/02/2015
Collected 04/08/2015 11:40 hrs
Printed 07/08/2015 08:02 hrs

Lab Brisbane
Enquiries Dr J Robson (07)3377 8666 Molecular Path



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Nicolaides**
PATHOLOGY

Quality is in our DNA

SULLIVAN NICOLAIDES PTY LTD ABN 38 078 202 196
NATA NCPSA ACCREDITATION NUMBER 1964

TAS

DR JAMES A FREEMAN
HOBART PRIVATE HOSPITAL
ARGYLE ST
HOBART TAS 7000

CLINICAL NOTES:

Surgery use: ☐ Normal: file ☐ Notes required ☐ Speak with Dr ☐ Make appointment ☐ On correct treatment ☐ Contact patient ☐ Patient notified

Hospital use: Referred to Dr: Name By: Nurse name Signature Date Reviewed by Dr: Name Signature Date

Hepatitis C PCR	07/07/15 13:50	04/08/15 11:40	Units	Reference
Specimen	Serum	Serum		
HCVL RNA	Pos *	Neg <<<		
Code Key				
HCVL RNA :	Neg = HCV RNA not detected			
HCVL RNA :	Pos = HCV RNA detected			

Comments on Collection 04/08/15 1140:

HCV RNA viral load was performed using the COBAS Ampliprep/
COBAS TaqMan HCV assay, version 2.0.
The lower limit of detection is 15 HCV RNA IU/mL.
The linear range is 15 (log 1.2) to 100,000,000 (log 8.0)
HCV RNA IU/mL.
Viral loads are considered high if >800 000 (>log 5.9) HCV RNA IU/mL.
Early viral treatment response (EVR) is defined by at least a 2-log
reduction in viral load following 12 weeks of therapy.

HIV drugs imported from India to UK



Conclusions

The current prices of treatment to cure Hepatitis C are too high to allow elimination of this epidemic within the next 15 years. Cost-effectiveness models for HCV DAAs have serious flaws which undermine their reliability

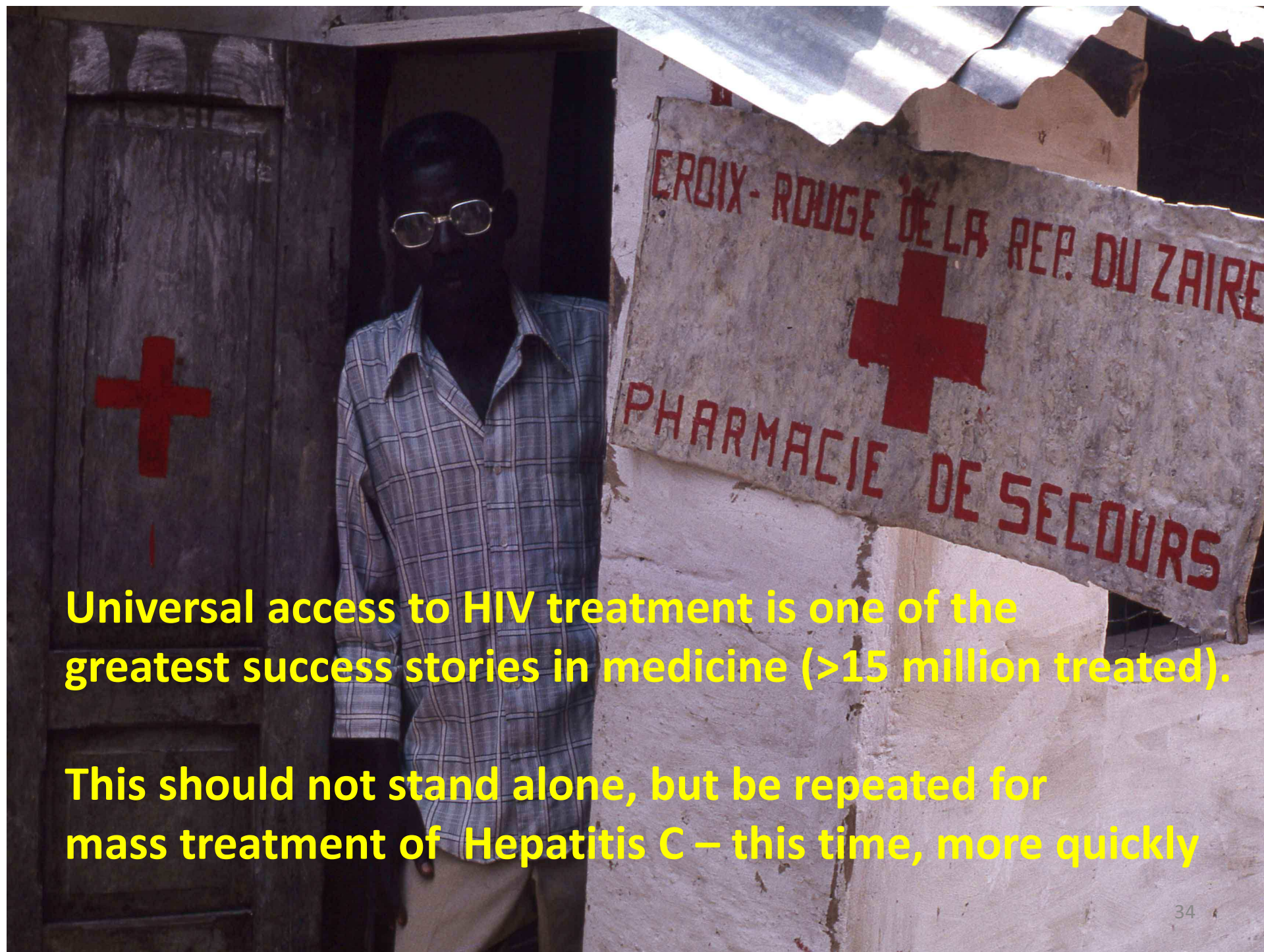
Worldwide, there are more people newly infected with Hepatitis C than being cured – the current situation is not working.

The drugs to cure Hepatitis C are fundamentally very cheap to produce

Pharmaceutical companies need to be more flexible – cure more people for a lower unit price, and they will still make money.

There will be increased competition in the near future (AbbVie, Merck, Janssen), which should lower prices, but this is not guaranteed.

Some countries have started access schemes via buyers clubs and local production to lower their prices. This system is leading to thousands of people being cured, who would not otherwise be treated.



Universal access to HIV treatment is one of the greatest success stories in medicine (>15 million treated).

This should not stand alone, but be repeated for mass treatment of Hepatitis C – this time, more quickly