



# TAG

Treatment Action Group

## HCV Webinar Series



Webinar #1:

### The Cost of Production for HCV Treatment

**Presenter: Dr. Andrew Hill**, Senior Research Fellow,  
Department of Pharmacology and Therapeutics,  
Liverpool University, United Kingdom

# What is the minimum cost of production of treatments for Hepatitis C?

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Pharmacology and Therapeutics

Liverpool University

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# Background – HIV/AIDS



PHILIP BLINDY

BILL SCHWARTZ

STAN

RONN CHARLES

EVAN

DENNIS LONG  
LOVE

ROBERT M. SMITH

Richard B.



Money for AIDS  
Not for War  
U.S. Out of Central America!  
Pledge of Resis

MORE  
AIDS  
FUND

For a  
Socialist  
Fren  
solution  
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UNIV  
HEA  
CA  
NO

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San Francisco - 1990



San Francisco - 1990



WPIB  
40 PC  
messing with  
F. S. ...



# AIDS KILLS



## AVOID MULTIPLE PARTNERS,

Always INSIST on USING

# CONDOMS!





**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”

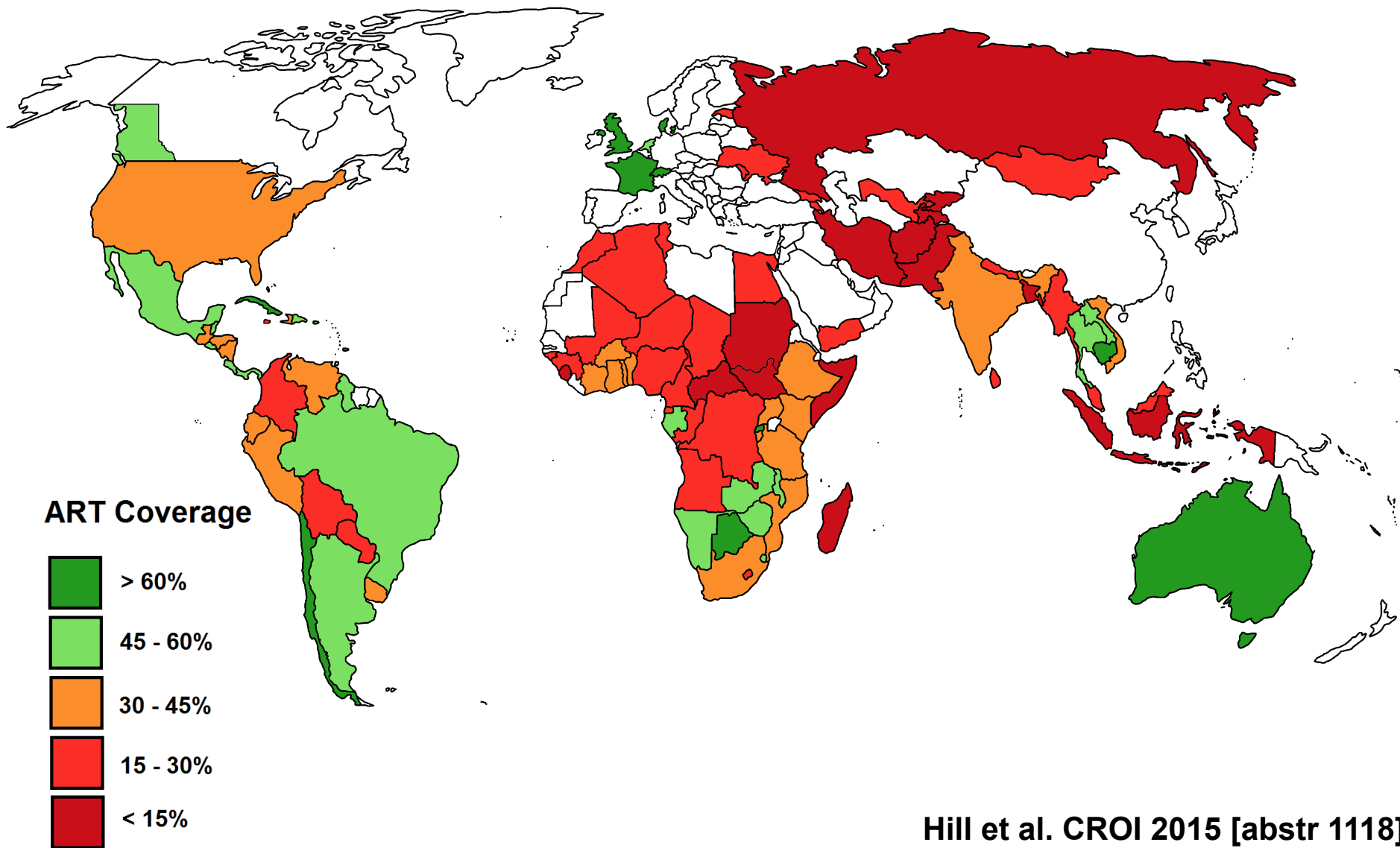
Dr Yussef Hamied  
Cipla,  
G8 summit,  
2000



# Thailand – HIV compulsory licenses



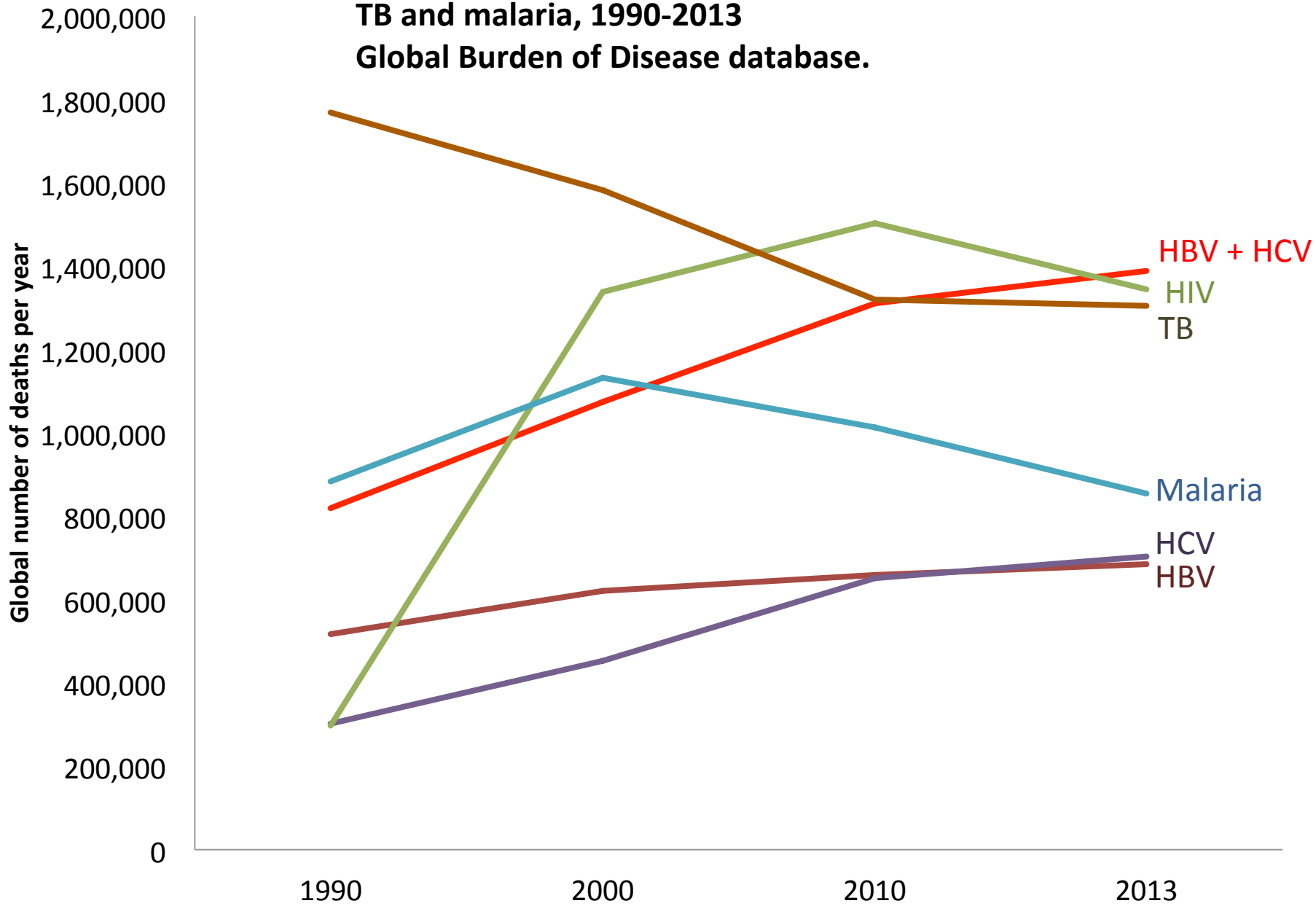
# Percentage of people on ART worldwide



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

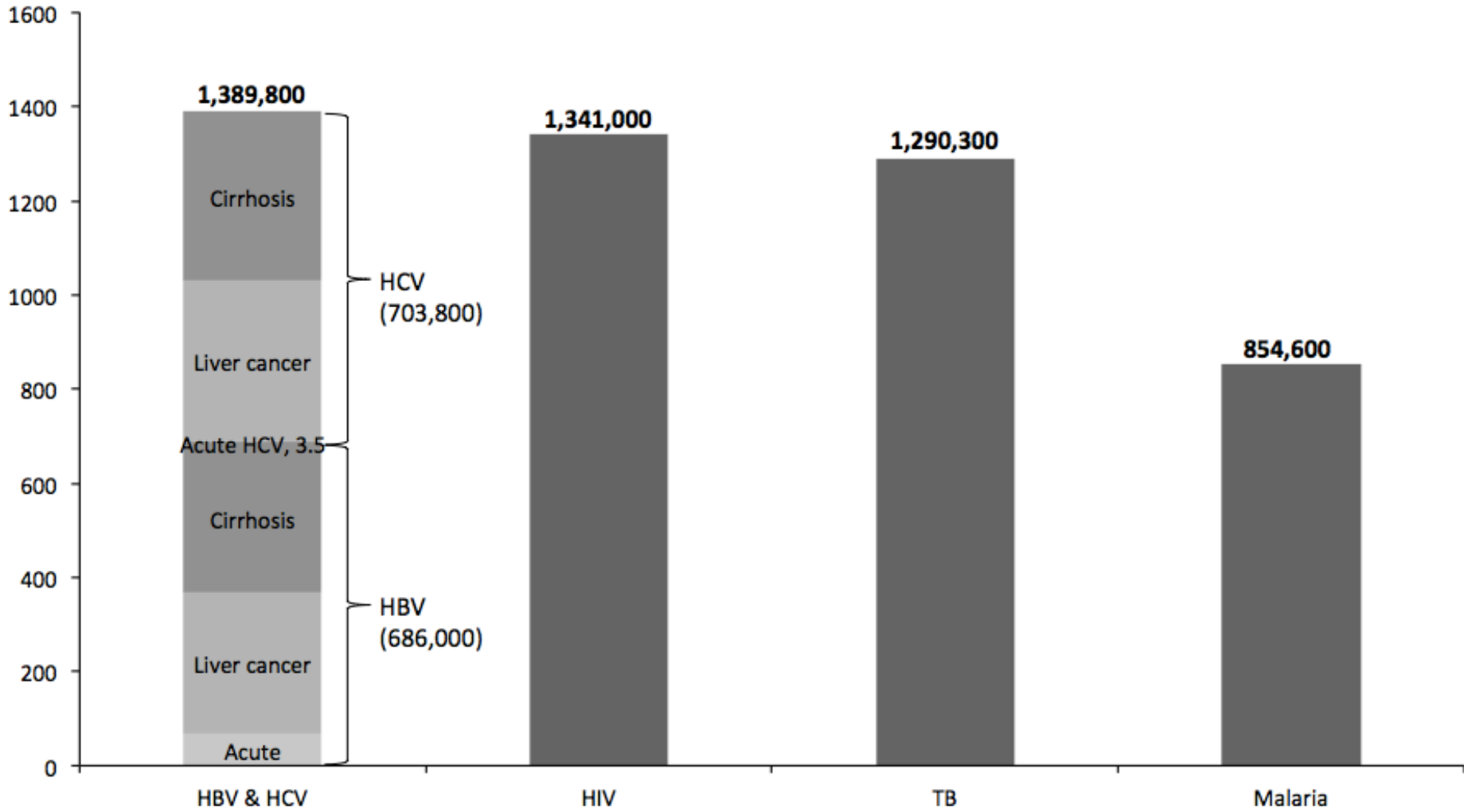
# Total deaths worldwide from HIV, Viral Hepatitis, TB and malaria, 1990-2013

Global Burden of Disease database.



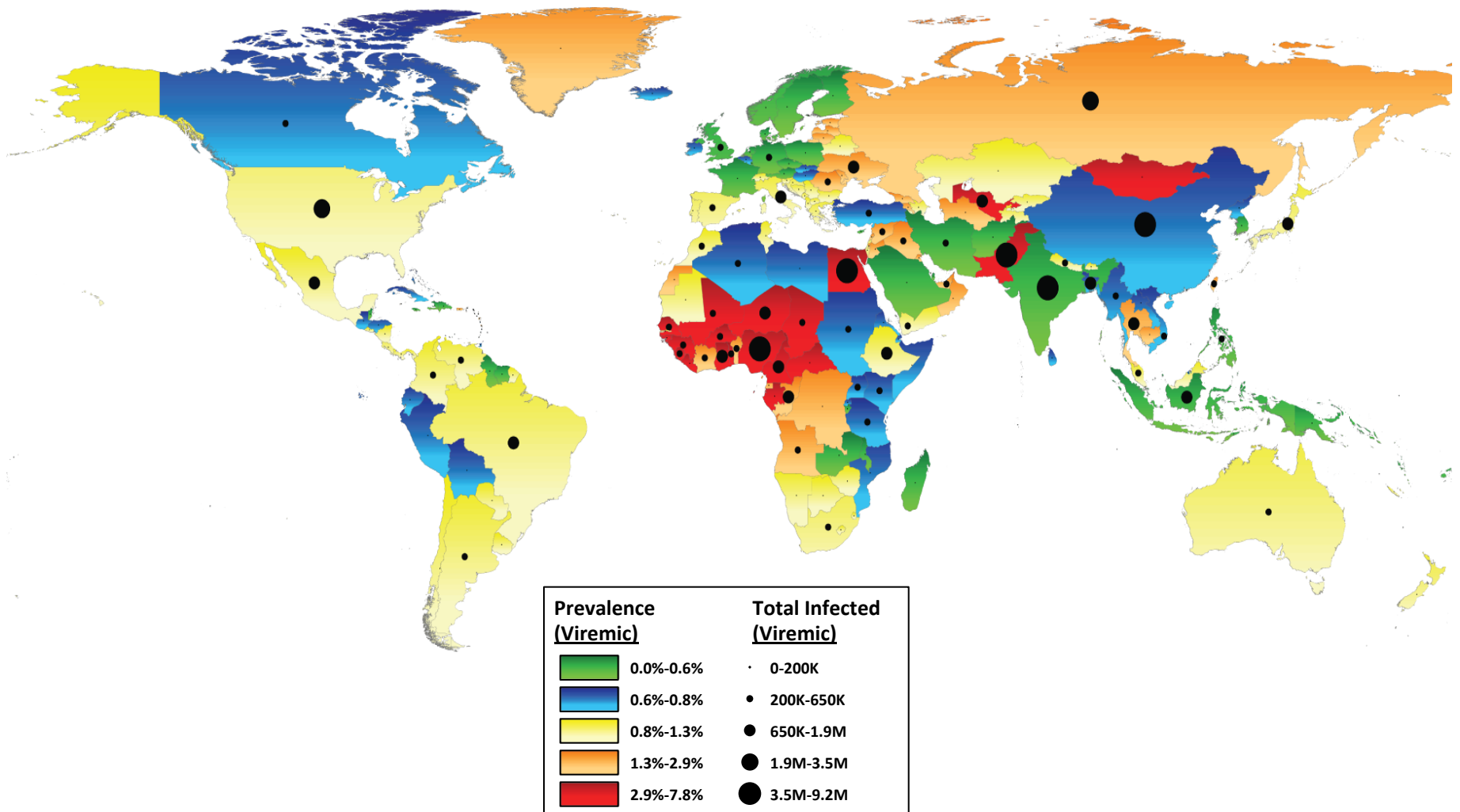
Source: <http://ghdx.healthdata.org/global-burden-disease-study-2013-gbd-2013-data-downloads>

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





# Global chronic HCV prevalence



# HCV genotypes 1-6 worldwide

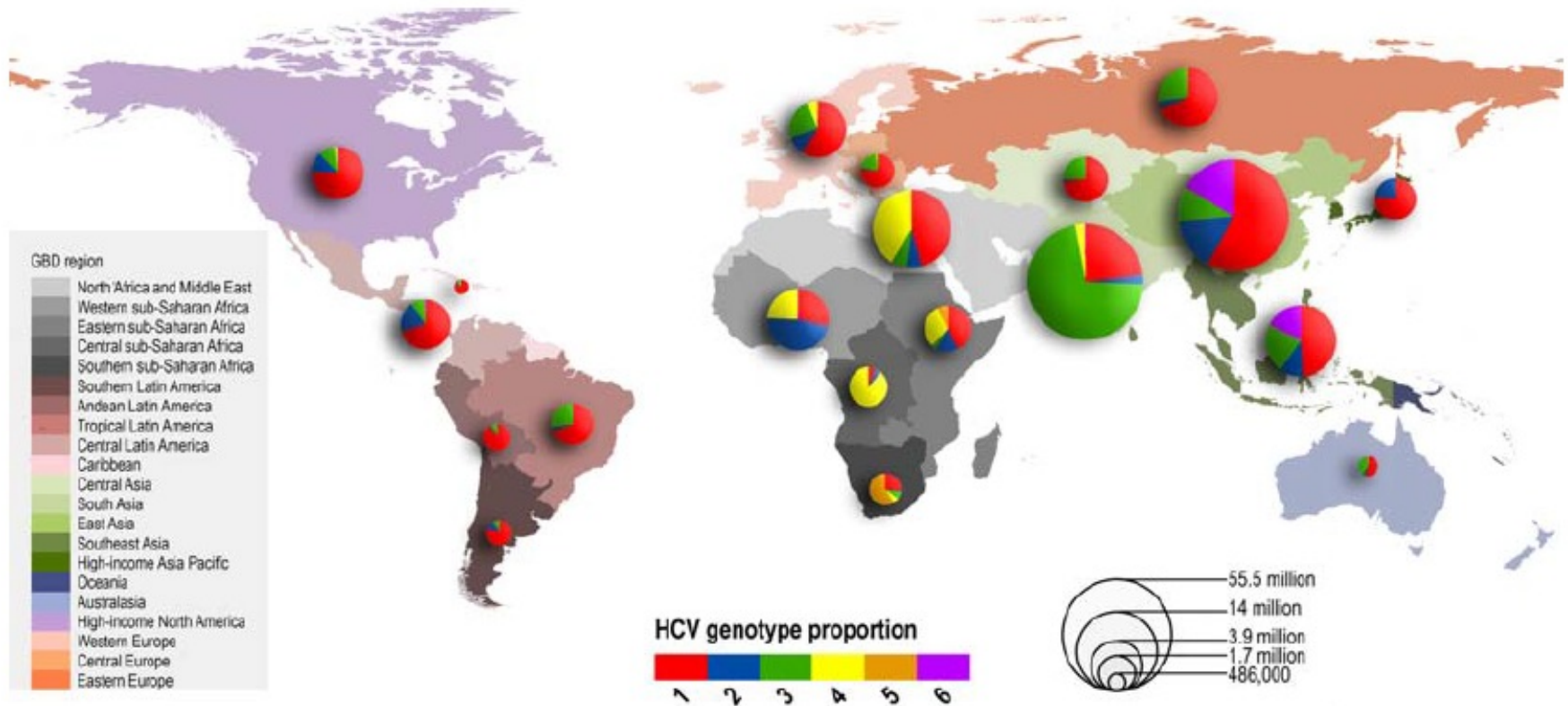
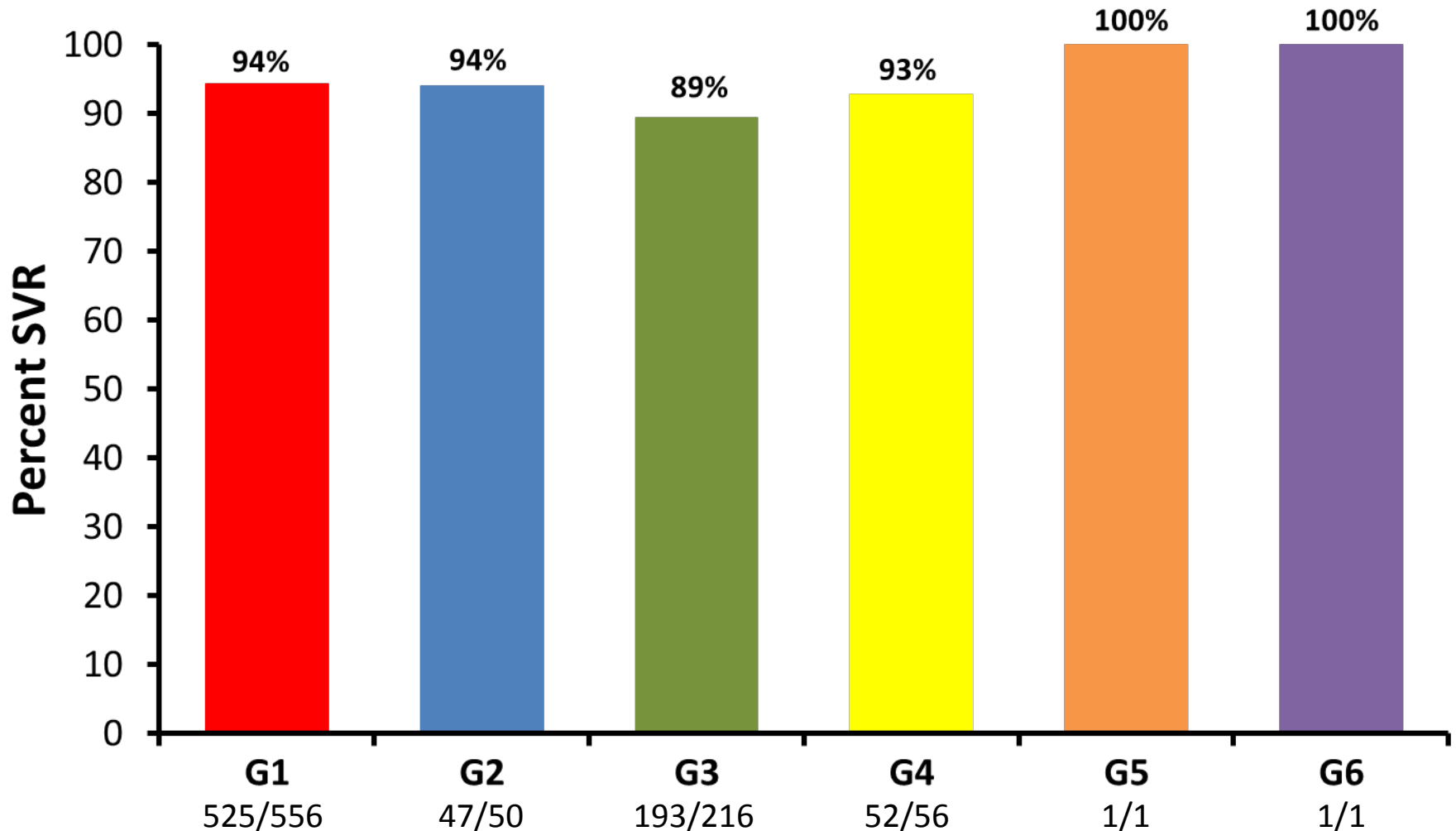


Fig. 1. Relative prevalence of each HCV genotype by GBD region. Size of pie charts is proportional to the number of seroprevalent cases

# Sofosbuvir + Daclatasvir ± 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).

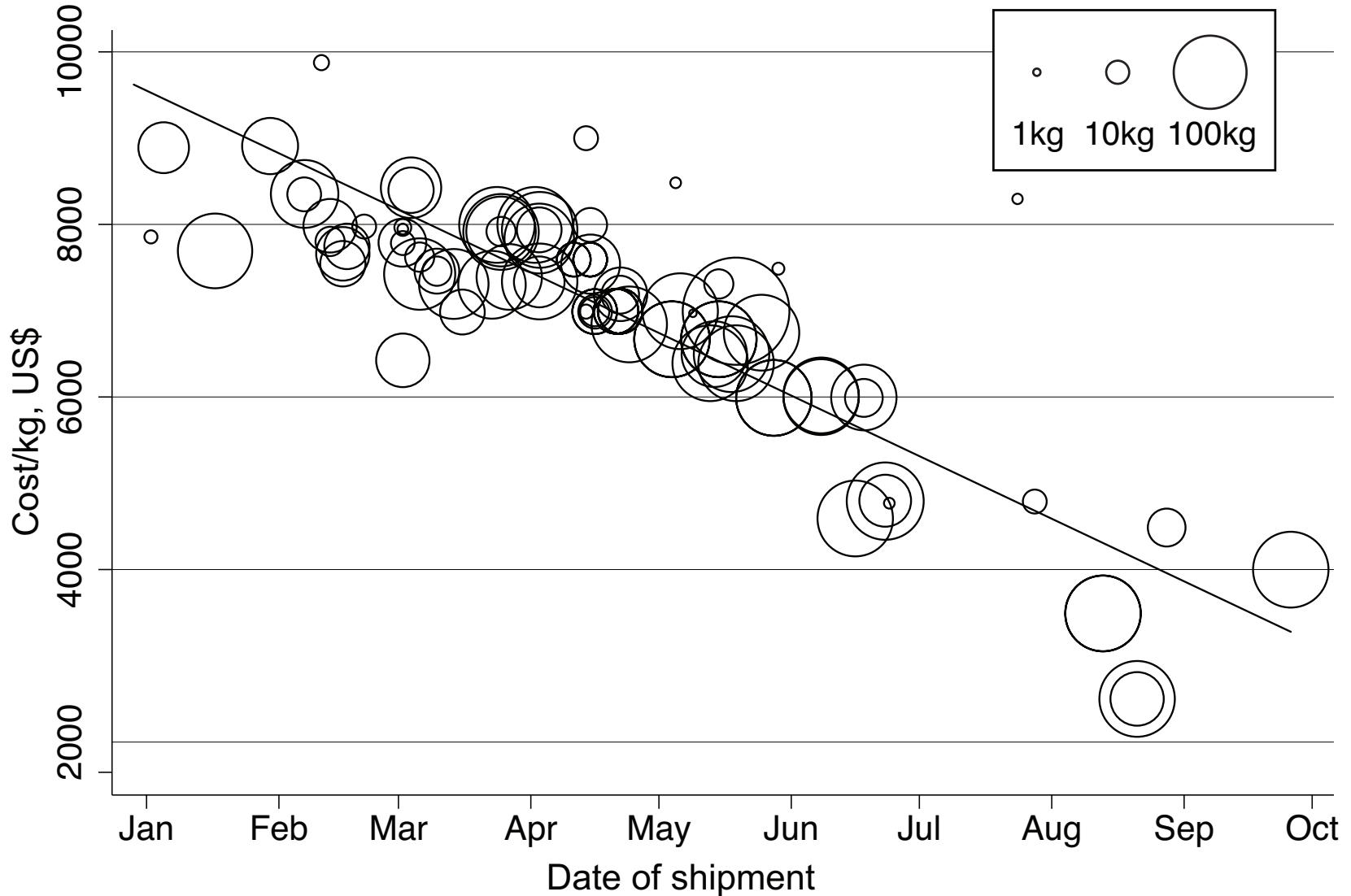
[www.indiainfodrive.com](http://www.indiainfodrive.com)

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

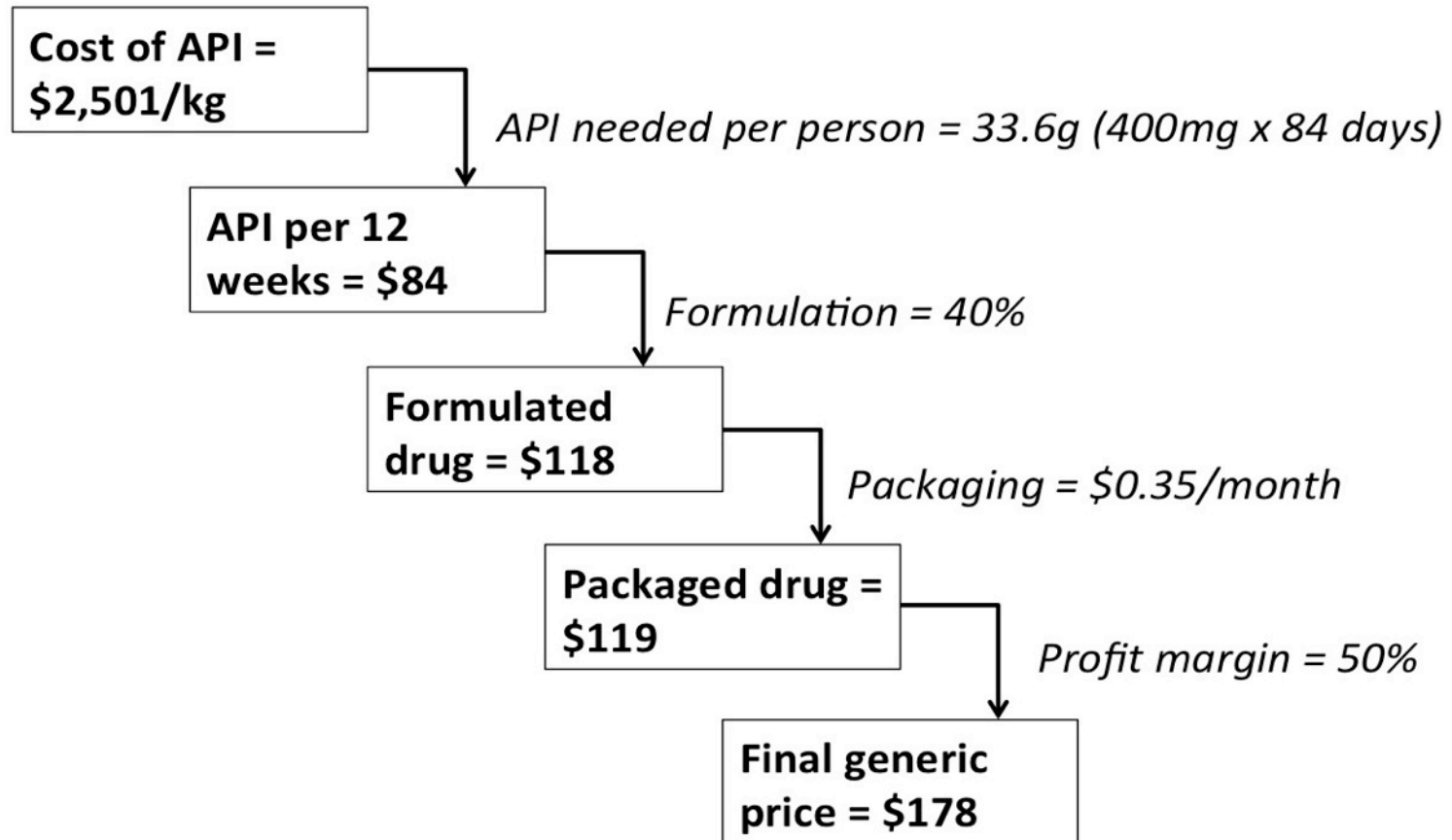
Collaboration with experts in chemical synthesis and mass production of medicines to evaluate prices. Cross-checks using different methods.

Surveys of costs of drugs by country

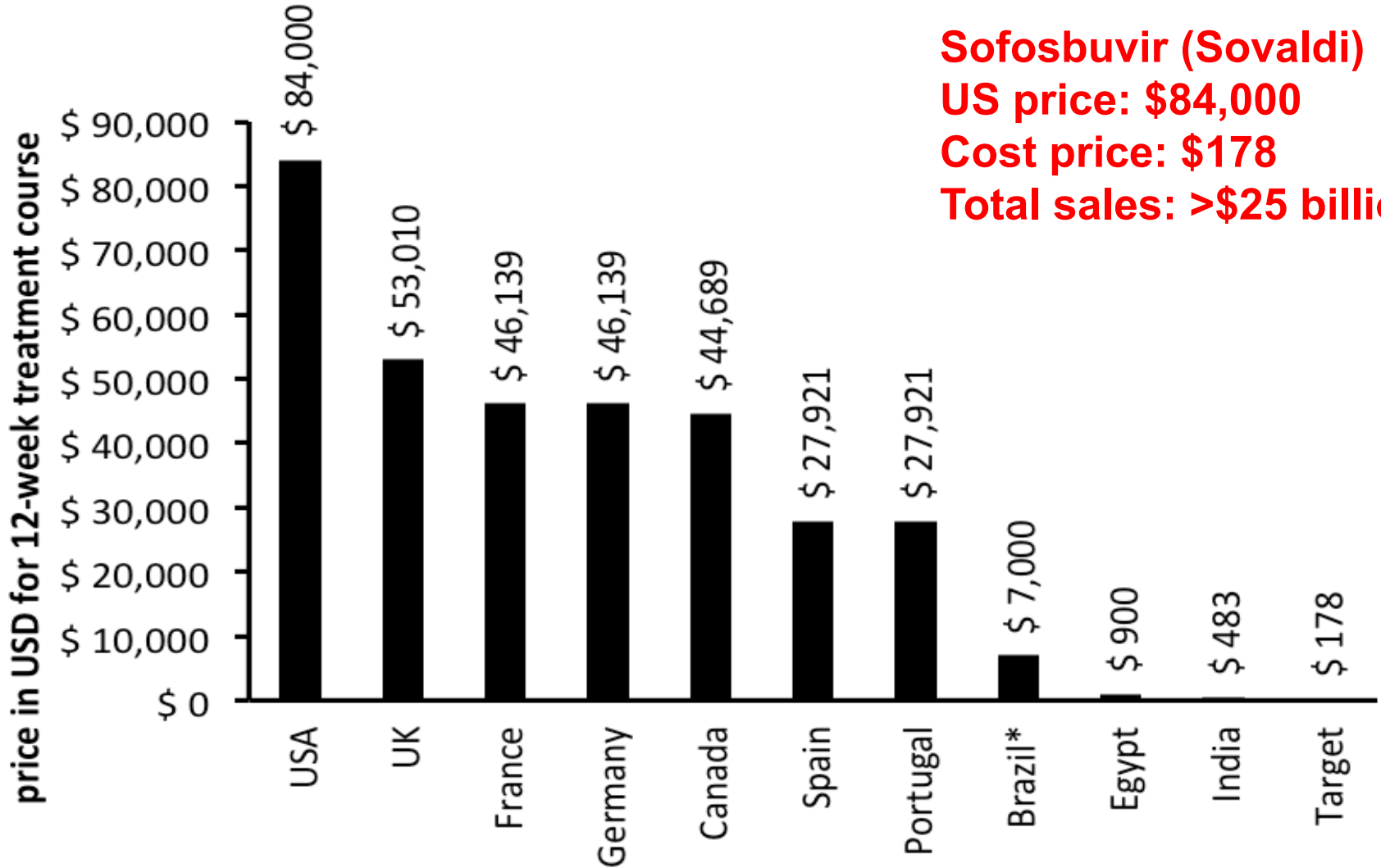
# Sofosbuvir API exported from India in 2015, weighted by size of shipment



# Current Costs of production - sofosbuvir

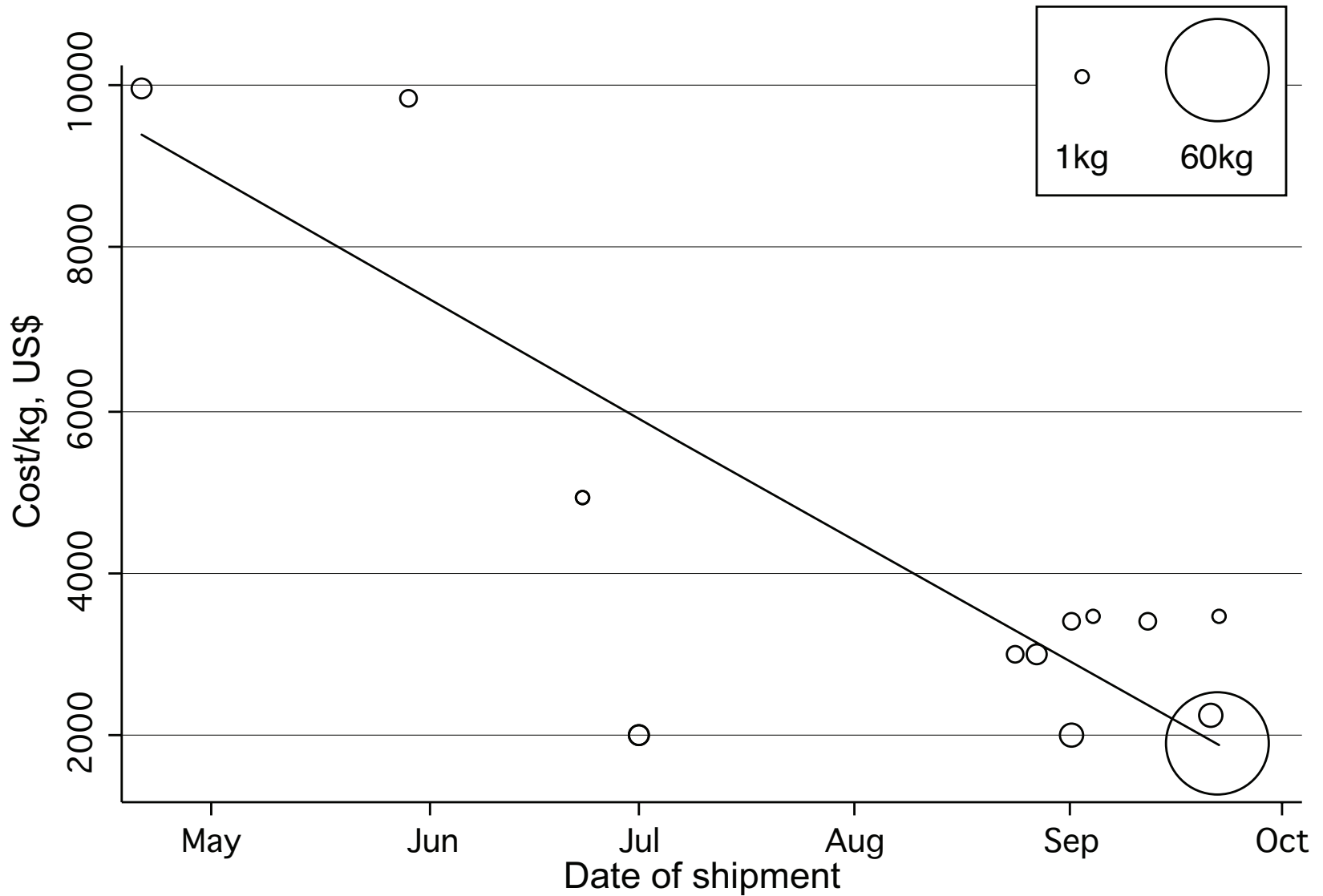


# Price of sofosbuvir by country (US dollars per 12 week course)



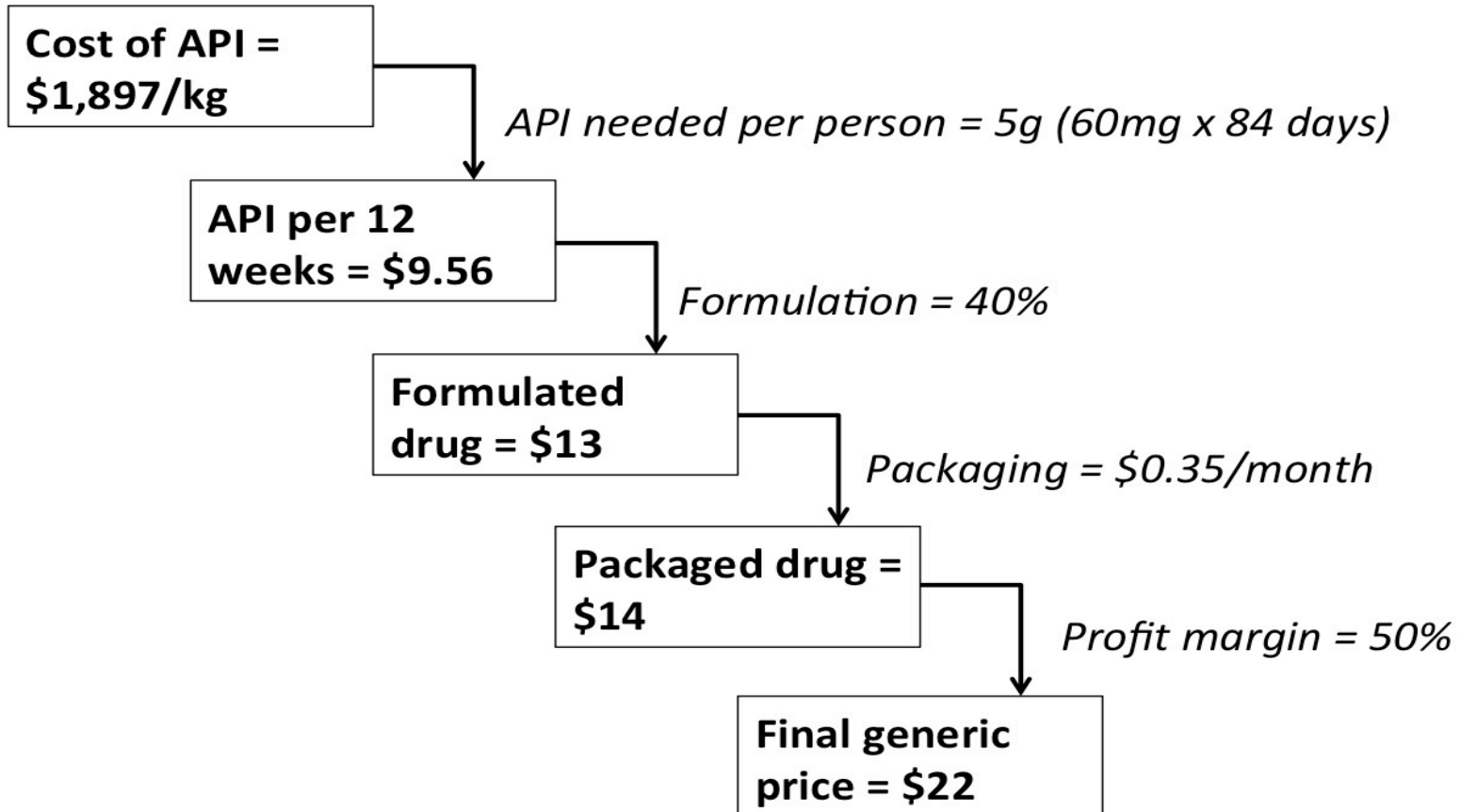
**Sofosbuvir (Sovaldi)**  
**US price: \$84,000**  
**Cost price: \$178**  
**Total sales: >\$25 billion**

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

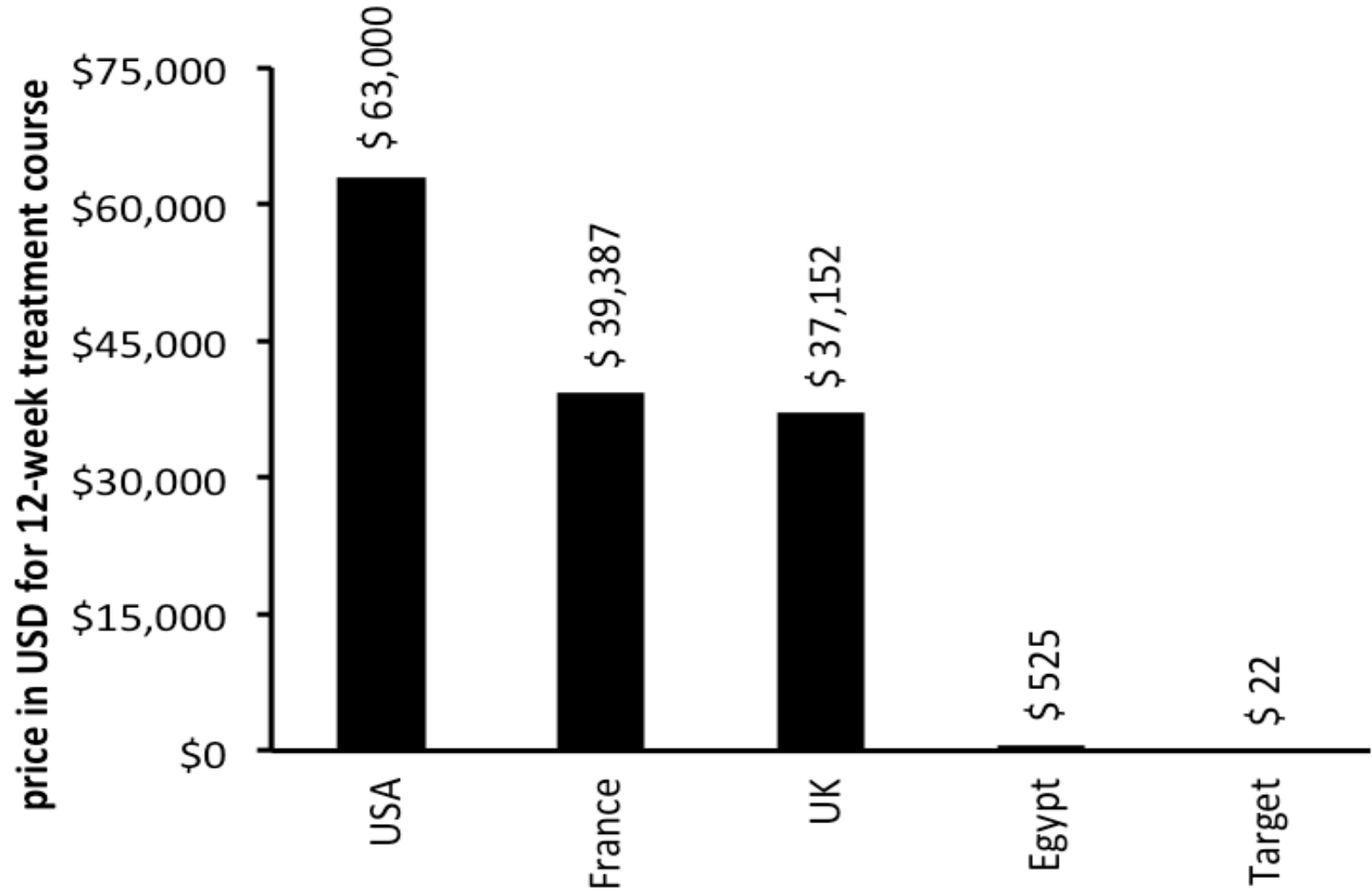




# Current Costs of production - daclatasvir



# 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”**

# **“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**

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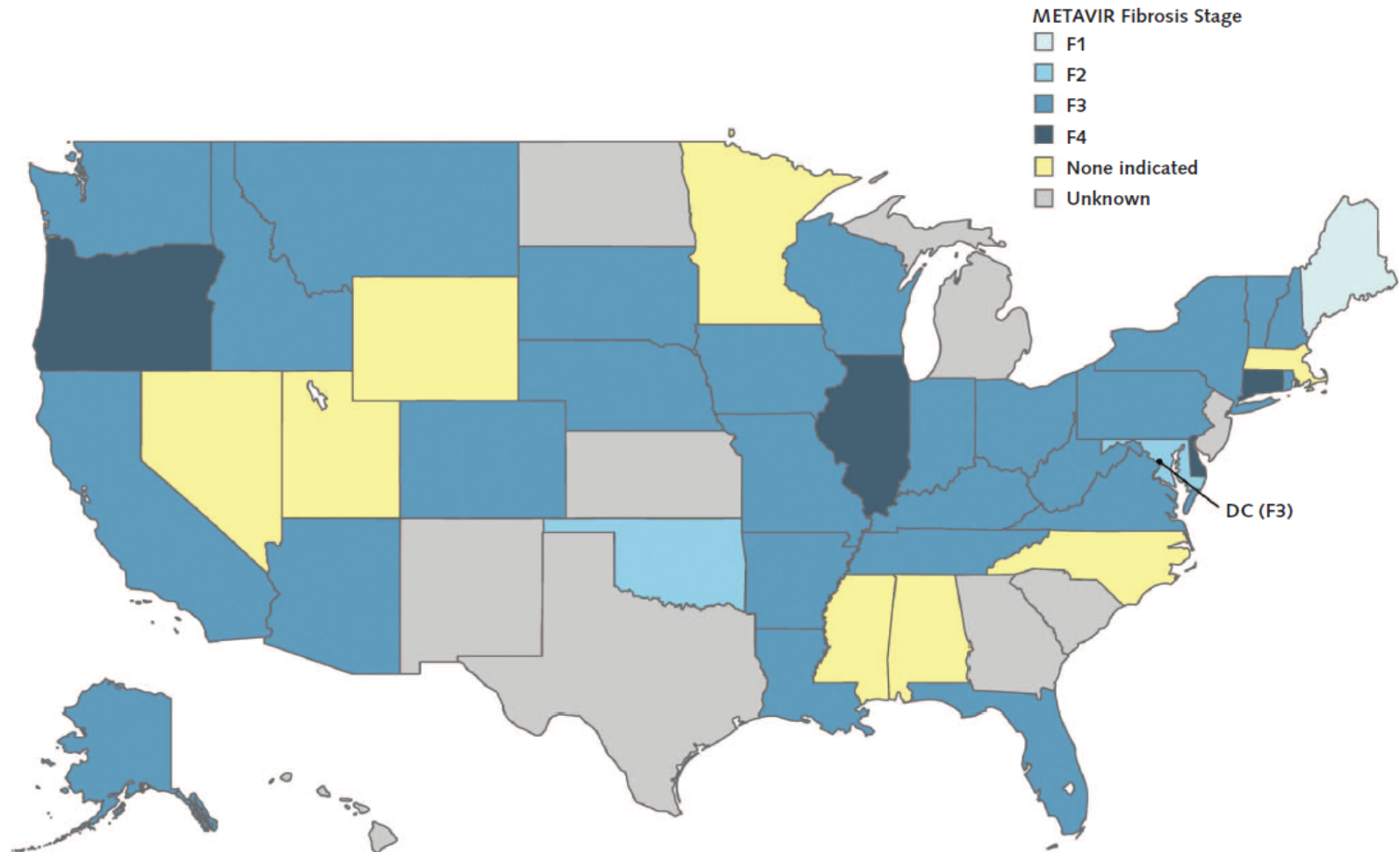
**Units cost of a cure = \$200 per person (minimum)  
Cost = \$680 million, not including medical care,  
diagnostics**



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

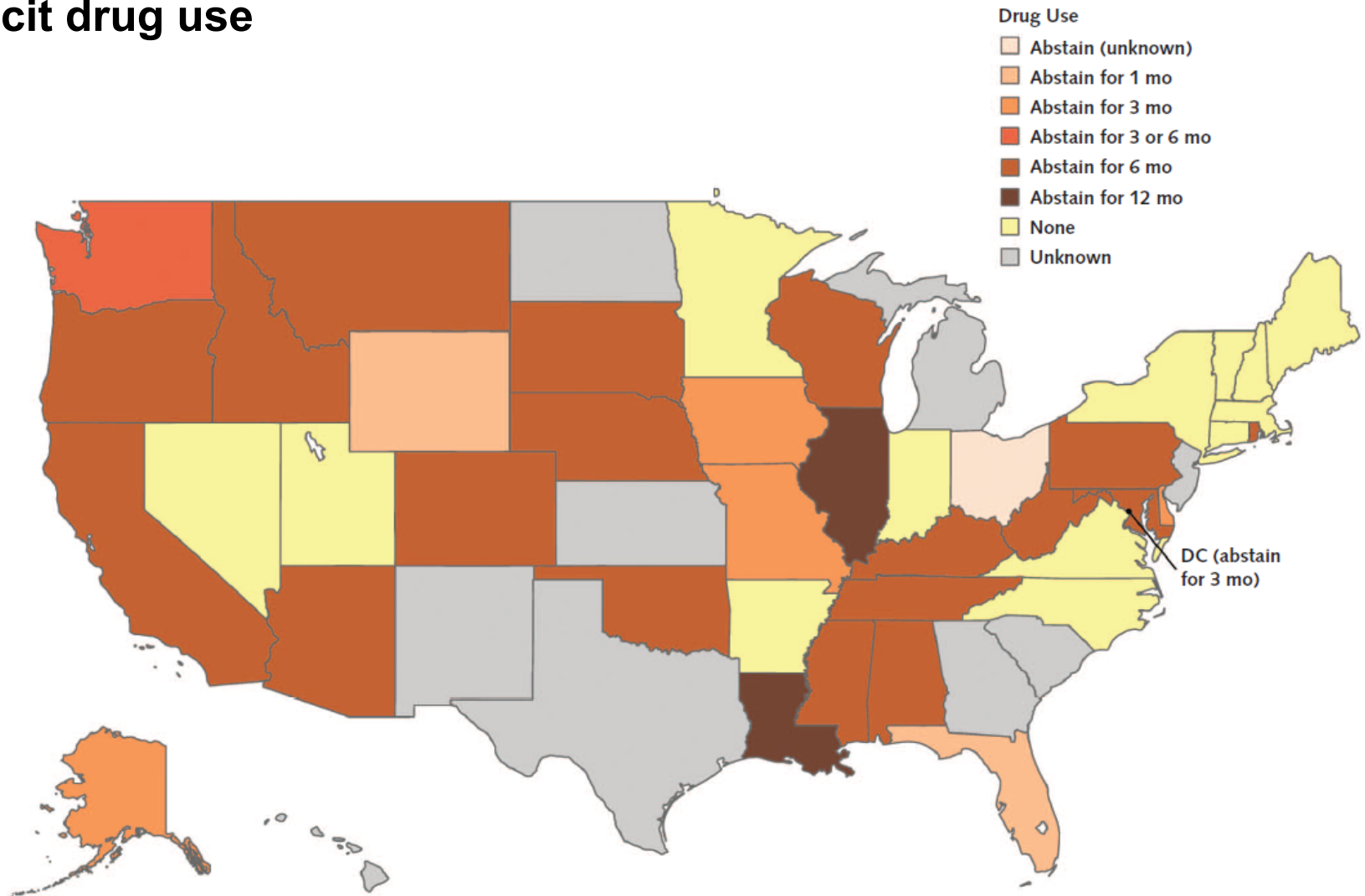
# Sofosbuvir Medicaid restrictions in US

## Liver disease stage

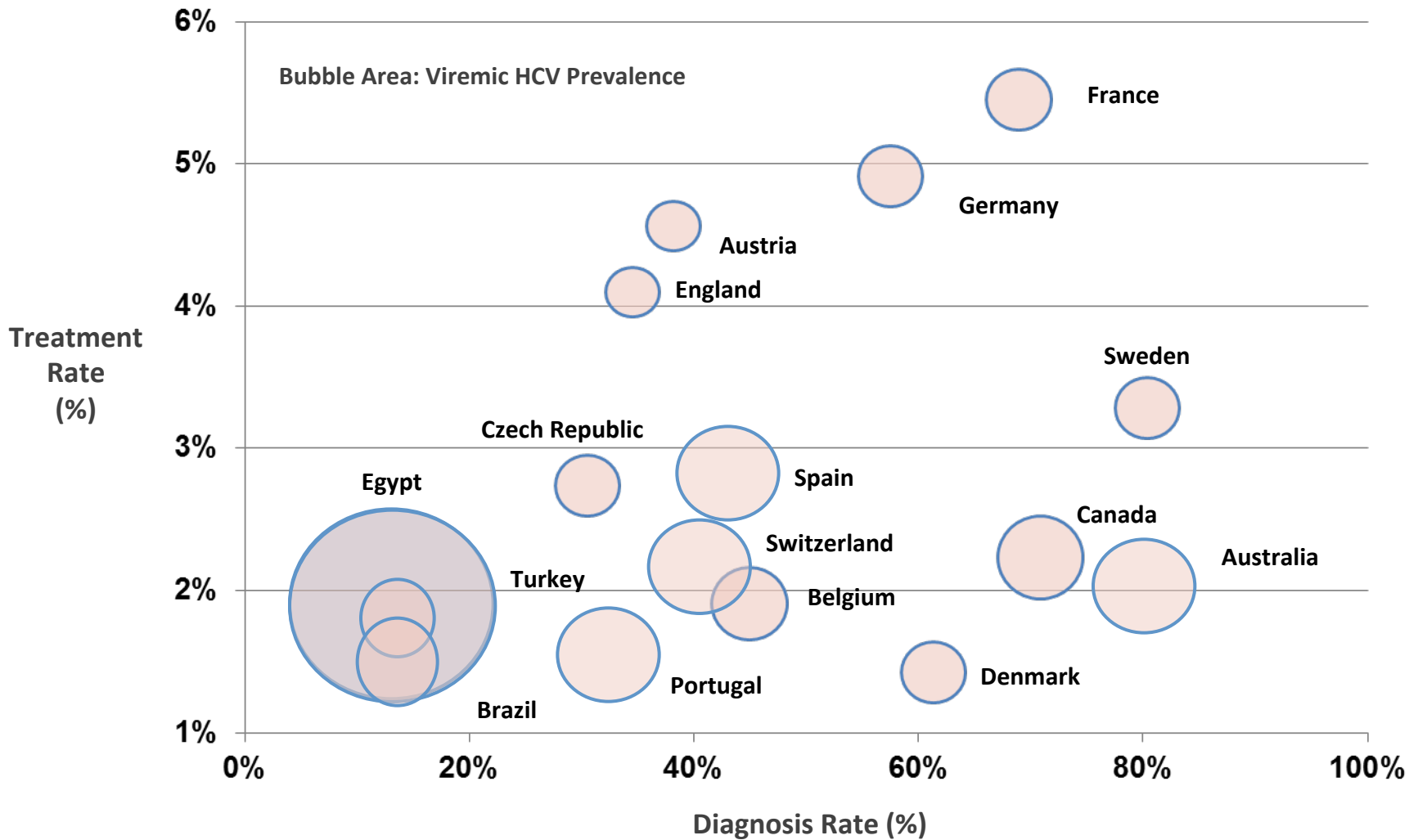


# Sofosbuvir Medicaid restrictions in US

## Illicit drug use



# HCV diagnosis and treatment uptake



# 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.

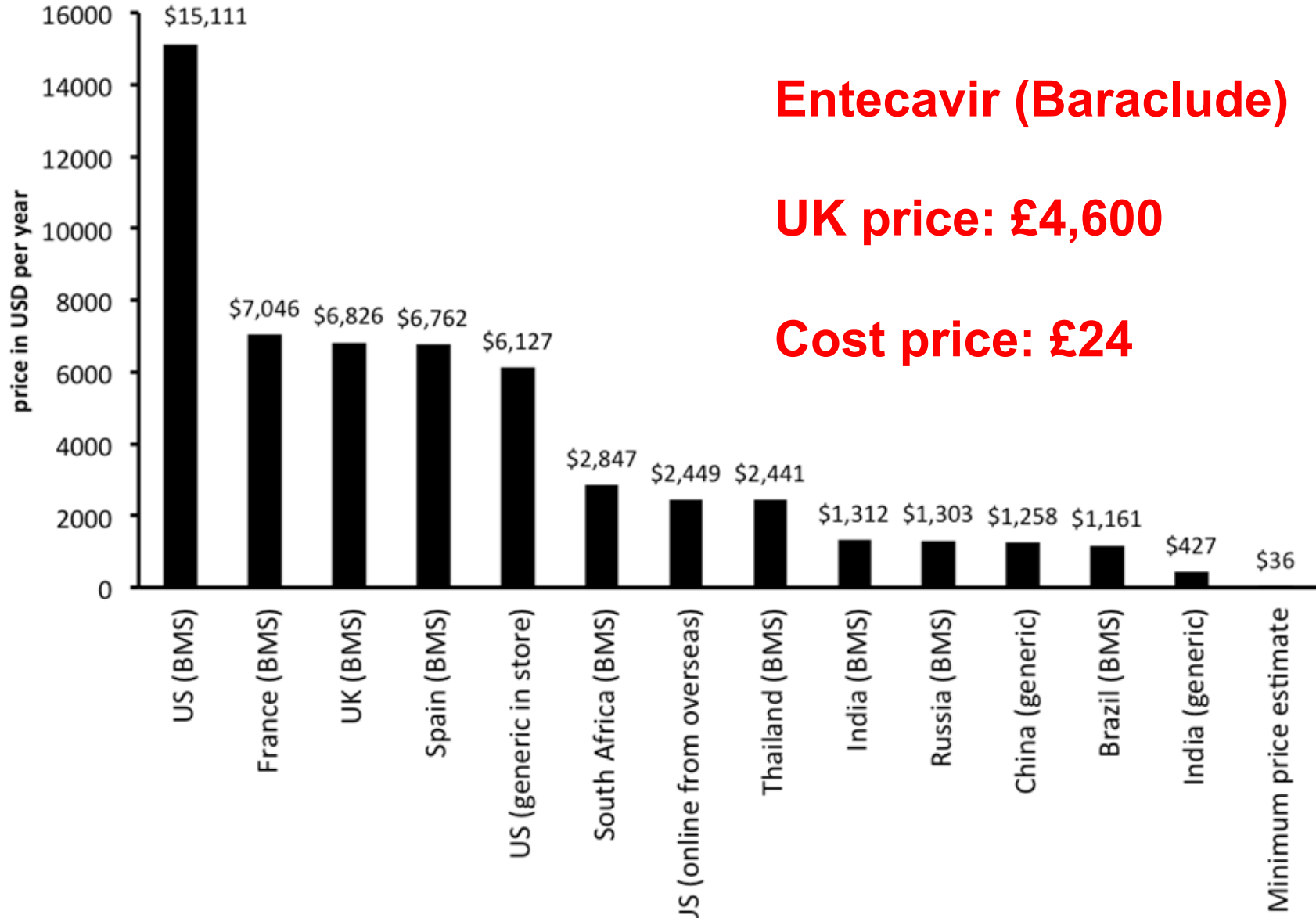
Many pharmaceutical companies use offshore schemes to avoid taxation.

**Could Hepatitis B also  
be eliminated  
worldwide by  
producing treatments  
cheaply?**

**Entecavir for Hepatitis B  
one year's supply (0.18g)**



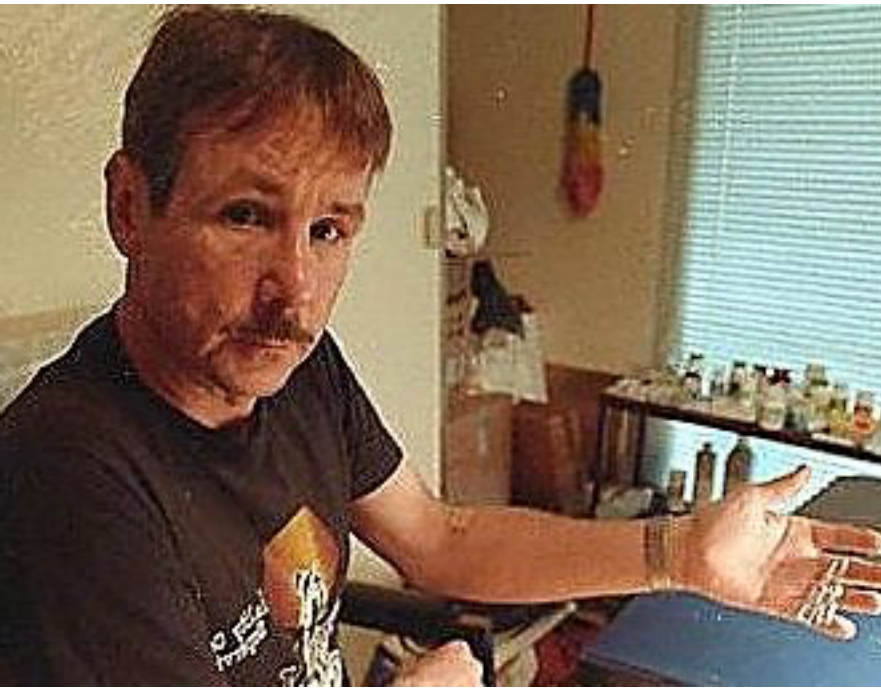
# Entecavir for Hepatitis B cost per person/year by country



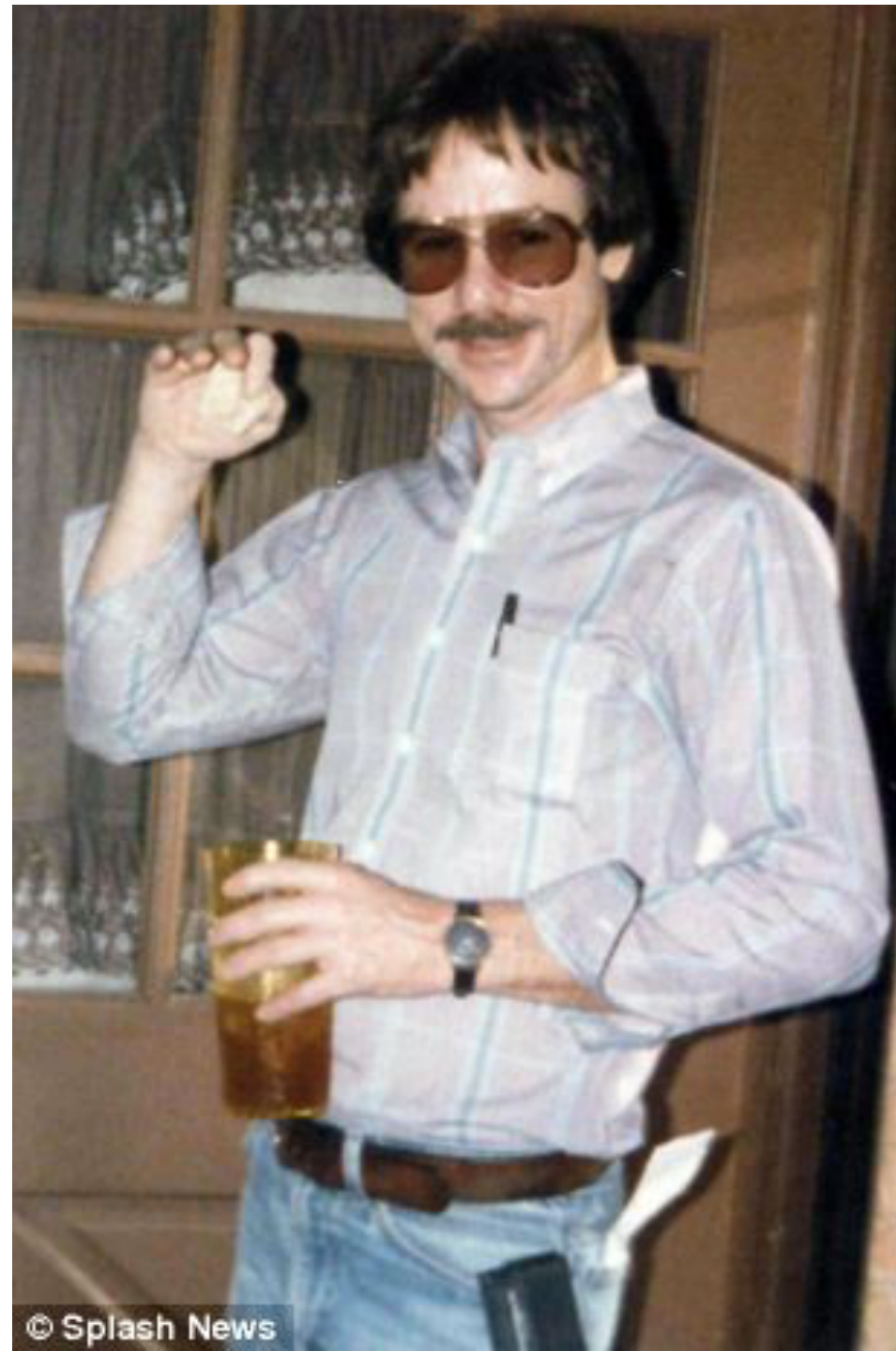


**What can be done, if  
medicines are not  
locally available?**

## The Original Dallas Buyers Club



Ron Woodroof founded what was known as the Dallas Buyers Club, in order to combat hospitals not using effective medication to combat AIDS. Woodroof was diagnosed in 1986, and was given very little time to live, but rather than accepting the prognosis, he researched various medicines and drugs to combat AIDS and began to take them. He then wanted to help other AIDS victims who had no other medicines, and sold the drugs in the group he founded: the Dallas Buyers Club. He died on September 12<sup>th</sup> 1992 in Texas, after six years of fighting the disease with his own treatments.



# 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](http://www.fixhepc.com)  
[www.iwantprepnw.com](http://www.iwantprepnw.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



**Sullivan  
Nicolaides**  
PATHOLOGY

Quality is in our DNA

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

TAS

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

CLINICAL NOTES:  
[Redacted]

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<br>13:50          | 04/08/15<br>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.

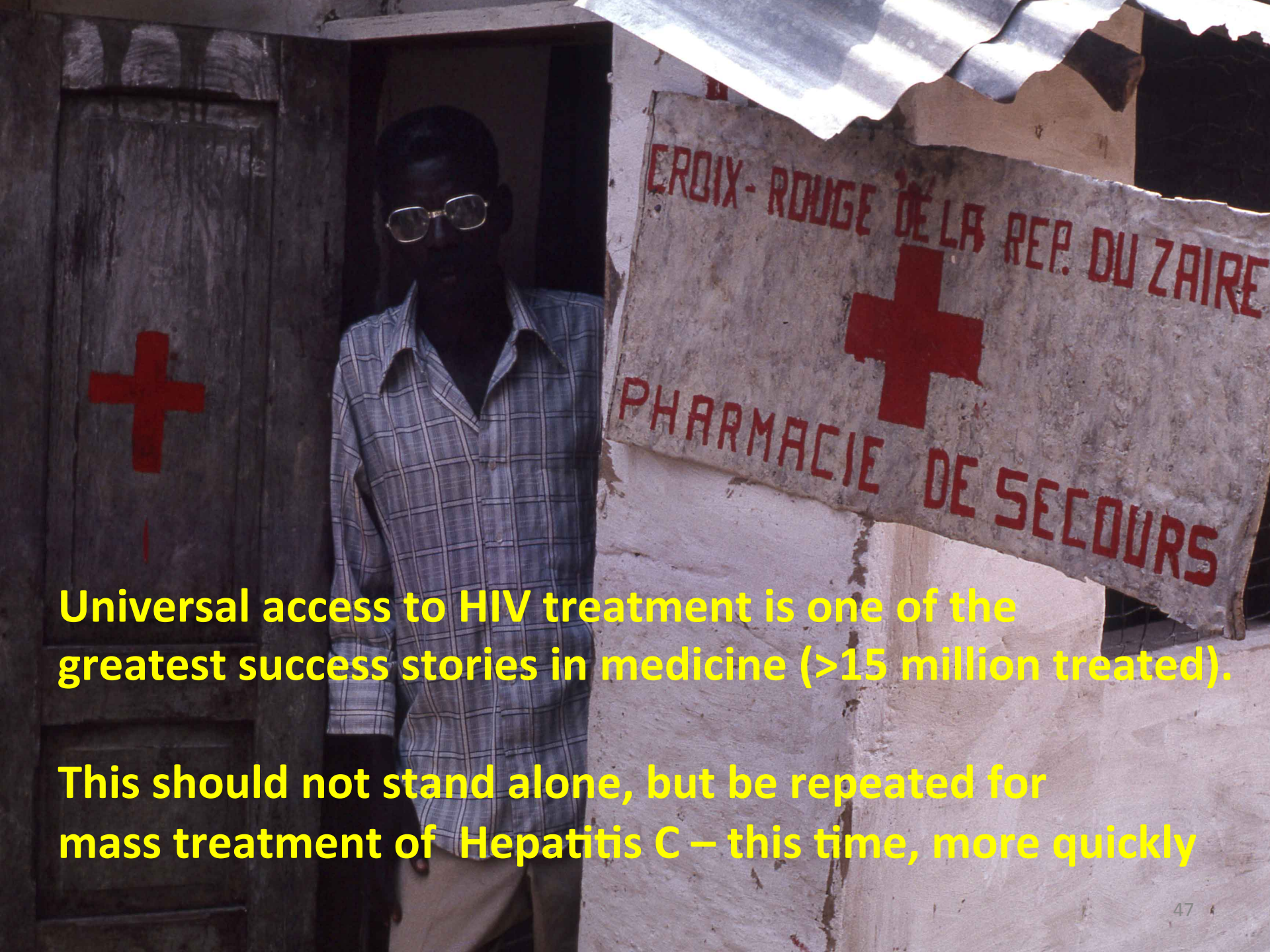
Worldwide, there are more people newly infected with Hepatitis C than being cured – the current situation is not working.

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**