



Efforts from the community to improve access

Karyn Kaplan

October 9, 2015

4th International Symposium on Hepatitis Care in Substance Users

“Faced with the abuse of power and greed of corporations, we cannot wait for our governments to act...

Activists are to be honored. Activists are my true friends. They stand by my side when I face discrimination and injustice...

They have the courage to stand up to those in power who use their positions for their own benefit...”

-Paisan “Ott”

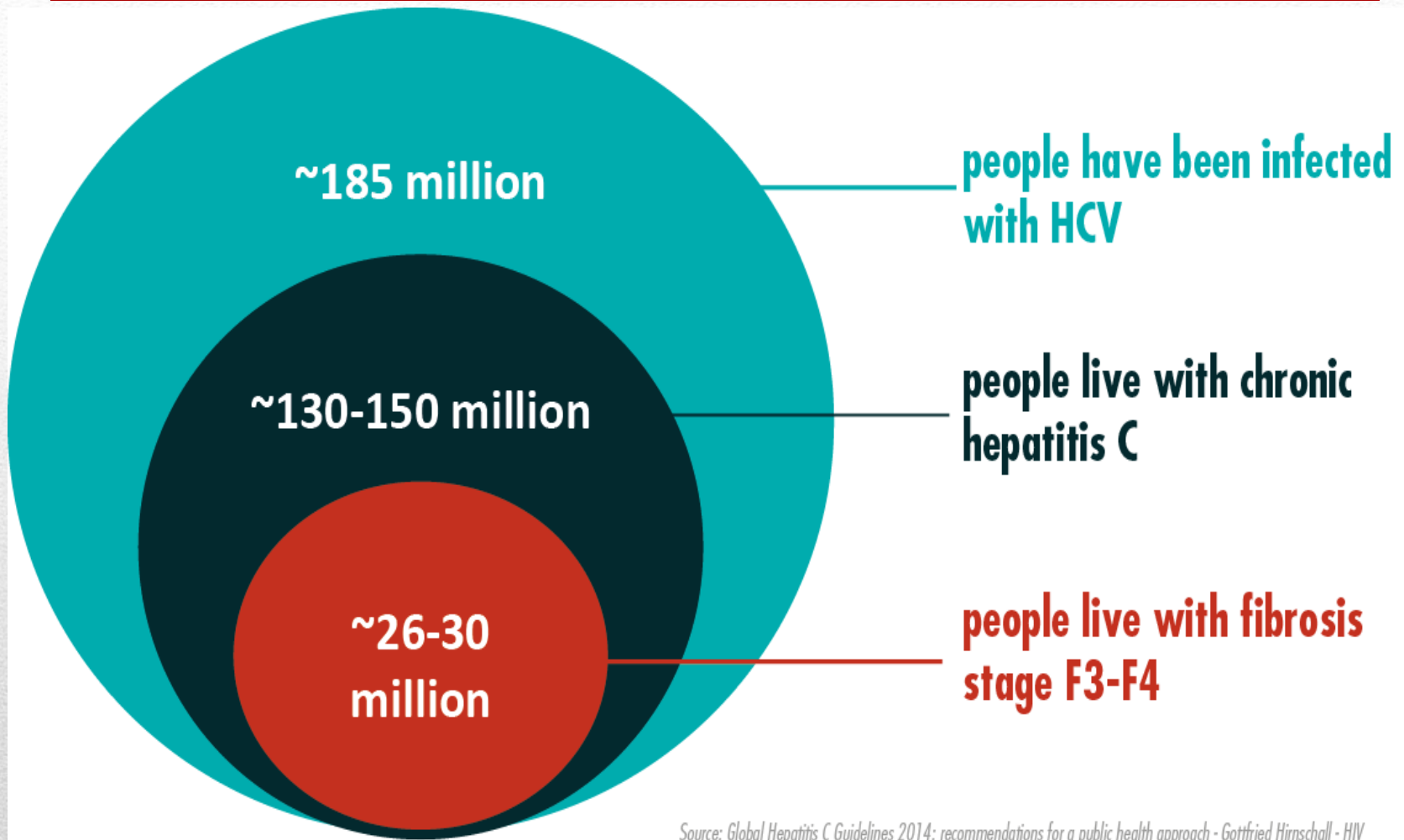
Suwannawong, IAC 2004



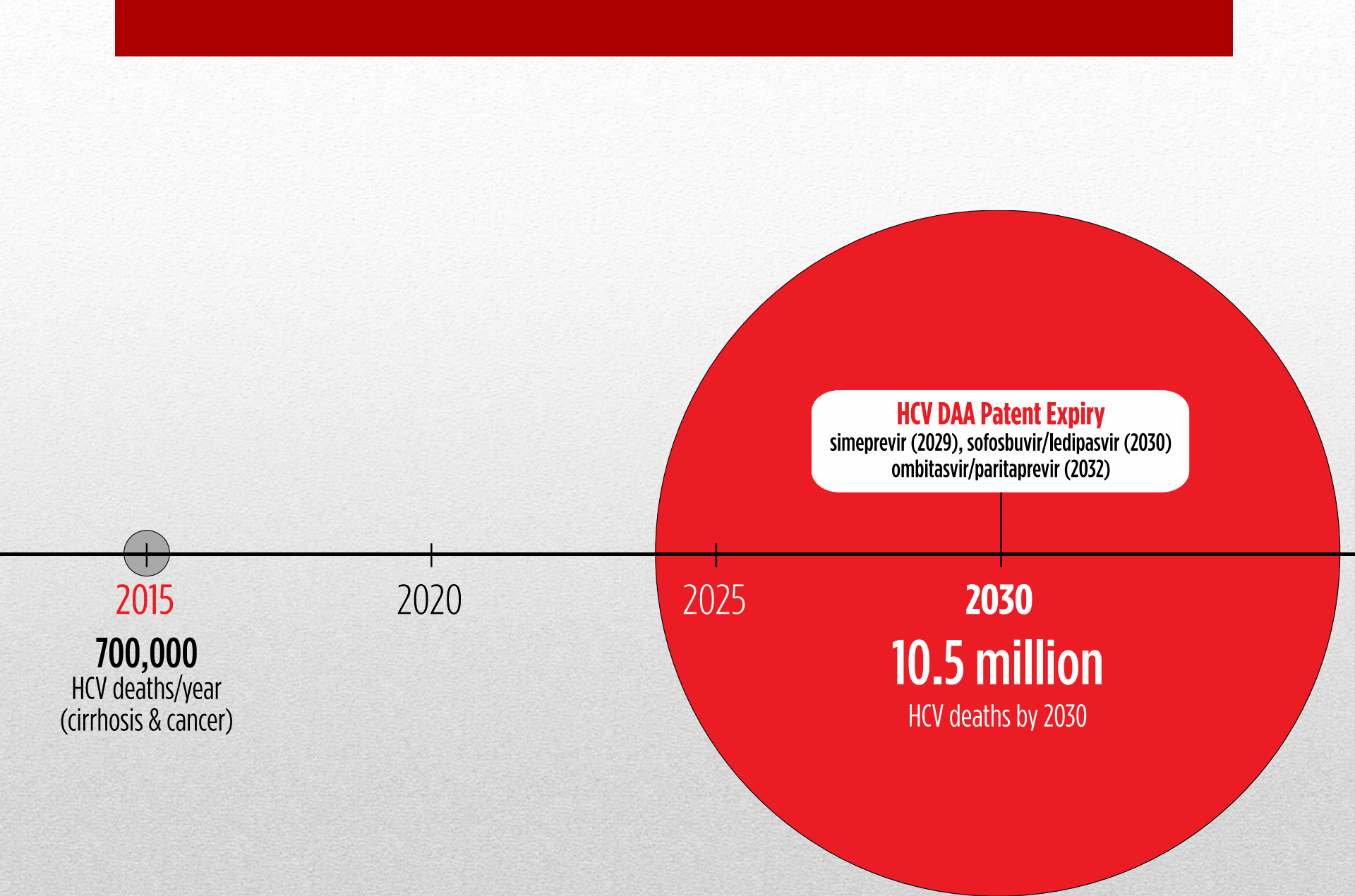
Activists and Access



Drug Smugglers



2.2% have treatment (WHO 2014)



Data from Global Burden of Disease report, 2013. Lancet January 10th 2015, 385: 117-171
FDA Orange Book. <http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm>. Infographic by TAG.

hep C Coalition



I - M A K

INITIATIVE FOR MEDICINES, ACCESS & KNOWLEDGE



GLOBAL NETWORK OF
PEOPLE LIVING WITH HIV

Therapeutics Research • Education • AIDS Training

TREATASIA

ACCESS[®] HCV TREATMENT

TAG

Treatment Action Group



**AIDS
ACCESS
FOUNDATION**

APN PLUS

POSITIVE CHANGE



International HIV/AIDS Alliance in Ukraine

INPUD

International Network of People who Use Drugs



ITPC

Strengthening Community Responses
to HIV Treatment & Prevention



OPEN SOCIETY FOUNDATIONS

- Community mobilization and participation
- Peer-led, rights-based approach
- Price of treatment – must have access to quality, affordable generics
- Intellectual property barriers
- Issues facing highly marginalized, criminalized groups with high HCV prevalence

HIV informs HCV activism

- Industry justifications (the lack of government commitment, global funding and adequate infrastructure)
 - High-level political will and resource commitments (GF, UTD, WHO, others)
 - Diverse campaign strategies
-

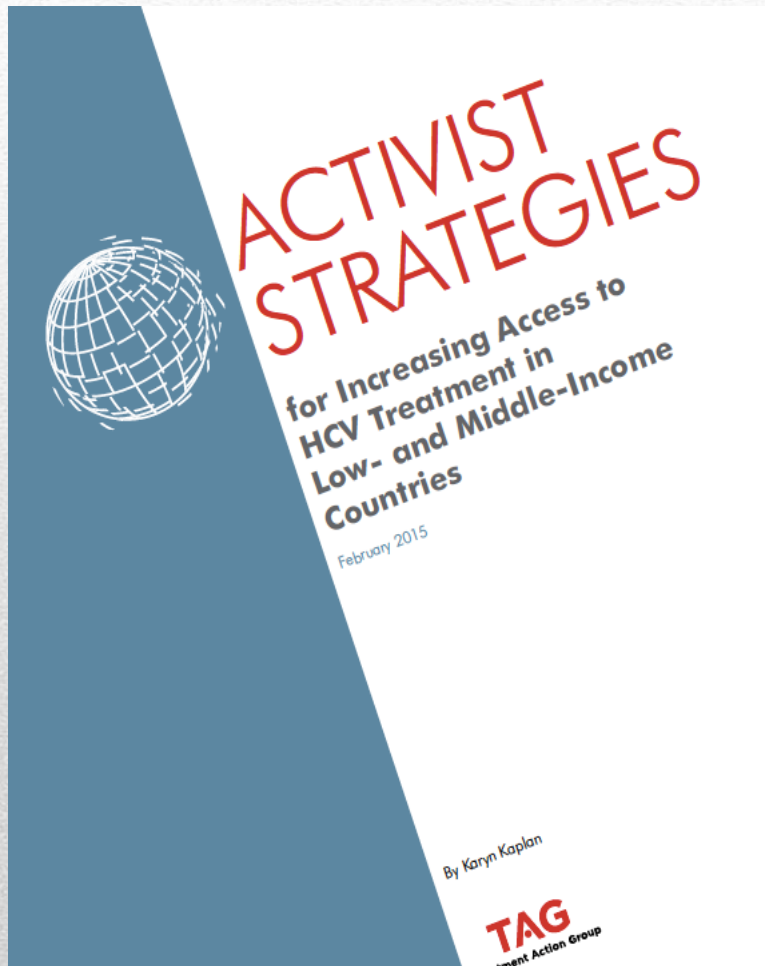
We call upon:

- **The pharmaceutical companies** - particularly Roche & Merck - to drastically reduce the price of diagnostics and treatment regimens for the estimated 170 million individuals suffering from chronic hepatitis C, particularly those with HIV co-infection.
- **Political leaders** to mobilize the adequate resources needed now and in the future--in anticipation of new HCV drugs--- to diagnose, monitor and treat high-prevalence populations, such as people living with HIV/AIDS and people who inject drugs.
- **The World Health Organization (WHO)** and other relevant United Nations (UN) agencies to develop treatment guidelines for HCV treatment for HIV/HCV co-infected people and HCV mono-infected persons in low and middle income countries and to develop a prequalification process for bio-similars that facilitates access to pegylated interferon.
- **Researchers** to gather and provide evidence on feasibility and effectiveness of treatment in low and middle income countries, with a focus on disproportionately affected populations, particularly people who inject drugs.
- **International donors** to support community mobilization and treatment preparedness and literacy, as well as treatment cost, which are crucial for access to treatment.

The Washington Call

@www.hepcoalition.org

Advocacy materials



P I L L S
C O S T
P E N N I E S

1st Hepatitis C Virus World Community Advisory Board Report

G R E E D
C O S T S
L I V E S

UN Leadership

MISSING

Leadership by WHO Director
Dr Margaret Chan



**The HCV time bomb
is ticking...**

**185 MILLION INFECTED
3-4 MILLION NEW INFECTIONS PER YEAR
350,000 DEAD ANNUALLY FROM HCV**



DEFUSE HEPATITIS C, THE VIRAL TIME BOMB: TEST AND TREAT HEPATITIS C




Position Paper for the 67th World Health Assembly, May 19–24, 2014

The World Health Organization (WHO) has referred to hepatitis C as a “viral time bomb.”

In 2010, the 63rd World Health Assembly (WHA) adopted the first resolution on viral hepatitis; a new resolution will be presented at this Assembly.

Globally, an estimated 185 million people have been infected with the hepatitis C virus (HCV). Since 2010, more than a million of them have died from HCV-related liver disease, **although hepatitis C is treatable and curable**. Since 2010, nine to twelve million people have become infected with hepatitis C, **although it is preventable**. Most new infections occur among people who inject drugs (PWID), yet access to sterile injection equipment and other HCV prevention tools is staggeringly inadequate, reaching only a tiny percentage of those who need it. This shocking public health failure allows the epidemic to continue spreading.



| Compare Data | | | |
|-----------------------------------------------|----------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------|
| |  Vietnam ✕ |  Georgia ✕ |  France ✕ |
| General Information ▾ | General Information | General Information | General Information |
| 1. Epidemiological data ▾ | 1. Epidemiological data | 1. Epidemiological data | 1. Epidemiological data |
| 2. Test and Diagnostics ▾ | 2. Test and Diagnostics | 2. Test and Diagnostics | 2. Test and Diagnostics |
| 3. Treatment ▾ | 3. Treatment | 3. Treatment | 3. Treatment |
| 4. Policy ▾ | 4. Policy | 4. Policy | 4. Policy |
| 5. Organization ▾ | 5. Organization | 5. Organization | 5. Organization |





Public demonstrations

Incredible India





Solidarity campaigns

Conclusion

IT'S POSSIBLE FOR  MERCK &  TO DROP THEIR PRICES!

**LIFE BEFORE
PRO\$FIT**

 *Have a heart...* 

**SAVE MY
LIVER!**

www.hepCoalition.org

**ALLS
COST
PENNES**


\$84,000

**GREED
COSTS
LIVES**

Pricing campaigns

**GILEAD'S HCV DRUG SOFOSBUVIR
APPROVED BY THE FDA**

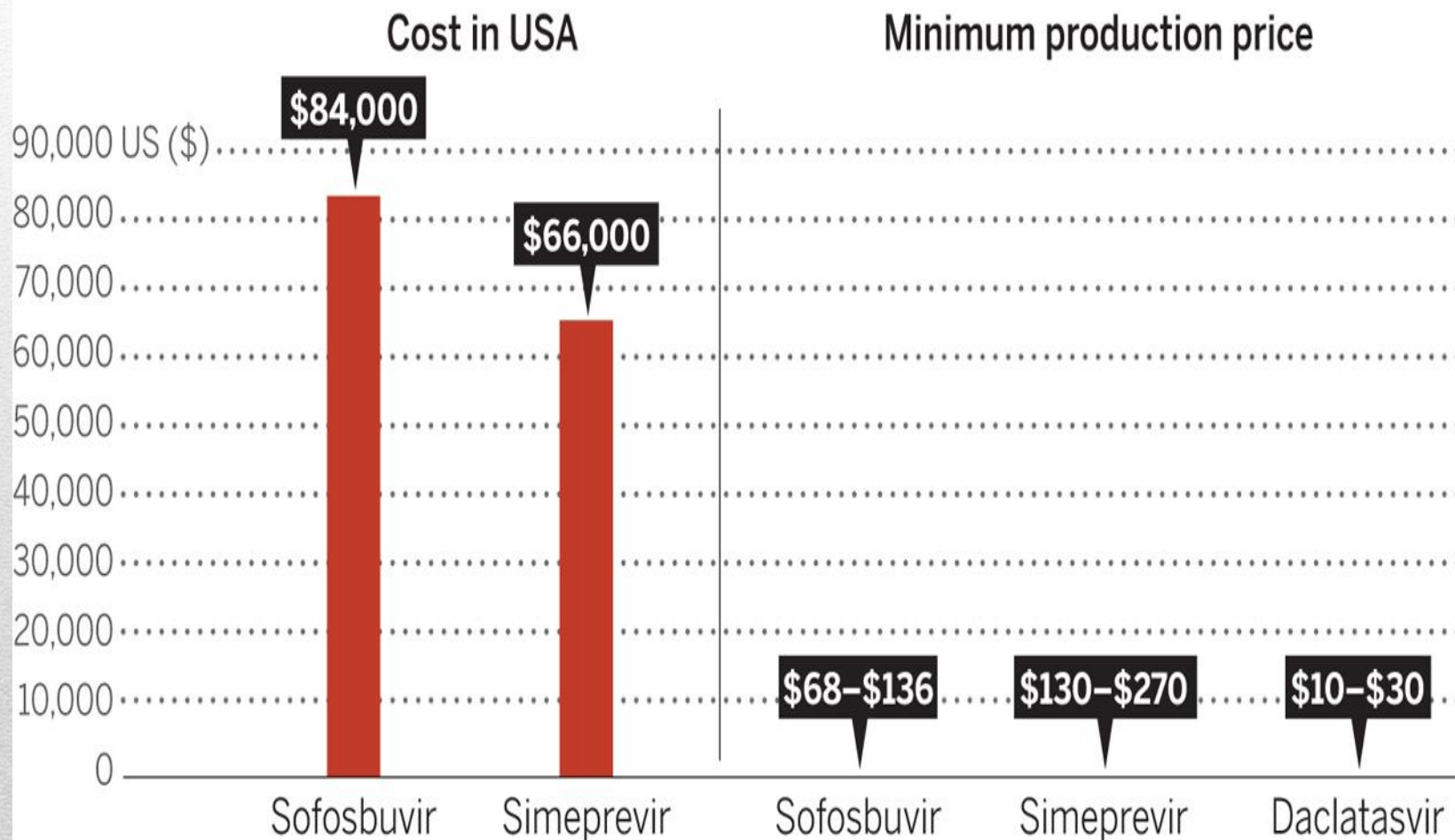


**BUT ACCESSIBLE
FOR HOW MANY?**

Sticker shock

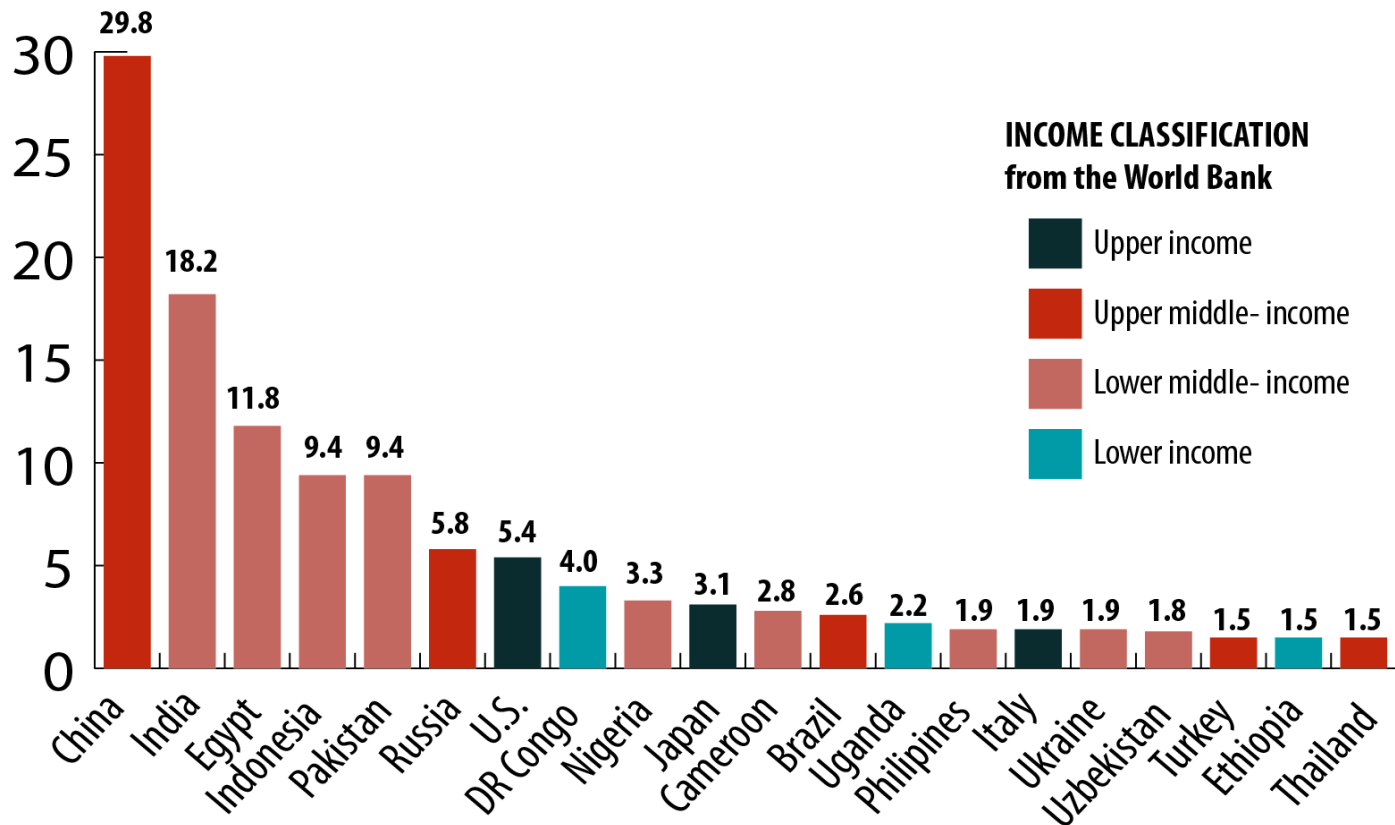
Costs of new drugs for hepatitis C per person, 12-week course

New generation drugs for HCV



Prevalence of Hepatitis C

NUMBER OF INFECTED PEOPLE
IN MILLION



Source: Evolving epidemiology of hepatitis C virus (Clin Microbiol Infect. 2011; 17(2): 107-115)

HCV is concentrated in middle-income countries

GILEAD'S LICENSE:

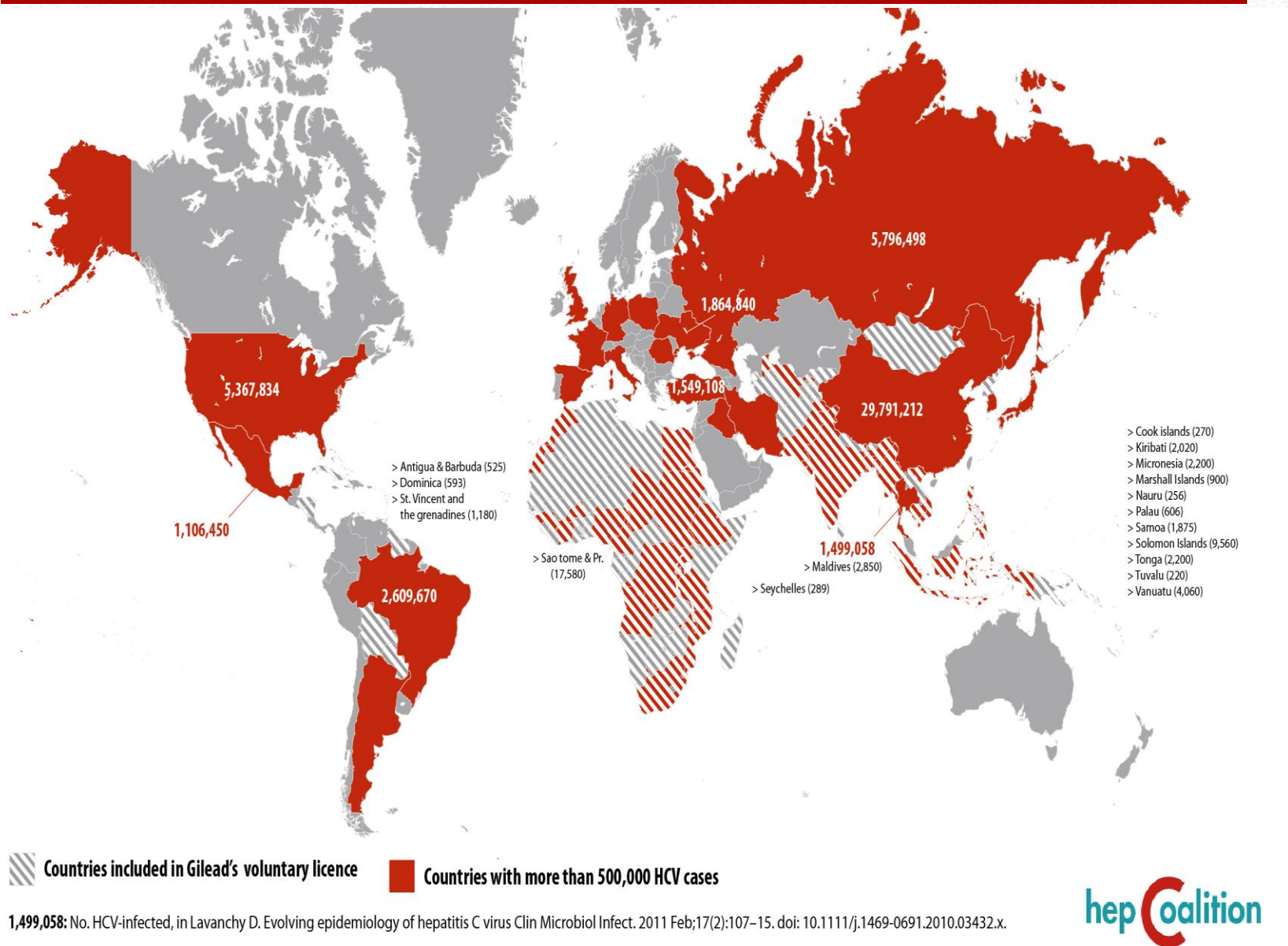
MYTH:

Gilead says that their reduced US\$900 price per course of sofosbuvir is fair.

FACT:

The same amount of sofosbuvir can be produced—profitably—for US\$ 101.

NO BARGAIN



Universal access, not restrictive voluntary licenses

Imposing non-evidence-based eligibility criteria:

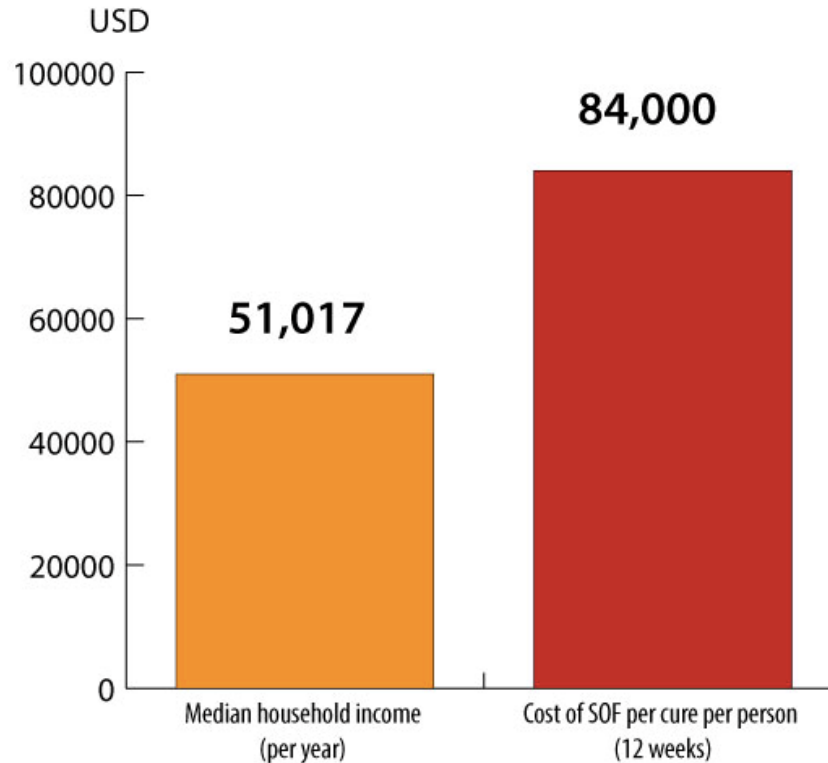
- Drug- and alcohol-free
- Chronic infectious disease

Restricting who can prescribe DAAs

Requiring proof that treatment is working

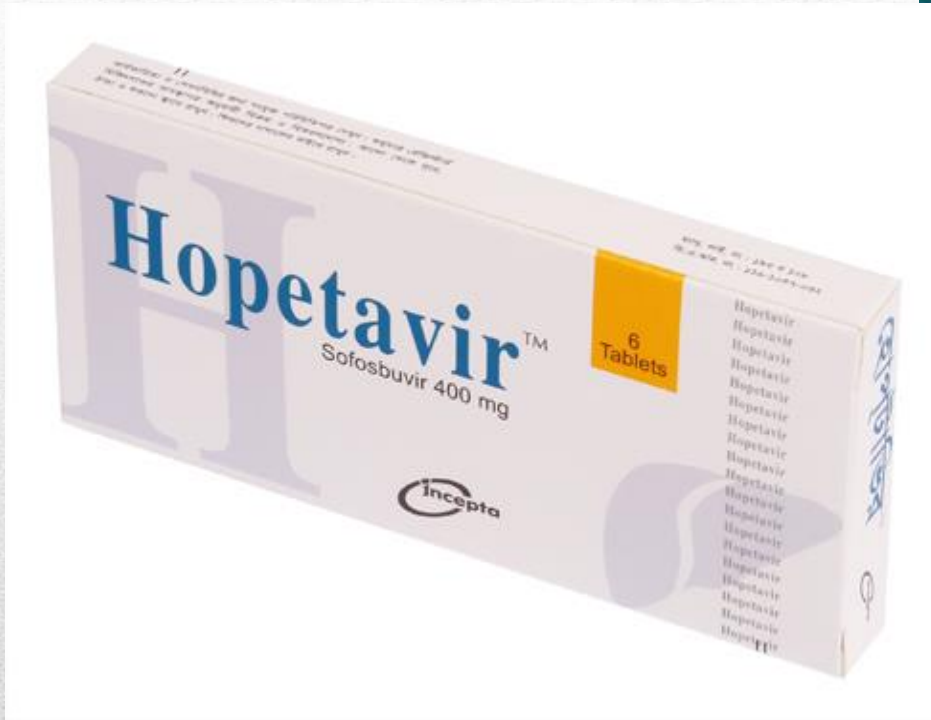
**High Prices =
Treatment Rationing**

**U.S. median household income (per year)
vs. cost of SOF per cure per person (in USD)**



High Prices = Bankruptcy

Bangladesh



India



Generic DAAs

High Cost of Hepatitis C Drug Prompts a Call to Void Its Patents

By ANDREW POLLACK

Activists in several countries are seeking to void patents on the blockbuster hepatitis C drug Sovaldi, saying that the price being sought by the manufacturer, Gilead Sciences, was prohibitive.

The Initiative for Medicines, Access and Knowledge, a legal group in New York, is expected to announce Wednesday that it has filed challenges in Argentina, Brazil, China, Russia and Ukraine. In all those countries except China, the organization is being joined by local patient advocacy groups.

The actions are a sign that the controversy over Sovaldi is spreading beyond the United States, where the \$84,000 charge for a course of treatment has strained Medicaid budgets, to middle-income countries.

high-income country by World Bank standards.

I-MAK, as the New York organization is known for short, estimates it would cost \$270 billion to treat the 40 million people with hepatitis C in those five countries, assuming Gilead charges most of the other countries the \$7,500 a treatment it is proposing in Brazil.

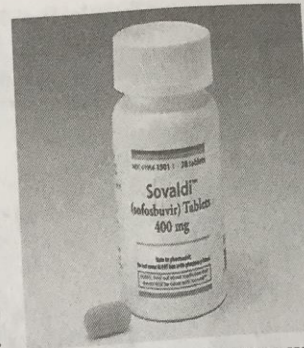
A generic version would lower the price in middle-income countries.

“What that means in simple terms is that people who need the drug are not getting it or are not

I-MAK officials said it would be too expensive for them to try to nullify Gilead’s patents in the United States. But they say they have received inquiries from others, whom they would not identify, who might be interested.

Gregg H. Alton, executive vice president for corporate and medical affairs at Gilead, said the company was “working to facilitate broad patient access to its hepatitis C treatments as quickly as possible in as many places as possible.” He said at least 50,000 people in lower-income countries had already been treated with sofosbuvir.

“We recognize that challenges to our intellectual property are an inevitable consequence of implementing such a worldwide access effort with such breakthrough products,” he said in an emailed statement. Gilead has also faced challenges to its patents for other drugs, some from



GILEAD SCIENCES, VIA ASSOCIATED PRESS

A course of treatment with Sovaldi costs \$84,000 in the United States.

cases, preventing liver damage, she said.

Ms. Vieira, coordinator of a coalition called the Working Group on Intellectual Property for the Brazilian Network for the Integration of Peoples, said that with more than \$16 billion in global hepatitis C sales since Sovaldi reached the market in late 2013, Gilead “has already recouped

said.

That may be a hard case to make. Even the deputy patent controller in India, a country in which it is notoriously difficult to patent drugs, wrote in his decision in January that he had “no hesitation to acknowledge the novelty and inventive step” of sofosbuvir.

Nevertheless, he denied the patent under a controversial clause in India’s patent law that requires a patented drug to be more effective in treating patients than an older, similar one. The clause was the reason the Supreme Court of India denied patent to Novartis for its highly effective leukemia drug, Glivec.

In the case of sofosbuvir, Gilead had failed to show that sofosbuvir was more effective than a compound disclosed in a filing by another company. Gilead says it was never developed as a drug. The compound has now been sent back to the



Hepatitis C Treatment w/o Borders

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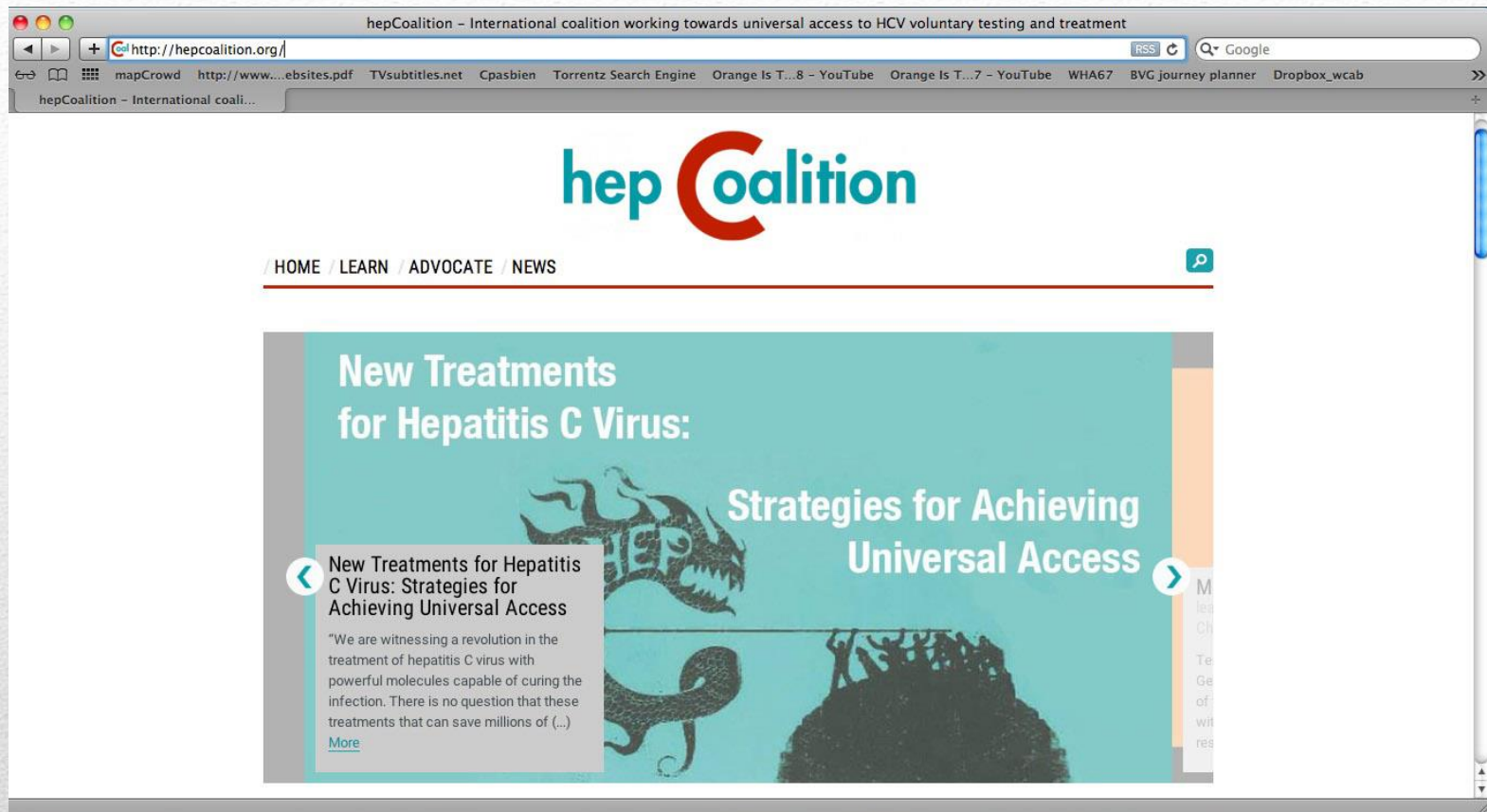
Add File

MEMBERS

370 members (369 new)

- MapCrowd **launch in 2016**
- Strengthen and expand hepCoalition (HIC and LMIC)
- Support access to generic DAC and SOF/DAC FDC
 - ✓ Expedite prequalification of generic DAC – push WHO
 - ✓ Support DAC patent oppositions
 - ✓ Fight for VLs with no geographical scope
- Decriminalization of drug use/people who use drugs
- Support scale-up of comprehensive harm reduction services and treatment for people who inject drugs

HepCoalition -- Next Steps



Visit: www.hepCoalition.org

**Special thanks: Chloé Forette, Tracy Swan,
and hepCoalition partners**