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)

- ~185 million people have been infected with HCV
- ~130-150 million people live with chronic hepatitis C
- ~26-30 million people live with fibrosis stage F3-F4

HIV / HCV
SILENCE = DEATH
I-Mak
Initiative for Medicines, Access & Knowledge

Global Network of People Living with HIV

Treat Asia
Therapeutics Research • Education • AIDS Training

Access
HCV Treatment

Tag
Treatment Action Group

Aids Access Foundation

APN Plus
Positive Change

Apalnc
International HIV/AIDS Alliance in Ukraine

InpuD
International Network of People who Use Drugs

Doctors of the World

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.
Advocacy materials

ACTIVIST STRATEGIES
for Increasing Access to HCV Treatment in Low- and Middle-Income Countries
February 2015

PILLS COST PENNIES

1st Hepatitis C Virus World Community Advisory Board Report

GREED COSTS LIVES
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

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.
Public demonstrations
Solidarity campaigns

Incredible India

Don't shut down the pharmacy of the developing world!
Pricing campaigns

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

LIFE BEFORE PROFIT

Have a heart...

SAVE MY LIVER!

www.hepCoalition.org

PILLS COST PENNIES

$84,000

GREED COSTS LIVES
Sticker shock

Gilead’s HCV Drug Sofosbuvir Approved by the FDA

$84,000

But accessible for how many?
Costs of new drugs for hepatitis C per person, 12-week course

New generation drugs for HCV

<table>
<thead>
<tr>
<th>Drug</th>
<th>Cost in USA</th>
<th>Minimum production price</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sofosbuvir</td>
<td>$84,000</td>
<td>$68–$136</td>
</tr>
<tr>
<td>Simeprevir</td>
<td>$66,000</td>
<td>$130–$270</td>
</tr>
<tr>
<td>Daclatasvir</td>
<td></td>
<td>$10–$30</td>
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</tbody>
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Andrew Hill and Graham Cooke Science 2014;345:141-142
Prevalence of Hepatitis C

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
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.

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 patent on sofosbuvir, which some experts say was not the result of an “inventive step” of research.

That may be a hard case to make. Even the deputy patent controller in India, a country in which it is notoriously difficult to challenge 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 drug.

The clause was the reason the Supreme Court of India denied Gilead’s patent to Novartis for its hepatitis C drug Glivec, which it was developing as a drug. The case was sent back to the lower court in December.

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

Cases of hepatitis C are on the rise, with an estimated 1 million cases in the United States, according to the Centers for Disease Control and Prevention.

Yet, in the United States, the drug is being prescribed to only 300,000 patients.
• 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

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