Access to hepatitis medicines

Dr Andrew Hill, PhD,
Department of Translational Medicine
University of Liverpool, UK
Worldwide, 69.6 million HCV infected in 2016

1.5 million cures

350,000 HCV related deaths

1.04 million non-HCV related deaths
Changes in HCV prevalence: 2016-2017

Worldwide, 68.5 million HCV infected in 2017 (-1.8%)

- 1.6 million new HCV infections
- 1.5 million cures
- 350,000 HCV related deaths
- 1.04 million non-HCV related deaths

Database: CDA Foundation
Changes in HCV prevalence: 2016-2017

USA: -9%
Canada: -6%
Brazil: -4%
Egypt: -11%
Spain: -9%
Russia: +4%
India: +1%
Japan: -13%
China: -13%
Australia: -13%
We need to diagnose and treat at least 5 million people worldwide every year, to achieve WHO elimination targets by 2030.
Can we afford this?

What is the real cost to cure Hepatitis C?
Active Pharmaceutical Ingredient
Raw drug substance

Database www.indiainfodrive.com shows exports of API from India to other countries, with costs of API, for many drugs

1 kg sofosbuvir = $1050 (30 patients)
1 kg daclatasvir = $1030 (190 patients)
### Prices and costs of drugs to treat HIV, HBV, HCV and TB

<table>
<thead>
<tr>
<th>DRUG</th>
<th>USA PRICE</th>
<th>GLOBAL LOWEST PRICE</th>
<th>ESTIMATED PRICE</th>
<th>PATENT EXPIRY (US)</th>
</tr>
</thead>
<tbody>
<tr>
<td>TDF/3TC/EFV</td>
<td>$28,204*</td>
<td>$107</td>
<td>$82</td>
<td>Generic</td>
</tr>
<tr>
<td>TDF/FTC</td>
<td>$17,258</td>
<td>$67</td>
<td>$54</td>
<td>Generic</td>
</tr>
<tr>
<td>Entecavir</td>
<td>$5,915</td>
<td>$409</td>
<td>$82</td>
<td>Generic</td>
</tr>
<tr>
<td>SOF+LDV</td>
<td>$91,207</td>
<td>$307</td>
<td>$79</td>
<td>2028-2032</td>
</tr>
<tr>
<td>SOF+DCV</td>
<td>$142,710</td>
<td>$78</td>
<td>$47</td>
<td>2028-2031</td>
</tr>
<tr>
<td>TB: RHZE</td>
<td>$945</td>
<td>$27</td>
<td>$38</td>
<td>Generic</td>
</tr>
</tbody>
</table>

*for TDF/FTC/EFV; HCV – per 12-week course, TB – per 6 month course, HIV and HBV – per year. Patent expiries from US FDA Orange Book (oral dosing)*
Lowest prices of SOF/DCV in selected countries

Price of a 12-week course in USD

- USA (NADAC): $142,710
- Denmark: $104,723
- Norway: $96,404
- Germany: $87,632
- United Kingdom: $84,281
- Sweden: $76,757
- France: $68,280
- Argentina: $65,616
- Saudi Arabia: $50,059
- Spain: $47,972
- Brazil: $37,729
- Australia: $33,800
- Thailand: $29,361
- Egypt: $120,000
- India: $100,000
- Estimated: $47
Hepatitis C drug sales 2014-17

Cumulative sales of all Hepatitis C drugs, 2014 to 2017:

$66 billion

Gilead Profits in 2015:

$18 billion

Reference: Gilead quarterly product sales summaries
SOF/DCV can now be produced for <$50 per 12-week treatment course.\textsuperscript{1}

At $50 per course, it would cost $3.5 billion to treat all 70 million people infected with HCV worldwide.

Global sales of HCV DAAs from 1Q2014 to 2Q2017 average $1.6 billion per month.

Therefore, all 70 million people with HCV worldwide could be treated for the equivalent of 10 weeks of commercial sales of the HCV DAAs.

\textsuperscript{1} Hill and Gotham 2017, July 2017, International AIDS Society Conference, Paris, France
Do we already have good quality generic drugs for HCV?

How well do they work in clinical practice?
Sofosbuvir/daclatasvir has the same cure rates as the best treatments available: ENDURANCE-3
Global Cure Rates for HCV Generics

- **GT1**: 93% (392/421)
- **GT2**: 100% (38/38)
- **GT3**: 89% (156/176)
- **GT4**: 93% (13/14)
- **GT5/6**: 100% (9/9)
High quality sofosbuvir and daclatasvir with bioequivalence can be made cheaply.

Global Analysis Projects World Far From Goal of Eliminating HCV

Russian Buyers Club: 98% cured with generic DAAs
Australian Buyers Club: 93% cured with generic DAAs
Conclusions

We already have high quality, bioequivalent generic drugs available, which can cure Hepatitis C in over 90% of patients.

Sofosbuvir/dacalatasvir is equivalent to the best treatments for Hepatitis C.

Minimum prices are already $78 - $120 per treatment course. These prices could fall below $50 in the future.

Some generics are already pre-qualified by WHO and approved by the Global Fund for AIDS, TB and malaria.
Pharmaceutical companies have already made huge profits:

$66 billion in Hepatitis C drug sales from 2014-2017, rising all the time

Enough is enough – now we need to lower HCV drug prices:

Low-income countries: $50 to $150 per cure  
Middle-income countries: $150 to $500 per cure  
High income countries: $500 to $3000 per cure

We can only eliminate Hepatitis C worldwide if we can negotiate affordable prices