

# Minimum prices of generic Hepatitis C Direct Acting Antivirals fall below US \$50 per person cured

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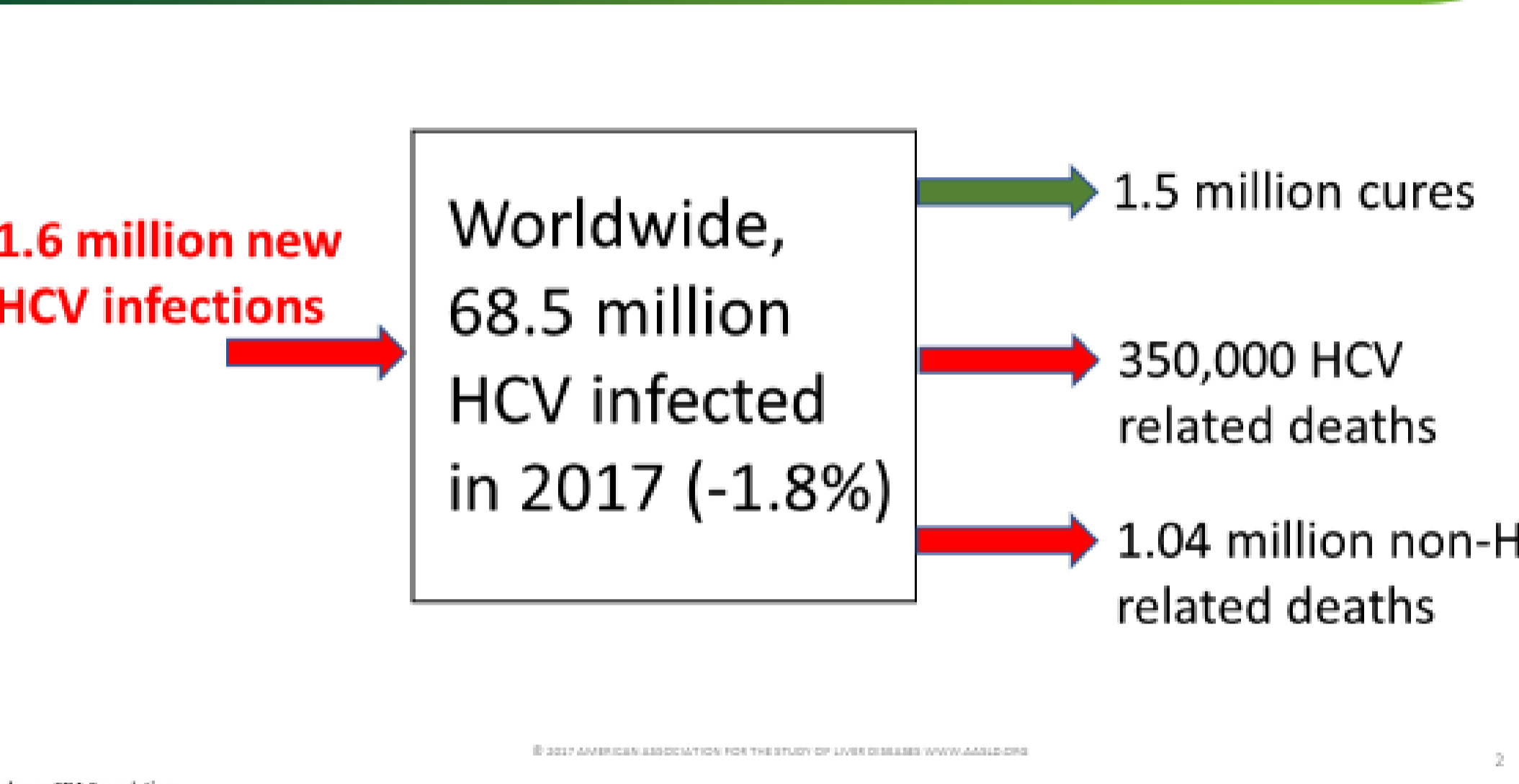
**Background:** Worldwide in 2016, there were 1.6 million people cured of Hepatitis C (HCV) using Direct Acting Antivirals (DAAs), but 1.5 million new HCV infections. Elimination of HCV will only be possible by 2030 if at least 5 million people are cured each year. The World Health Organization has pre-qualified 3 generic API forms of SOF and 2 formulations of DCV. Using data on exports of raw materials in 2015-18, we calculated currently feasible generic prices of HCV DAAs, and compared to current national prices.

**Methods:** Data on per-kilogram prices of sofosbuvir (SOF), daclatasvir (DCV), ledipasvir (LDV) and velpatasvir (VEL) active pharmaceutical ingredients (API) exported from India were extracted from an online database (www.datamyne.com). All costs were calculated in US dollars (\$). To calculate the cost of the amount of API needed for a 12-week treatment course, we added cost estimates for formulation (\$0.01 per tablet), packaging (US\$0.35/month), and a profit margin of 26%. National prices were extracted from online price databases.

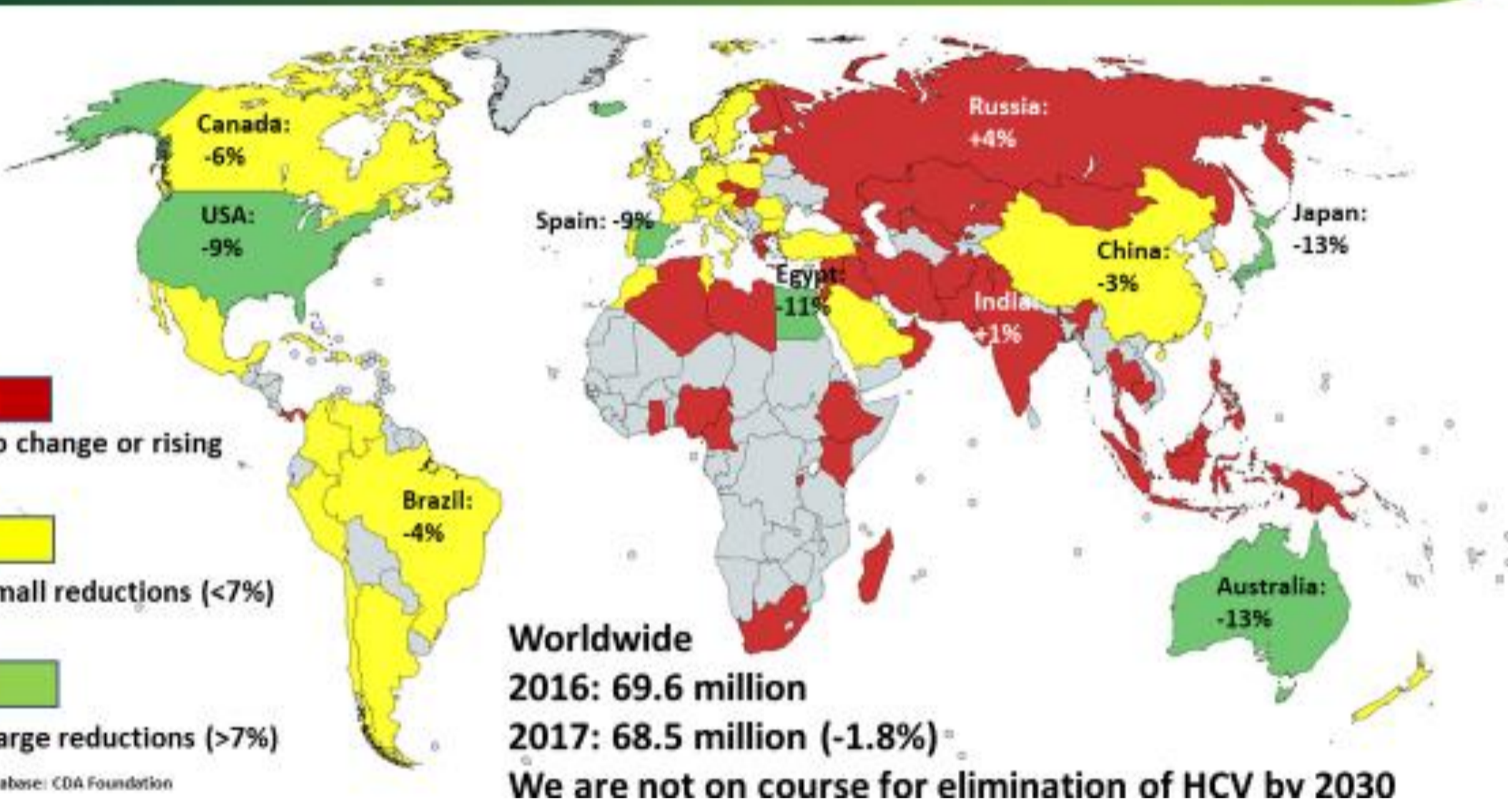
**Results:** The cost of exported SOF API has fallen from \$10,100/kg in January 2015 to \$970/kg in January 2018. Costs of API are currently \$750/kg for DCV, \$2250 for LDV and \$9046 for VEL. The predicted minimum production price for SOF/DCV is now \$48 per 12-week treatment course. Five generic formulations of SOF and four generic DCV have shown bioequivalence with originator drugs, by FDA criteria. As shown in Table 1, prices of generic SOF/DCV for public tenders in India are close to predicted minimum costs of production. Prices for sale to individuals in India are higher (Table 1). Prices of SOF/DCV in Egypt, Pakistan and Iran are also under \$100 per 12-week course. By contrast, in high income countries, costs per 12-week course are approximately \$8000 to \$20,000, including discounts. Global sales of DAAs worldwide now total over \$77 billion since launch.

**Conclusions:** The costs of generic production of HCV DAAs are falling rapidly. SOF/DCV combination treatment can now be produced for US\$48 per patient per 12-week course. SOF/DCV is already on sale in India for \$69 per cure. At these low prices, elimination of HCV worldwide could be feasible. Countries need to demand lower prices for HCV DAAs, to make elimination strategies affordable.

## Changes in HCV prevalence: 2016-2017



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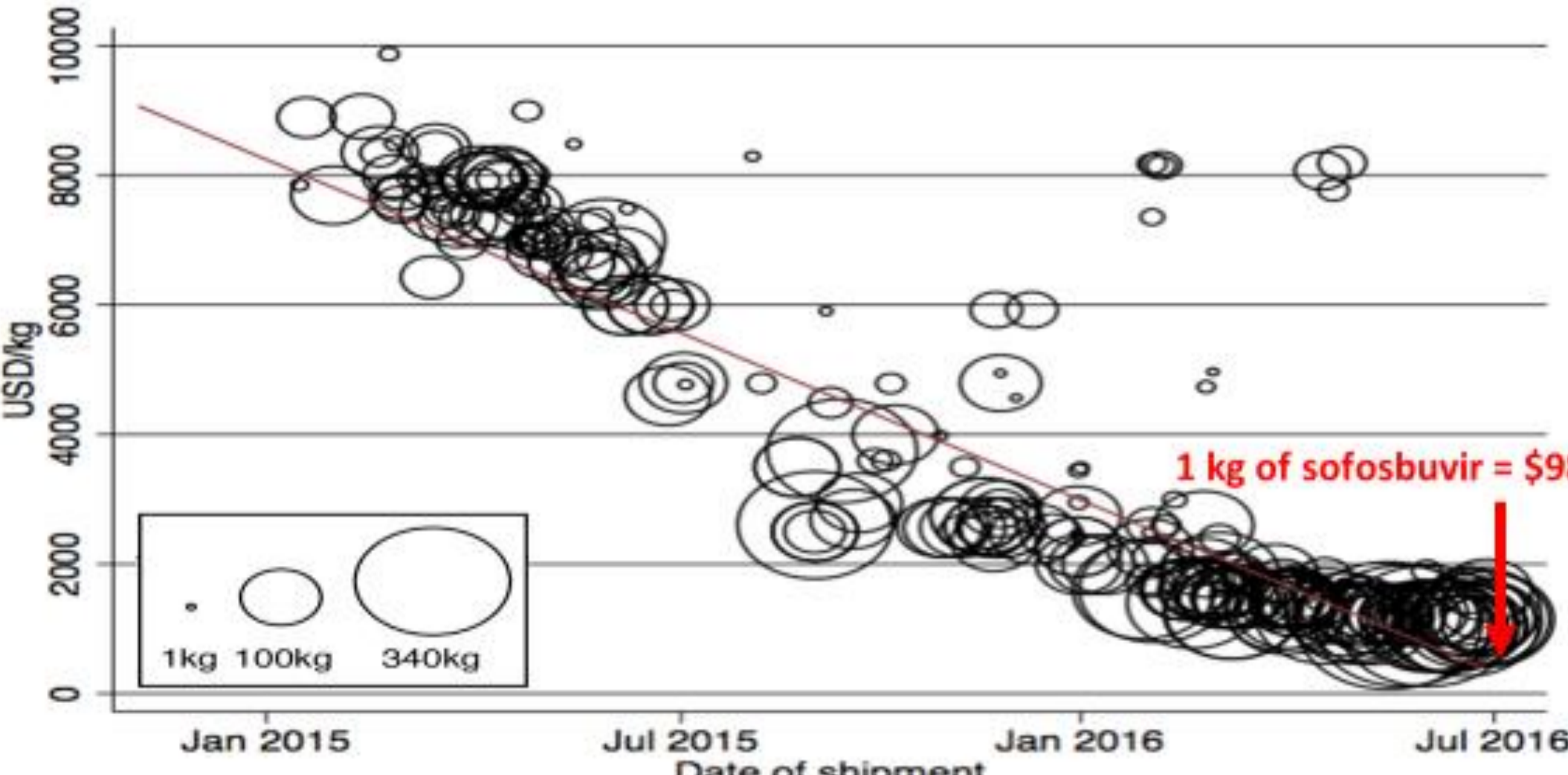


## Hepatitis C DAA sales, 2014-2018

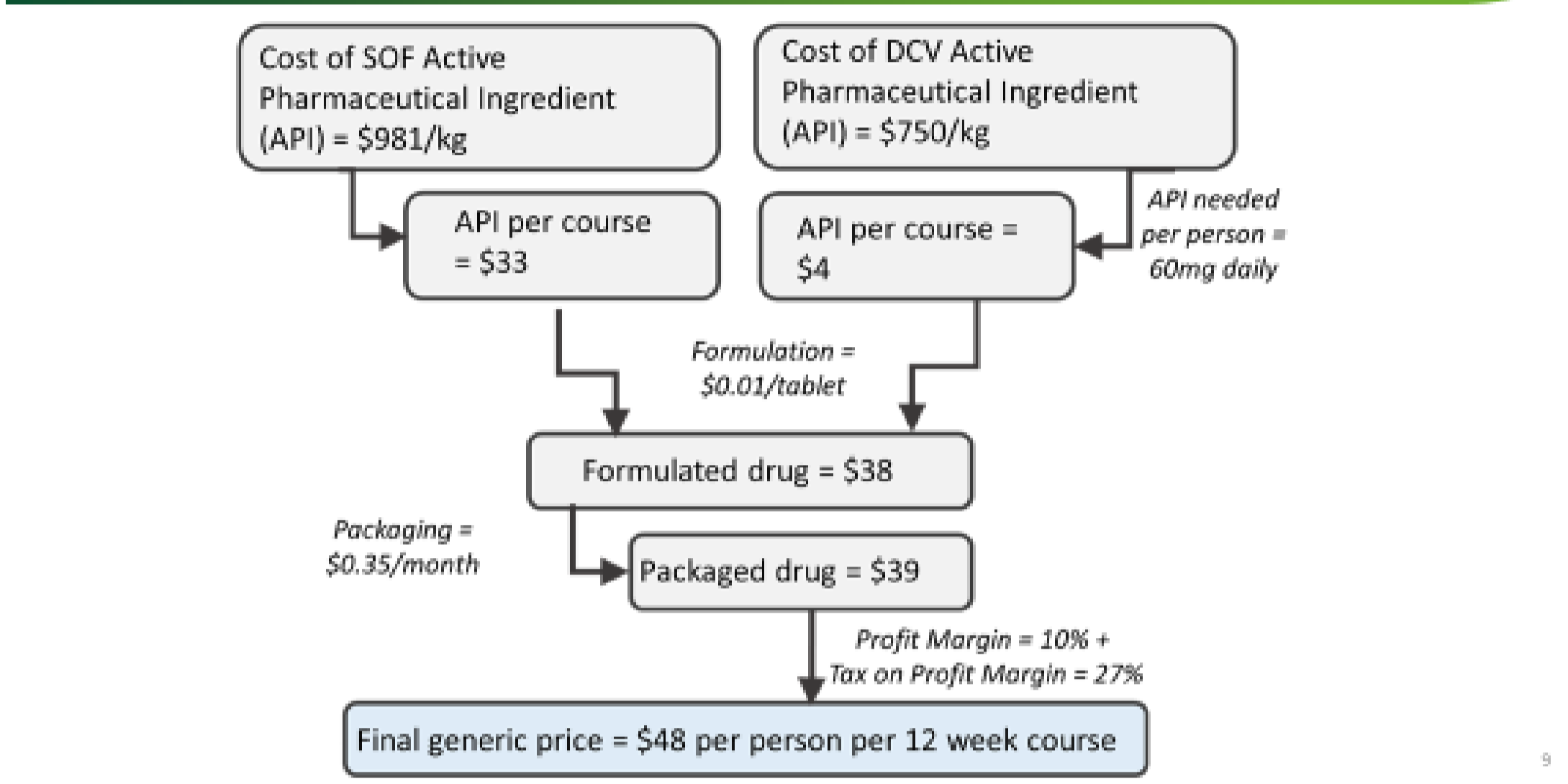


**Active Pharmaceutical Ingredient**  
 Raw drug substance Database  
 www.indianfordrive.com shows exports of API from India to other countries, with costs of API, for many drugs  
 1 kg sofosbuvir = \$981 (30 patients)  
 1 kg daclatasvir = \$750 (190 patients)

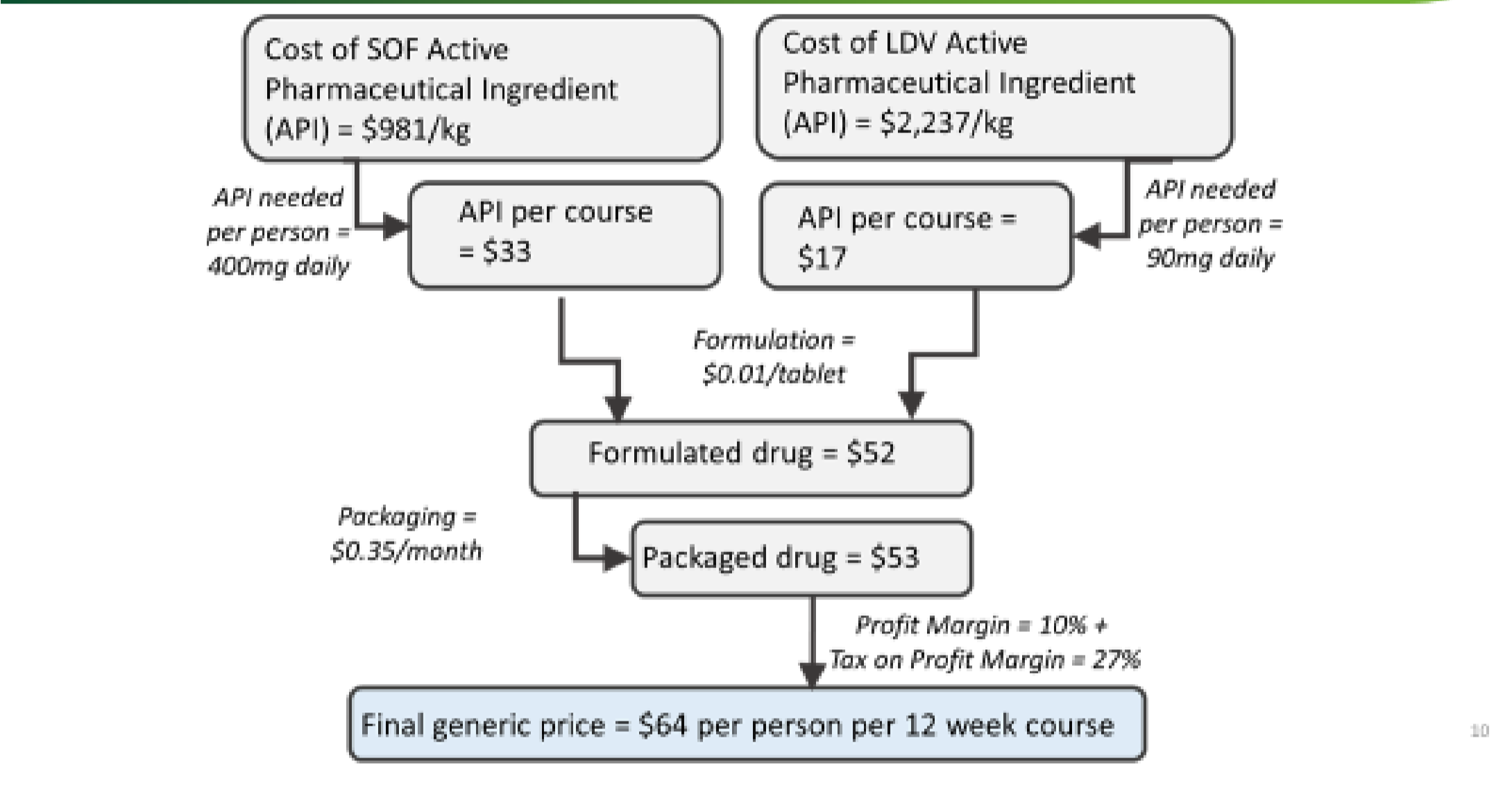
## Changes in cost/kg of SOF API



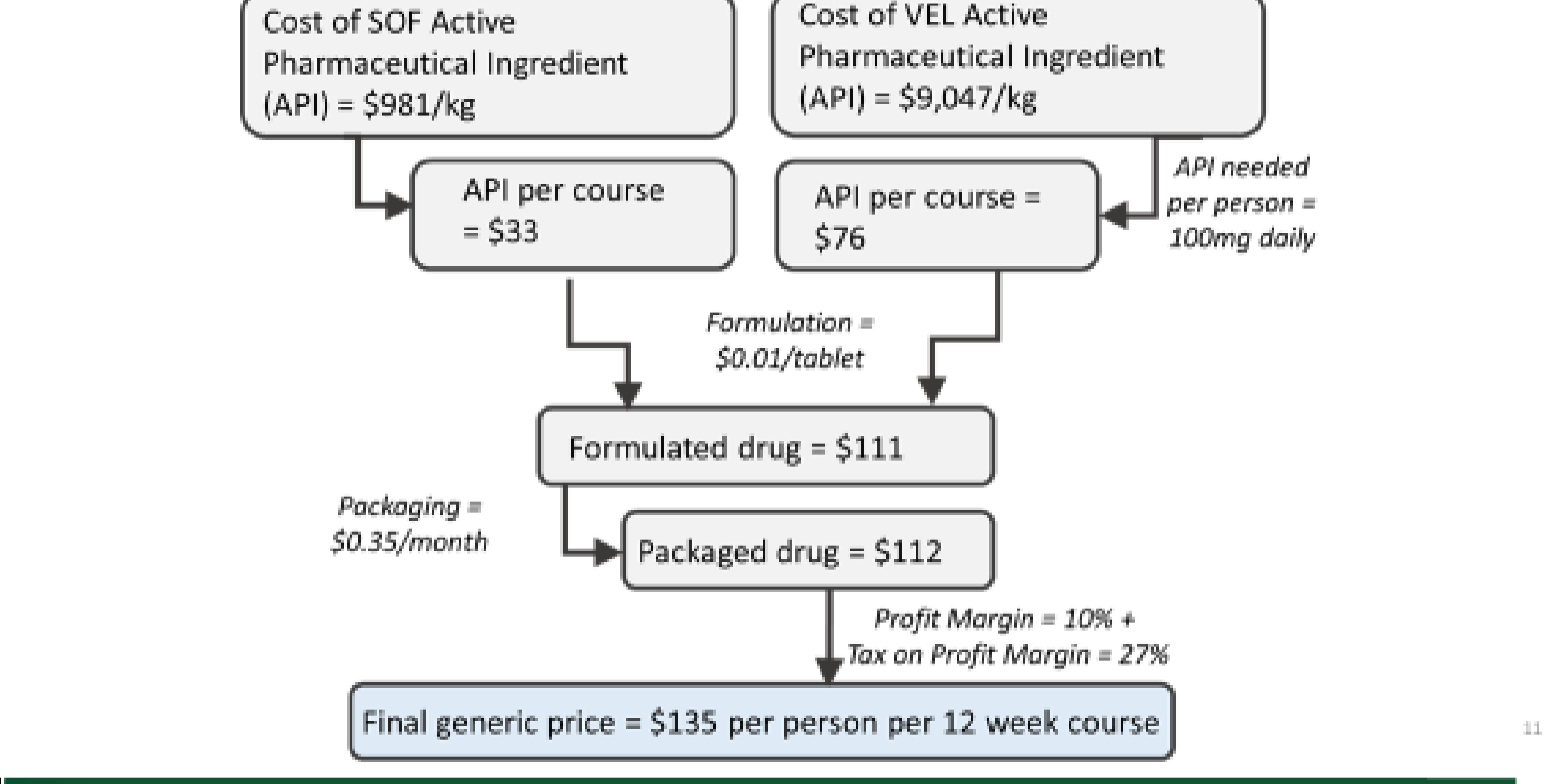
## Cost per cure, SOF/DCV: \$48



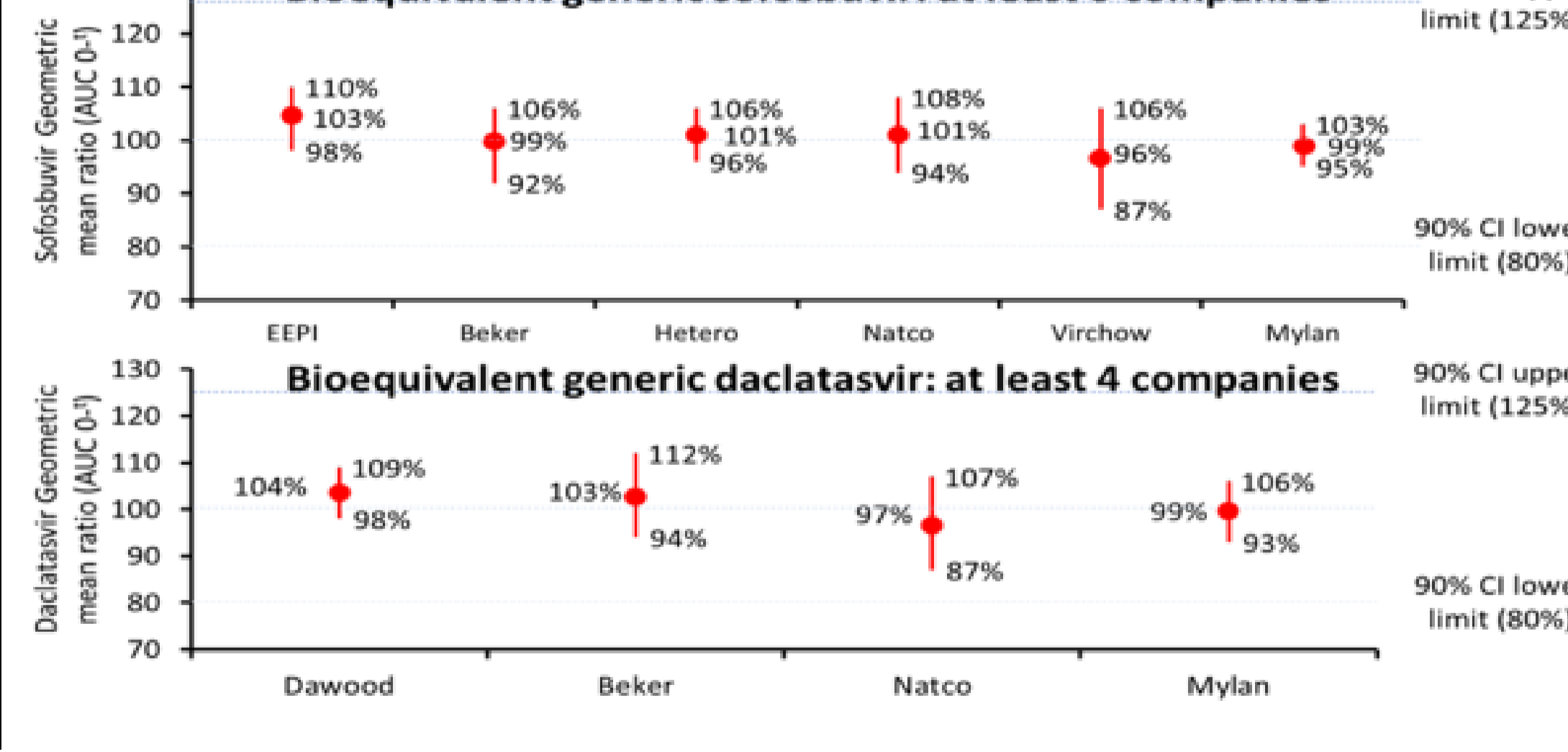
## Cost per cure, SOF/LDV: \$64



## Cost per cure, SOF/VEL: \$135



## Bioequivalent generic HCV DAAs



## Gilead selling generic DAAs in USA

**Press Release: Gilead Subsidiary to Launch Authorized Generics of Eplclusa® (Sofosbuvir/Velpatasvir) and Harvoni® (Ledipasvir/Sofosbuvir) for the Treatment of Chronic Hepatitis C (September 24<sup>th</sup> 2018)**

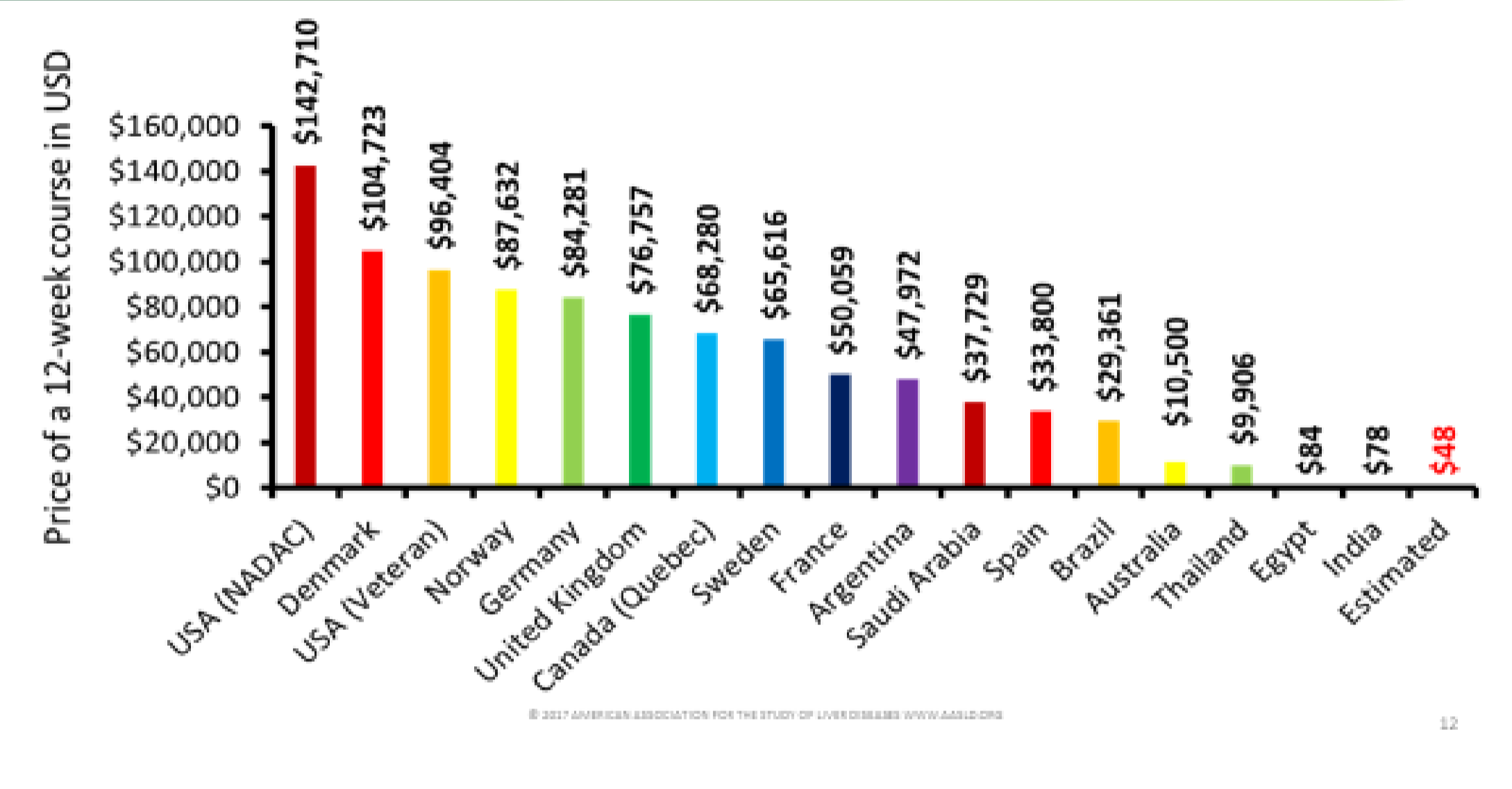
Price of generic SOF/LDV in USA: \$24,000 / cure  
 Cost of generic production: \$68 / cure

## WHO approved generic HCV DAAs

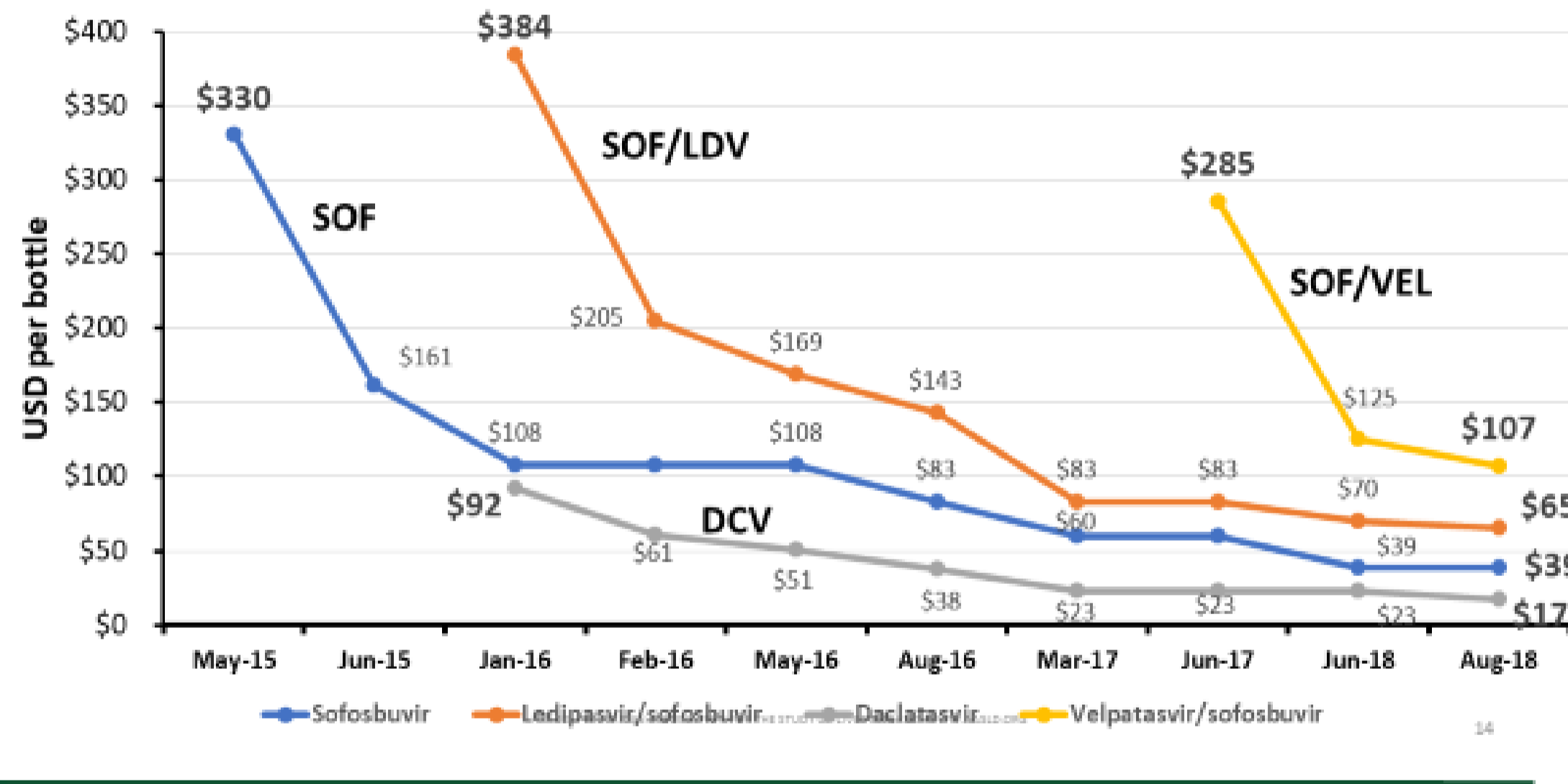
**WHO pre-qualified:**  
 Sofosbuvir – Mylan, Hetero and Cipla

**Global Fund / WHO Expert Review Panel:**  
 Daclatasvir – Mylan, Hetero and Cipla  
 SOF/DCV - Cipla  
 SOF/LDV – Strides

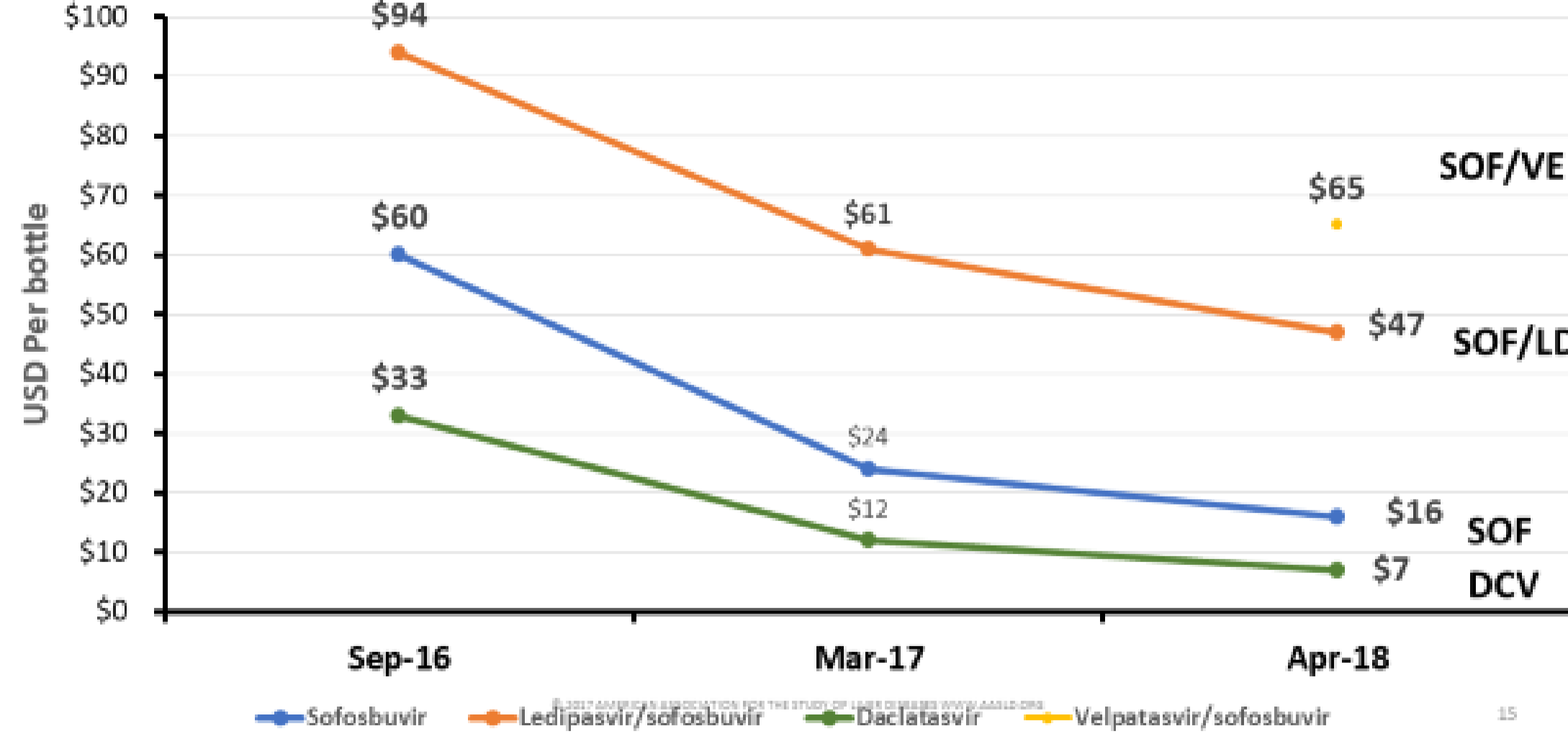
## List prices of SOF/DCV by country



## Indian private market: monthly prices



## Indian public market: monthly prices



## The real cost of HCV elimination

SOF/DCV can now be produced for <\$50 per 12-week treatment course.

At \$50 per course, it would cost \$3.5 billion to treat all 69 million people infected with HCV worldwide

Global sales of HCV DAAs from 1Q2014 to 2Q2018 average \$1.6 billion per month. Currently at \$1 billion per month.

**Therefore, all 69 million people with HCV worldwide could be treated for the equivalent of 4 months of commercial sales of the HCV DAAs**