

Specialty Drug Prices: A Major Health Care Cost Driver

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February 4, 2015

Specialty Drugs Costs Rising Dramatically

- The upward trend in specialty drug prices and their growing portion of pharmacy spend is very concerning
- Specialty drug prices increased 19% in 2012 – without which, overall pharmaceutical spending growth would have decreased. Double-digit increases are projected for 2014 and 2015
- In 2013, specialty drugs accounted for 1% of prescriptions written in the U.S., but 25% of drug spending
- U.S. spending on specialty prescription drugs is projected to **quadruple** rising from \$87.1 billion in 2012 to \$401.7 billion in 2020

Specialty drug trend

3 FACTS TO KNOW ABOUT THE FUTURE OF **SPECIALTY DRUG SPENDING**

1 U.S. spending on prescription drugs totaled \$263.3 billion in 2012—**25% of which was spent on specialty drugs.**

Source: Express Scripts, Drug Trend Report, Specialty Therapy Class Forecast, April 2014.

2 Spending on specialty drugs is estimated to quadruple by 2020—rising from \$87.1 billion in 2013 to \$401.7 billion in 2020.

Source: CVS Caremark, Specialty Trend Management Where to go Next Insights 2013

3 By 2020, specialty drug spending alone will represent **50% of all drug spending.**

Source: The Express Scripts Lab, The 2013 Drug Trend Report, April 2014.



the campaign for
SUSTAINABLE Rx PRICING

The Perfect Storm Has Arrived

- Now, we're seeing approvals of high-priced specialty drugs that are **non-orphan**, meaning they are not just for rare diseases
- Add to this trend a lack of true competition in the market . . . and you have a recipe for disaster
- Case study: Gilead's Sovaldi and Harvoni
- Treatments for hepatitis C, a contagious viral infection that causes chronic liver disease and affects 3 to 5 million Americans

Gilead's Hep C Treatments



- \$1,000 per pill
- Approved 2013
- \$84,000 for 12 week course
- Some patients need 24 weeks
- Once daily oral used with interferon
- Moderate to high cure rate

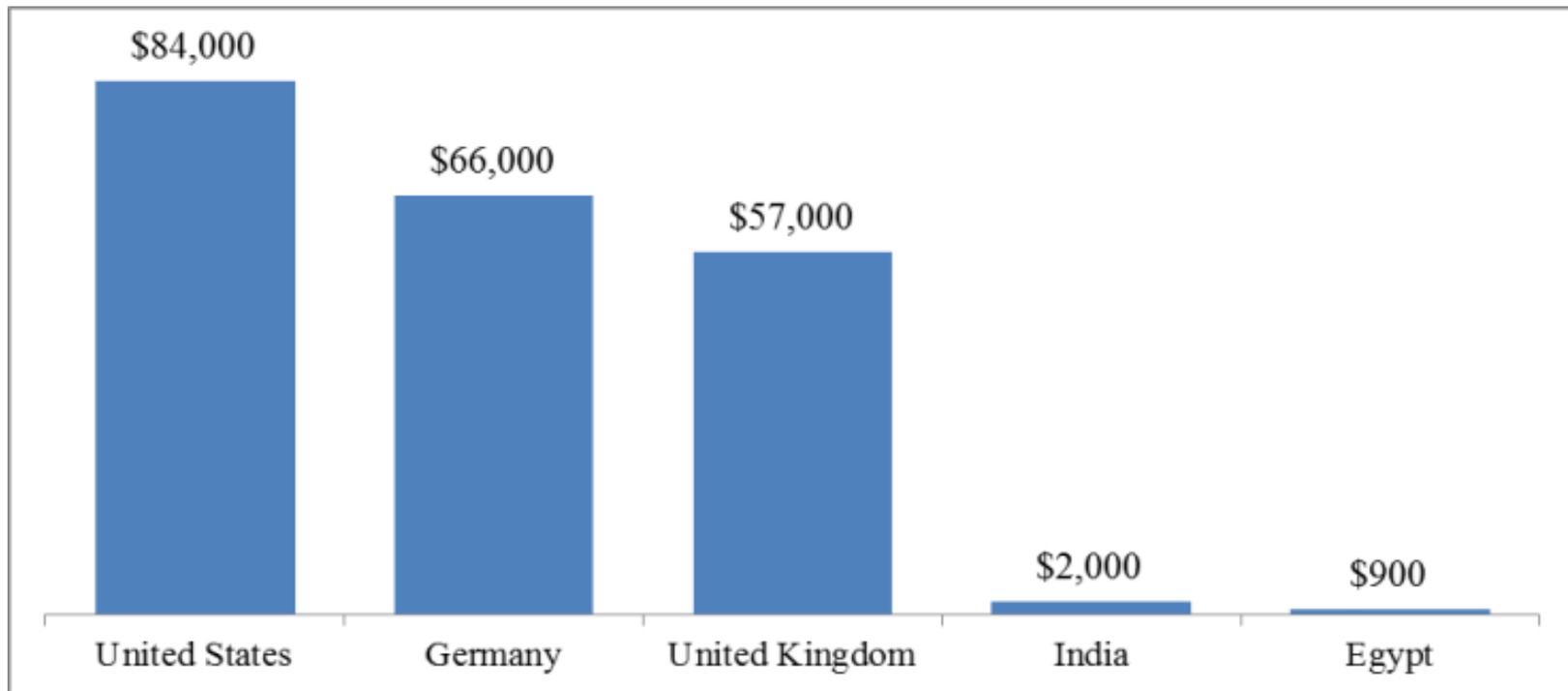
- \$1,125 per pill
- Approved 2014
- \$94,500 for 12-week course
- \$63,000 for 8-week course
- One pill containing two drugs
- All oral treatment
- Fewer side effects
- High cure rate

Gilead acquired Pharmasset and the rights to sofosbuvir for \$11 billion
Sofosbuvir generated over \$12 billion in revenue in 2014 (Sovaldi + Harvoni)

Orphan Drug Pricing for a Non-orphan Drug

- No one questions the clinical efficacy of the new hepatitis C drugs. They are significant advancements. But hepatitis is not a rare disease.
- This price tag on a drug for widespread use hinders access to a medication that can eradicate a serious public health disease.
- The pricing stands in the way of achieving the public health benefits that these drugs promise.
- To treat 3 million HCV patients in the U.S. at list price would cost around \$300 billion -- about the same amount we annually spend for all other drugs combined.

Sovaldi's pricing disparities



Source: AARP.org and B. Berkrot and D. Beasley, "U.S. lawmakers want Gilead to explain Sovaldi's hefty price," Reuters, March 21, 2014.

Economics are Driving Treatment Decisions

- Professional guidelines and public payers are recommending that Sovaldi be provided only to those with more advanced stages of liver disease.
- Physicians are being encouraged to consider “available resources” and “prioritize”.

“Based on available resources, immediate treatment should be prioritized as necessary so that patients at high risk for liver-related complications and severe extrahepatic hepatitis C complications are given high priority” - *American Society for the Study of Liver Diseases, Recommendations for Testing, Managing, and Treating Hepatitis C*

- Because of the price of these drugs, patients (and society) may not be able to fully benefit from it because they are not sick enough.

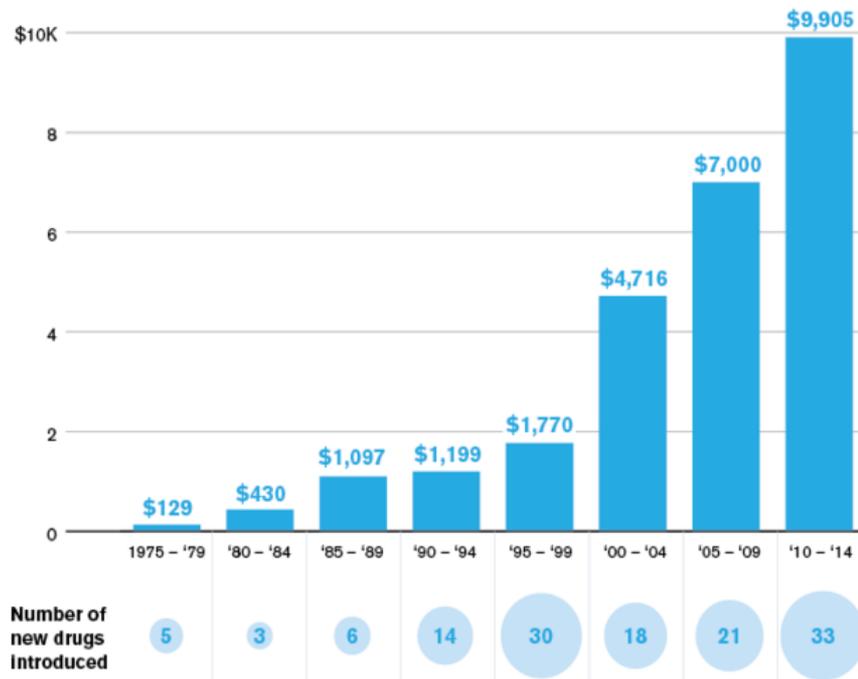
Sovaldi – the Canary in the Pipeline

Cancer Drugs Too

Cancer Drugs Hit Market at Ever-Higher Prices

U.S. prices for new cancer drugs have soared since the 1970s despite an increasing number of available brands.

Median monthly cost for new cancer drugs during the five-year period



Note: Costs are monthly Medicare prices for each drug the year it was introduced, adjusted for inflation.

Source: Peter Bach and Geoffrey Schnorr at Memorial Sloan Kettering Cancer Center

Bloomberg Graphics

Of 58 cancer drugs approved by the FDA between 1995 and 2013, launch prices increased by 10% a year, or about \$8,500.

The FDA approved 12 cancer drugs in 2012. Eleven of them were priced at \$100,000 per year.

Price of cancer drugs on the market for years are also increasing at dizzying rates.

Imatinib (Gleevec) was \$30,000 a year when it was approved in 2001 – it now costs \$92,000 per year.

Cancer drug prices doubled within the last decade, from an average of \$5,000 per month to \$10,000 per month.

“But Sovaldi is worth the price...”

- One argument is that these drugs are a value to the health care system because liver transplants are expensive. The math doesn't support this.
- Out of 3 million U.S. hepatitis C patients, only 30,000 (1%) will be transplant candidates.
- To treat all patients at the list price could cost up to \$300 billion

Treatment	Cost per treatment	Total Spent by System
Transplant	\$580,000	Up to \$17.4 billion
Sofosbuvir (alone)	\$84,000	Nearly \$300 billion

This is not a value to the health care system.

It is a return to the manufacturer.

Follow the money.

“But the market is working...”

- Yes, there are other similar hepatitis C drugs just now coming to market. But they are not creating true price competition.
- AbbVie’s hepatitis C drug approved in December – priced at \$83,319 for a course of treatment. That’s less than a **one percent** difference!
- Even discounts to large purchasers are illusory if the drug was excessively priced in the first place and the price goes up in future years.
- Drug makers know the price pressures will come – the list price anticipates discounts.

So What's the Answer?

- Body of law around Rx licensing and patents is vast and complex.
- No easy policy approaches, especially at the state level.
- We need a robust public dialogue about **sustainable drug pricing** and how drug prices impact affordability.
- We have to ask ourselves whether the price reflects the value of these medications.
- What are we willing to sacrifice to pay these prices?
- Drug makers can simply do the right thing - price their products fairly so that all who can benefit can access them without bankrupting the system.
- We can prevent this looming crisis – but the status quo is unacceptable.