Price and Affordability of Hepatitis C Drugs: How Did We Get Into This Mess?

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Disclosures

- Dr. Graham has joined Trek Therapeutics, a public benefits corporation

HCV Treatment: A Time for Celebration

- SVR rates >90% for nearly all patient groups
  - Gaps in cure rates for African Americans and HIV-coinfected patients finally closed
- Almost everyone can become a “treatment candidate”
- Potential to
  - Lower overall mortality
  - Improve quality of life
  - Reduce long-term costs of complications
  - Implement cure as prevention

Challenges Posed by High Price of HCV Drugs

- Media focus on $1,000 a pill gave cover to (and driven by) payers to impose rationing
- Payers disregard science/guidelines
- Loss of perspective by patients and providers about the value of HCV treatment and cure
- Difficulty advocating for treatment access due to lack of price transparency
- Hesitation to implement broader HCV screening and awareness programs
- Reinforcement that people with HCV infection are not “worth” expensive treatments

Cost is not Price

- Cost includes manufacturing and distribution costs, costs to meet regulatory requirements
  - Development costs are “sunk costs”
  - Marketing
- Price is the $$ amount actually paid to acquire a drug/regimen
  - Complicated supply chain
  - Rebates/discounts
  - Confidential negotiations

Drug Pricing: What Physicians Want to Know

- Actual price paid (?)
  - Paid by whom?
  - How will this information be used?
- At what price point will everyone be allowed to be treated?
  - At what point would onerous prior authorization requirements be relaxed?

"Standard of Care" Regimens for Hepatitis C Have Been Expensive for Years: Examples for Treatment of Genotype 1, Naïve, Non-Cirrhotic Patients

Regimen	SVR rates	WAC Price	Cost per SVR
Pegasys + Ribavirin x 48 weeks[1]	41%	$41,758	$101,849
Telaprevir + PegIFN + Ribavirin x 24 weeks[2]	75%	$86,843	$115,791
Sofosbuvir + PegIFN + Ribavirin x 12 weeks	90%	$94,421	$104,912
Sofosbuvir+Ledipasvir x 8 weeks	94%	$63,000	$67,021 ($36,191?)*
Sofosbuvir + Ledipasvir x 12 weeks	99%	$94,500	$95,454 ($51,545?)*

Package inserts for products; *http://blogs.wsj.com/pharmalot/2015/02/04/what-the-shocking-gilead-discounts-on-its-hepatitis-c-drugs-will-mean/

Pharma Pricing Strategies

- Cost-effectiveness models
- Budget impact models
- Benchmarking against similar regimens
- Surveys and focus groups with payers (commercial and public insurance, PBMs) to understand what market will bear
- Expectations of shareholders
- Cost of investment in drug development
- Cost of manufacturing and marketing

Ultimately, price is what the market will bear

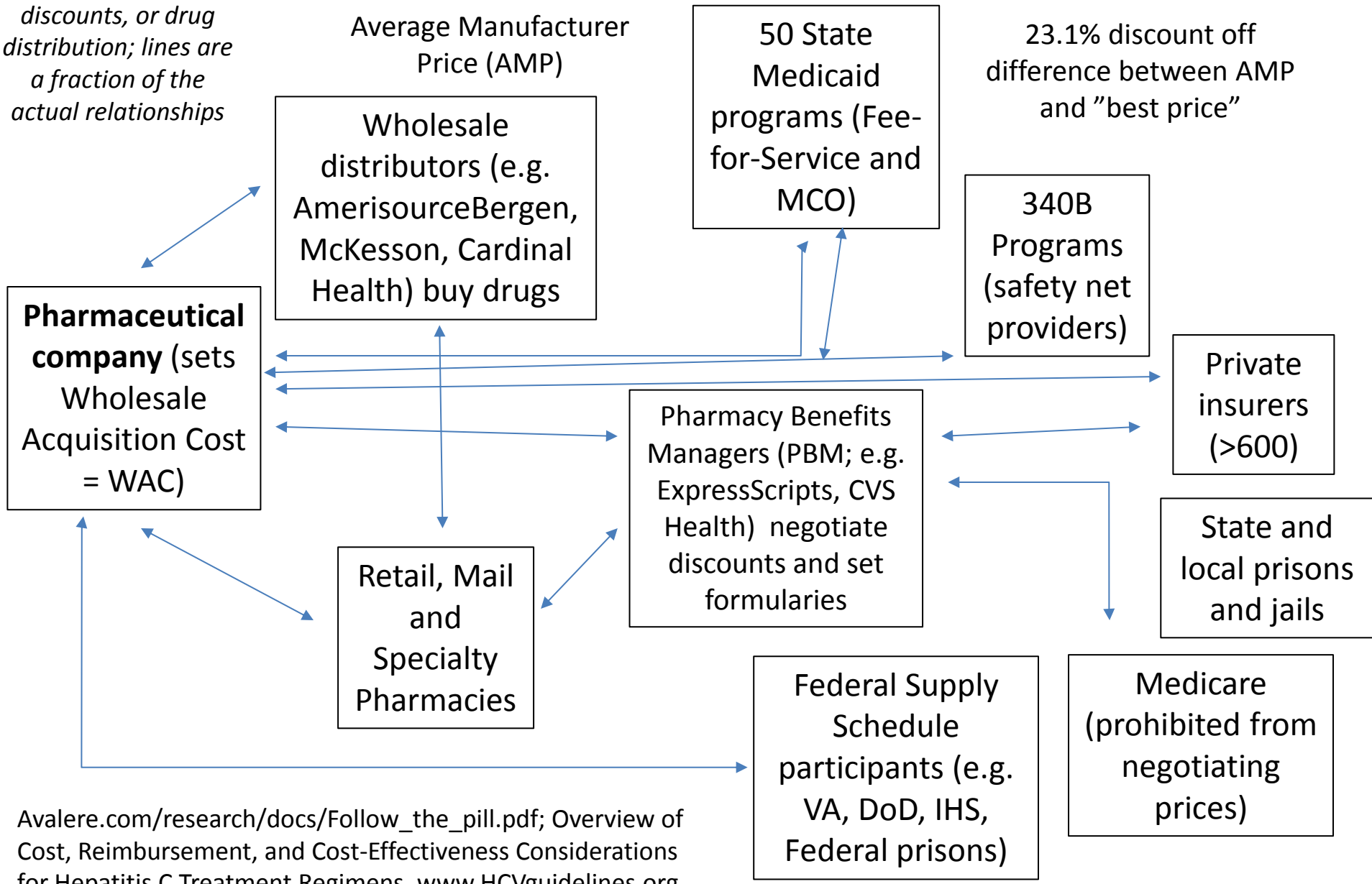
Let's Pretend We Are the Team Helping Set New Hepatitis C Regimen XYZ Price

Factor	Price Implication
Lifetime cost of not treating anyone[1]	$100.3 billion
Cost-effectiveness vs no treatment at $50,000/QALY[1]	$139,000
Benchmark (WAC 2013): Telaprevir+Peg-IFN+RBV x 24 weeks	$97,680
Real-world all cost-per-cure PI/P/R[2]	$125,915 – $302,070
Benchmark (WAC 2014): Sofosbuvir+Peg-IFN+RBV	$94,421
Cost-per-cure of drugs: SOF/P/R (90% SVR)	$104,912
Maximum market will bear (WAC; 2014): Sofosbuvir+Simeprevir x 12 weeks	$150,000
Premium for all-oral regimen (difference in cost-per-cure for P/R versus SOF/R in genotype 2)	$42,000
Premium for one-pill-once-a-day	$1,000
Cost-per-cure XYZ x 12 weeks (if 95% SVR)	X + 5%
Price for XYZ for 12 weeks	???

[1]Rein, CID 2015; [2]Sethi, AASLD 2013; 1847; Washington Post, Dec 1, 2015 (Senate Finance Committee investigation)

Who Pays What Price?

Relationships can represent negotiated payments, rebates or discounts, or drug distribution; lines are a fraction of the actual relationships

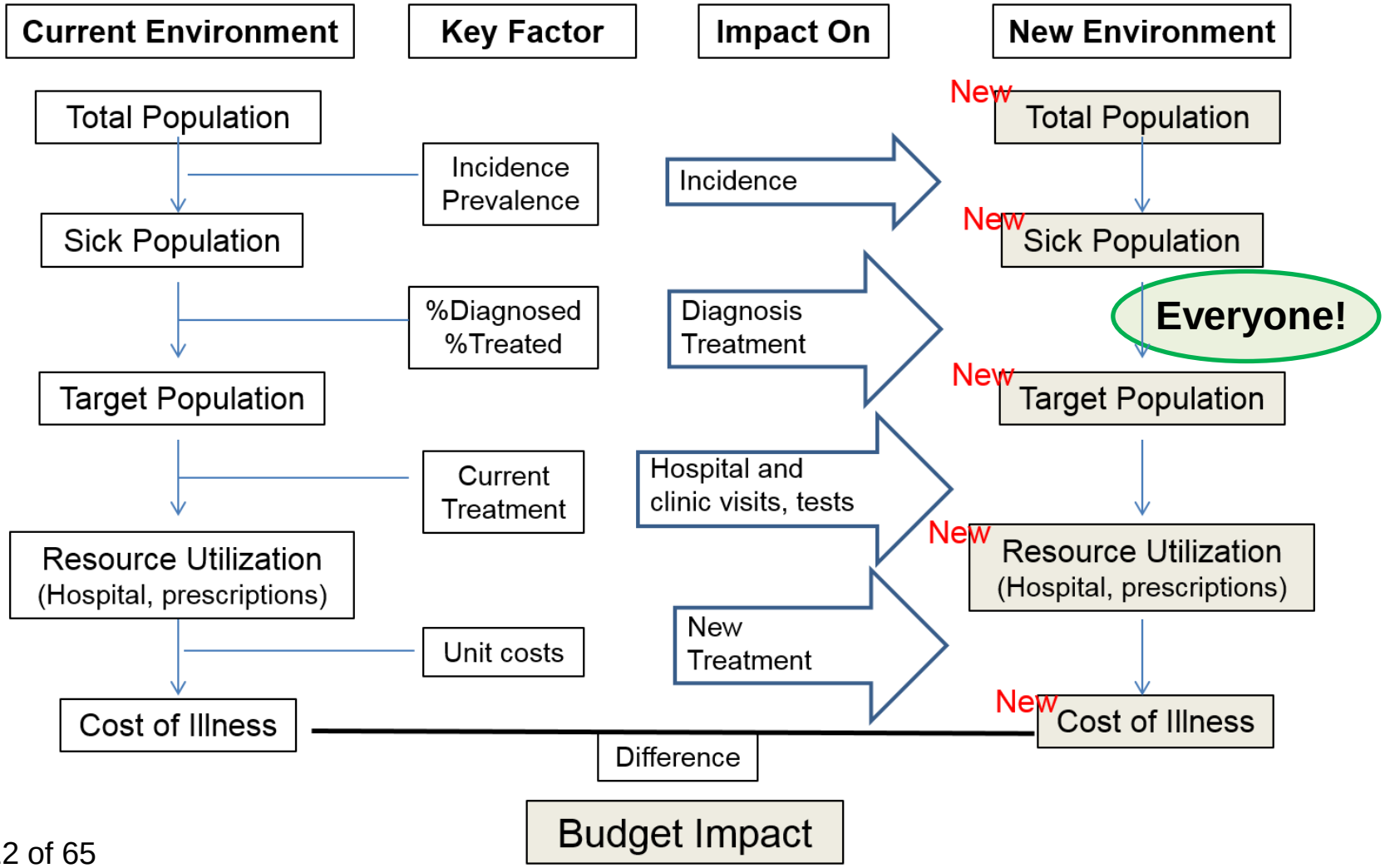


Avalere.com/research/docs/Follow_the_pill.pdf; Overview of Cost, Reimbursement, and Cost-Effectiveness Considerations for Hepatitis C Treatment Regimens. www.HCVguidelines.org

Uncertainties in Estimating HCV Treatment Investment: What Payers Want to Know

- How many people will be treated?
- Over how many years will treatment be spread?
- What will happen to drug regimen costs over time?

Budget Impact Model



Mauskopf et al; Principles of Good Practice for Budget Impact Analysis: Report of the ISPOR Task Force on Good Research Practices – Budget Impact Analysis; Value in Health 2007; 10(5): 336-347.

Institute for Clinical and Economic Review: "The Comparative Clinical Effectiveness and Value of Simeprevir and Sofosbuvir in the Treatment of Chronic Hepatitis C Infection" for the California Technology Assessment Forum

Factor	Result
Enrollee plan	1 million enrollees
1.7% prevalence HCV infection	17,000 enrollees
50% undergo treatment in one year	8,500 enrollees
Estimated HCV treatment cost (per 1 enrollee)	$70,588
Total treatment (8,500 x $70,588)	$600 million
Cost of HCV treatment per enrollee ($600 million/1 million enrollees)	$600/year
Cost per member per month	$50

Conclusion: Simeprevir and sofosbuvir are superior in terms of clinical effectiveness compared to 1st generation PIs and Peg-IFN/RBV, but of "low value" due to high cost (as prices of DAAs have decreased, this value is now "high")

Payer Dilemmas

- Most payers had no idea how much they were actually spending per treated patient (or per cure) in the interferon era
  - PI/P/R in cirrhotic patients ~ $266,000 per cure[1]
- Pharmacy budgets often separate from medical budgets
  - Pharmacy budgets don't get "credit" for avoidance of medical costs
  - Annual budgets
    - "Is it cost effective?" (off-sets over the long term)
    - "Is it affordable?" (costs over one year)

Payer Actions

- May create own cost-effectiveness and budget impact models
- Treatment guidelines
  - Usually derived from existing guidelines
- Formulary placement
- Reimbursement/contracting
- Prior authorization criteria

Limitations on Access to HCV Treatments

- **Limits Based on Stage of Fibrosis**
- **Restrictions Based on Substance Use**
- **Prescriber Limitations**
- **Other restrictions**
  - HIV Co-Infection limitations
  - “Once per lifetime” limitations
  - Genotype limitations
  - Previous history of treatment adherence requirements
  - Specialty pharmacy restrictions
  - Exclusivity agreements with insurers

Barua S, Greenwald R, Grebley J, Dore G, Swan T and Taylor L. Restrictions for Medicaid Reimbursement of Sofosbuvir for the Treatment of Hepatitis C Virus Infection in the US. Ann Intern Med June 30, 2015 (online)

MassHealth FFS Sovaldi Prior Authorization Criteria: Less Restrictive Than Most States

Coverage

+ Preferred drug

Fibrosis

+ No restrictions (form inquires)

Substance Use

+ No restrictions (form inquires about current use)

Prescriber Limitations

+ No restrictions

Additional Restrictions

+ No additional restrictions based on HIV Co-infection or previous adherence

Recommended regimens for patients with HCV genotype 1a or 1b infection who have compensated cirrhosis, in whom prior PEG-IFN and RBV treatment has failed

	Cost (with discount)
• **Daily fixed-dose combination of ledipasvir/sofosbuvir for 24 weeks** **Rating:** Class I, Level A	**$102,600**
• **Daily fixed-dose combination of ledipasvir/sofosbuvir plus weight-based RBV for 12 weeks…** **Rating:** Class I, Level B	**$52,650**
• **Daily fixed-dose combination of paritaprevir/ritonavir/ombitasvir plus twice-daily dosed dasabuvir and weight-based RBV for 24 weeks is recommended for patients with HCV genotype 1a…** **Rating:** Class I, Level A	**92,683**
• **Daily sofosbuvir plus simeprevir with or without weight-based RBV for 24 weeks…** **Rating:** Class IIa, Level B	**$162,000**

Adapted from www.hcvguidelines.org

MassHealth: Estimated Volume

- 7,658 members with HCV
  - PCC members continuously enrolled 12/6/13-7/30/14 with an ICD-9 code for HCV
- Currently 1,075 members approved for regimens
    - Over 90% of PAs approved
    - ~14% of diagnosed patients engaged in treatment

Examples of Approaches to Improve Access to HCV Treatment

- Share successful appeal letters
  - National Viral Hepatitis Roundtable is collecting examples to share (NVHR.org)
- Share stories with media (obtain institutional and patient permission)
- Join local P&T committees
- Educate local payers (public and private) about hepatitis C and the value of treatment
  - Presume that ultimate goal is elimination of HCV
  - Individual or small group with one payer
  - State DPH, local advocates, coalition of HCV treaters and ALL payers
- Consider joining in lawsuits to force access
  - Harvard Law School is developing model suits