



BERKELEY CENTER
FOR HEALTH TECHNOLOGY

Two-Part Drug Pricing to Promote Access and Innovation in the United States

James C. Robinson

Leonard D. Schaeffer Professor of Health Economics
Director, Berkeley Center for Health Technology
University of California, Berkeley



Subscription (Two-Part) Drug Pricing



- Under traditional (one-part) pricing, each dose sold must be priced to cover its marginal costs plus a share of fixed costs
 - The extent of the R&D load for each individual drug varies across nations and across payers within nations, but must be covered somehow across the firm's entire drug portfolio
- Under subscription (two part) pricing, unit prices are set equal to marginal costs, but payer also purchases a 'subscription' to grant it access to the brand (this rewards and finances R&D)
- Subscription varies by size of covered population, but not by number of doses prescribed



Traditional Pricing Models Generate Payer Resistance

- Economic efficiency is achieved when price is set equal to marginal cost of production
- But this condition cannot be met in the presence of fixed costs, such as for R&D
- Patent and regulatory exclusivity allows price to be set above costs, supporting R&D.
- But then consumers with under-utilize, unless demand is subsidized by insurance.
- But then insurers will resist utilization

Moderately Managed

- Specialist approval required
- Requires prior failure or contraindication with 1 DMARD (e.g., MTX)
- Initial authorization time limit ≥ 3 months but ≤ 6 months

Highly Managed

- Requires prior failure or contraindication with 1 DMARD AND 2 conventional therapies
- Severe RA only
- Initial authorization time limit < 3 months

Very Highly Managed

- Requires prior failure or contraindication with 1 or 2 biologic therapies, in addition to DMARD
- Severe RA only
- Initial authorization time limit

Degree of management is Increasing



Payer Resistance to One-Part Pricing: HCV Drugs in the USA

Annals of Internal Medicine

MEDICINE AND PUBLIC ISSUES

Restrictions for Medicaid Reimbursement of Sofosbuvir for the Treatment of Hepatitis C Virus Infection in the United States

Soumitri Barua; Robert Greenwald, JD; Jason Grebely, PhD; Gregory J. Dore, MBBS, PhD; Tracy Swan; and Lynn E. Taylor, MD

The aim of this study was to systematically evaluate state Medicaid policies for the treatment of hepatitis C virus (HCV) infection with sofosbuvir in the United States. Medicaid reimbursement criteria for sofosbuvir were evaluated in all 50 states and the District of Columbia. The authors searched state Medicaid Web sites between 23 June and 7 December 2014 and extracted data in duplicate. Any differences were resolved by consensus. Data were extracted on whether sofosbuvir was covered and the criteria for coverage based on the following categories: liver disease stage, HIV co-infection, prescriber type, and drug or alcohol use. Of the 42 states with known Medicaid reimbursement criteria for sofosbuvir, 74% limit sofosbuvir access to persons with advanced fibrosis (Meta-Analysis of Histologic Data in Viral Hepatitis [METAVIR] fibrosis stage F3) or cirrhosis (F4). One quarter of states require persons co-infected with HCV and HIV to be receiving antiretroviral therapy or to have suppressed HIV RNA

levels. Two thirds of states have restrictions based on prescriber type, and 88% include drug or alcohol use in their sofosbuvir eligibility criteria, with 50% requiring a period of abstinence and 64% requiring urine drug screening. Heterogeneity is present in Medicaid reimbursement criteria for sofosbuvir with respect to liver disease staging, HIV co-infection, prescriber type, and drug or alcohol use across the United States. Restrictions do not seem to conform with recommendations from professional organizations, such as the Infectious Diseases Society of America and the American Association for the Study of Liver Diseases. Current restrictions seem to violate federal Medicaid law, which requires states to cover drugs consistent with their U.S. Food and Drug Administration labels.

Ann Intern Med. 2015;163:215-223. doi:10.7326/M15-0406 www.annals.org
For author affiliations, see end of text.

This article was published online first at www.annals.org on 30 June 2015.



Payer Resistance to One-Part Pricing: HCV Drugs in Britain

INVESTIGATION

A pill too hard to swallow: how the NHS is limiting access to high priced drugs

A joint investigation by The BMJ and Cambridge and Bath universities uncovers how NHS England tried to limit access to expensive new drugs for hepatitis C. **Jonathan Gornall**, **Amanda Hoey**, and **Piotr Ozieranski** report

Jonathan Gornall *freelance journalist*¹, Amanda Hoey *consultant*, Piotr Ozieranski *lecturer*³

¹Suffolk, UK; ²Department of Sociology, University of Cambridge, Cambridge, UK; ³Department of Social and Policy Sciences, University of Bath, Bath, UK

Highly priced medicines are challenging health systems around the world in unprecedented ways. And none more so than the new sofosbuvir based antiviral drugs introduced by Gilead Sciences in 2014. Offering greatly reduced treatment durations and high cure rates, these medicines hold out the real prospect of eliminating hepatitis C in countries where they are widely administered, with all that implies for long term savings in healthcare costs.

But launch of these drugs has ignited a global debate about high priced medicines. With launch prices ranging from around \$90 000 (£69 000; €82 000) per patient in the US to almost £35 000

Our investigation finds that NHS England was unable to adopt innovative funding mechanisms to reduce the price because of NHS procurement law.

In interviews with clinicians, patient groups, and drug company representatives, a picture emerges of how NHS England failed to plan ahead for expensive drugs it knew were in the pipeline, exaggerated the numbers likely to come forward for treatment and the financial burden for them in its submissions to NICE, and, in a “shroud waving” exercise, claimed thousands of other NHS patients would die if NICE gave the go ahead to the hepatitis C drugs.



Emerging Applications of Subscription (Two-Part) Drug Pricing



1. HCV drugs for low-income (Medicaid) patients
2. Antibiotics for drug-resistant infections
3. Specialty drugs for low-income nations
4. Combination and targeted therapies in oncology



HCV Drugs for Low-Income Patients

- The discounted (one part) price of HCV drugs is approximately \$40K per dose and the cost of manufacturing and distribution is \$2K per dose, hence each dose has \$38K in R&D loaded on
 - One part price: $\$40K = \$R/n + \$2K$
- National Academy of Medicine estimates subscription price (\$R) for the entire Medicaid population at \$2B, plus \$140K for manufacturing and distribution
 - Two part price: $(\$2B + \$140K)/n$

HealthAffairsBlog

A Good Deal For Eliminating Hepatitis C: Saving Money And Lives

Neeraj Sood, Gillian Buckley, and Brian Strom

April 24, 2017



Antibiotics for Drug-Resistant Infections

- Bacteria are developing resistance to existing (cheap, generic) antibiotics, due to overuse
- Low (generic) prices undermine incentives for pharma firms to invest in antibiotic R&D
- Two-part pricing; R&D prize combined with per-dose price set at generic levels

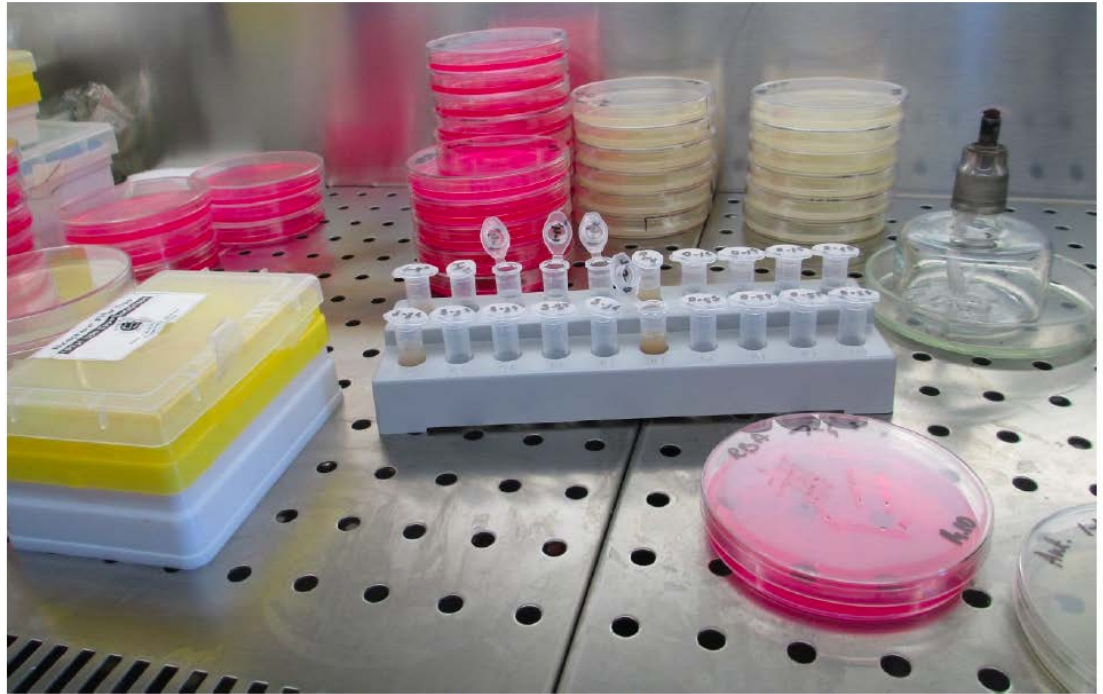


Lawmakers propose \$2B prize fund for new antibiotics—if developers waive exclusivity

by Phil Taylor | Apr 13, 2017 8:40am

US proposal:

\$2B prize for new antibiotics for drug-resistant infections, plus generic pricing for each dose



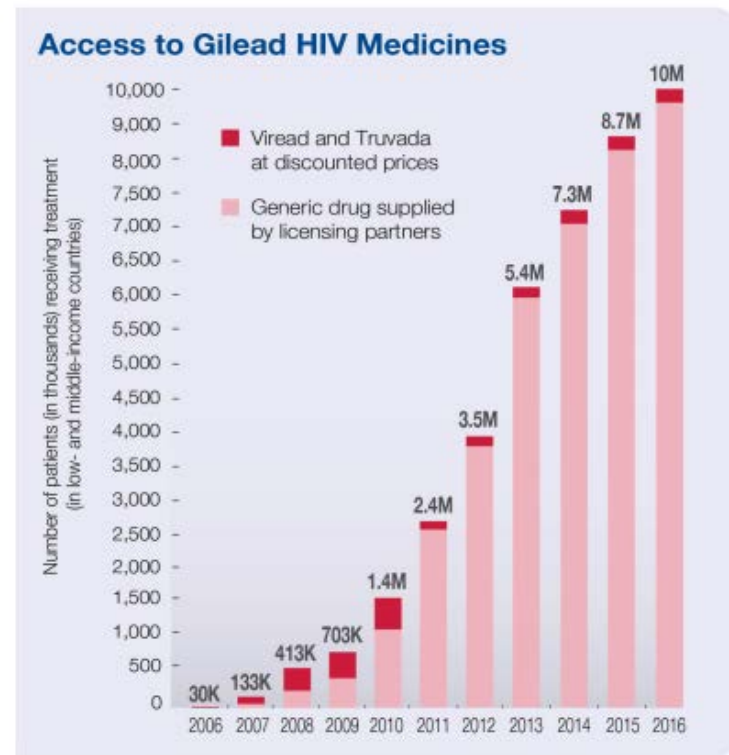
A new bill intends to stimulate R&D into drugs for serious and life-threatening bacterial infections.

A bill tabled by senior Democrats would set up a \$2 billion prize fund that will try to encourage the development of more effective antibiotics for serious infections.

Tucked away in the wide-ranging [Improving Access to Affordable Prescription Drugs Act](#), the antibiotic research clause calls for "up to three" prizes for products that "provide added benefit for patients over existing therapies in the treatment of serious and life-threatening bacterial infections demonstrating in superiority trials."

Specialty Drugs for Low-Income Nations

- Low-income nations can only afford prices at generic levels (no payment for R&D)
- Selected firms are licensing their branded drugs at low or zero rates (for R&D), adding a price per dose at generic levels to cover marginal costs of distribution



Pfizer Announces Two-Part Pricing for Cancer Drugs in Africa

As Cancer Tears Through Africa, Drug Makers Draw Up a Battle Plan

In a deal similar to the one that turned the tide against AIDS, manufacturers and charities will make chemotherapy drugs available in six poor countries at steep discounts.

Global Health

By DONALD G. McNEIL Jr. OCT. 7, 2017

NAIROBI, Kenya — In a remarkable initiative modeled on the campaign against AIDS in Africa, two major pharmaceutical companies, working with the American Cancer Society, will steeply discount the prices of cancer medicines in Africa.

Under the new agreement, the companies — Pfizer, based in New York, and Cipla, based in Mumbai — have promised to charge rock-bottom prices for 16 common chemotherapy drugs. The deal, initially offered to a half-dozen countries, is expected to bring lifesaving treatment to tens of thousands who would otherwise die.

Pfizer said its prices would be just above its own manufacturing costs. Cipla said



Combination and Targeted Therapies

- Many difficult pricing (and hence patient access) problems for specialty drugs derive from the current need to combine (1) payment for R&D with (2) payment for costs of manufacturing and distribution
- These could be alleviated by charging (1) subscription price per patient or per covered population (rather than per dose) and (2) modest per-dose price to cover distribution
- Some pharmaceutical firms are exploring these possibilities



Oncology

- Some cancer indications respond to multiple drugs (targeted, immune-oncology) better than to one
- But the composite price of 2 or more oncology drugs (targeted and/or immune) pushes the total price above \$300K/patient
 - The marginal costs for oncology drugs is only 15% of price
 - Manufacturers and payers are constrained by rule that drug prices be uniform across indications
 - Two part pricing could provide a solution:
 - Subscription price (per population) varies by indication
 - Unit price (per dose) is uniform across indications
 - This also obviates need for a separate price for companion diagnostic tests, which is important since the clinical value to the patient depends on the tests and drugs jointly, not separately





BERKELEY CENTER
FOR HEALTH TECHNOLOGY

James C. Robinson PhD, MPH

Director, Berkeley Center for Health Technology
Leonard D. Schaeffer Professor of Health Economics
Division Head, Health Policy and Management
UC Berkeley School of Public Health
james.robinson@berkeley.edu

Website: <https://bcht.berkeley.edu>

University of California, Berkeley

