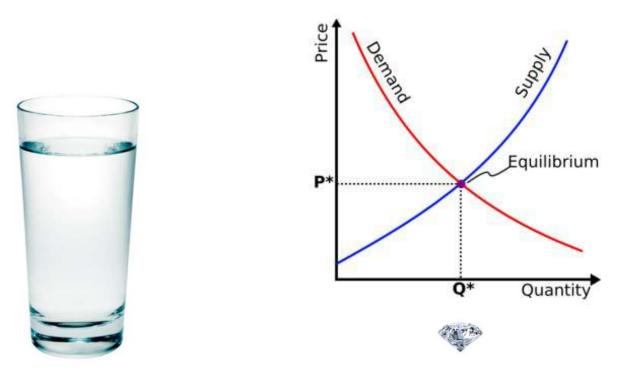
15.482 Healthcare Finance Spring 2017/69 Andrew W. Lo, Unit 10, Part 1: Pricing, Value and Ethics

Unit Outline

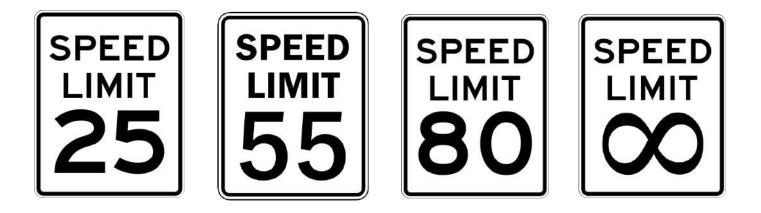
- Pricing
- Ethics
- Pricing Issues for Cancer Drugs
- Price vs. Value
- Questcor Pharmaceuticals

Pricing

What Determines "Value"?



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RESEARCH AND PRACTICE

American Journal of Public Health | September 2009, Vol 99, No. 9

Long-Term Effect Speed Limit in th

Lee S. Friedman, PhD, Donald He

Results. We found a 3.2% increase in road fatalities attributable to the raised speed limits on all road types in the United States. The highest increases were on rural interstates (9.1%) and urban interstates (4.0%). We estimated that 12545 deaths (95% confidence interval [CI]=8739, 16352) and 36583 injuries in fatal crashes (95% CI=29322, 43844) were attributable to increases in speed limits across the United States.

Conclusions. Reduced speed limits and improved enforcement with speed camera networks could immediately reduce speeds and save lives, in addition to reducing gas consumption, cutting emissions of air pollutants, saving valuable years of productivity, and reducing the cost of motor vehicle crashes. (*Am J Public Health.* 2009;99:1626–1631. doi:10.2105/AJPH.2008.153726)

Because of their uniqueness, we excluded Massachusetts and Hawaii from our analysis. Neither state's roads fit within our 4 interstate categories. Furthermore, a random state effect was included in the mixed-regression model to account for the state effect. A class variable with only 1 state would not be appropriate for mixed-regression modeling and would require an alternative modeling procedure. It is probable that excluding Massachusetts and Hawaii resulted in a underestimation of the effect of raised speed limits on the traffic death toll in the United States.

| U.S. Department of Transportation | February 28, 2013 1200 New Jersey Avenue, SE Washington, DC 20590 |
|--|---|
| Office of the Secretary of Transportation | |
| MEMORANDUM TO: | SECRETARIAL OFFICERS MODAL ADMINISTRATORS |
| From: | Polly Trottenberg Under Secretary for Policy X6-4540 Robert S. Rivkin General Counsel x6-4702 |
| Subject: | Guidance on Treatment of the Economic Value of a Statistical Life (VSL) in U.S. Department of Transportation Analyses |

\$9,100,000.00

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Sovaldi



\$84,000 to cure Hepatitis C

FiercePharma

U.S. lawmakers want Gil Sovaldi's hefty price

BY BILL BERKROT AND DEENA BEASLEY

Fri Mar 21, 2014 4:56pm EDT



(Reuters) - U.S. lawmakers have asked Gilead Sciences Inc of its new hepatitis C drug Sovaldi, which is encountering and state Medicaid programs.

Published on FiercePharma (http://www.fiercepharma.com)

Senator asks VA to yank patent on Gilead's Sovaldi to crush its price

May 13, 2015 | By Eric Palmer

Gilead Sciences (<u>SGILD</u>) has been able to withstand scathing criticism at home over the prices of its hep C cures, negotiate with stingy price watchdogs abroad and face down criticism in developing countries by giving generics producers access to formulations and technology. But can it stand up to a possible attack by the U.S. military?

Sen. Bernie Sanders--the Independent from Vermont who recently announced his plans to seek the Democratic nomination for president--asked Veterans Affairs Secretary Robert McDonald to break the patents on Gilead's <u>hepatitis C</u> treatment <u>Sovaldi</u> using a wartime provision to fighting profiteering. His call came after learning that the VA has stopped treating new hep C patients with the hep C cures because it didn't have the money.



Sen. Bernie Sanders (I-VT)

Unit 10 - Part 1

Sovaldi

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CHRIS CAMPBELL, STAFF D JOSHLIA SHEINKMAN, DEMOCRATIC

To the Health Car

On December 1. Gilead Sciences. follow-on drug, H

Based on more that window into how Our investigation and profit maximi the drugs' wholes

"Our investigation showed that in considering how to price its drugs, Gilead prioritized revenue and profit maximization over patient access. Furthermore, the company was determined to keep the drugs' wholesale prices high and payer discounts low 'whatever competitors do or whatever the headlines." the headlines."3 Gnear 5 pricing and sales strategy fee many m

Sovaldi and Harvoni.⁴ As a result, "patients who could benefit from these drugs did not receive them due to the high cost."5

Sovaldi

Letters

JAMA Oncology April 2, 2015

RESEARCH LETTER

Five Years of Cancer Drug Approvals: Innovation, Efficacy, and Costs

The price of cancer drugs has risen, drawing criticism from leading academics.^{1,2} The annual cost of a new cancer medication now routinely exceeds \$100 000, and medical bills have become the single largest cause of personal bankruptcy.² Although some contend that the high cost of drugs is required to support research and development efforts,³ the fact remains that when costs and revenues are balanced, the pharmaceutical industry generates high profit margins.⁴

High profits may be justified if novel products offer significant benefits to patients (thus producing indirect economic value through the patients' restored health) or if they represent significant pharmacologic advances over their predecessors—offering new mechanisms of actions and emblematic of high-risk research. We investigated whether novelty of medications or their relative benefits affected drug pricing.

Methods | We identified all oncologic drugs approved by the US Food and Drug Administration (FDA) between January 1, 2009, and December 31, 2013. Oncologic drugs were approved based on improvements in overall survival (OS), disease response rate

Table. Last 20 Oncologic Drugs Approved Between 2009 and 2013 by the US Food and Drug Administration

| Drug and Indication | Cost per Year of Treatment, \$" | Parent Drug | Mechanism of Action | Clinical Benefit |
|--|---------------------------------------|-------------|---|------------------------------|
| Sorafenib for papillary thyroid cancer | 140 984 | NA | First approved VEGFR and RAS tyrosine kinase inhibitor | Median PFS, 10.8 vs 5.8 mo |
| Crizotinib for non-small-cell lung cancer | 156 544 | NA | Anaplastic lymphoma kinase inhibitor | Median PFS, 7.7 vs 3.0 mo |
| Ibrutinib for mantle cell lymphoma | 157 440 | NA | Bruton tyrosine kinase inhibitor | RR, 66%; median DOR, 17.5 mo |
| Obinutuzumab for chronic lymphocytic leukemia | 74 304 | Rituximab | Anti-CD20 monoclonal antibody | Median PFS, 23.0 vs 11.1 mo |



drugs approved based on time-to-event end points and drugs approved on the basis of RR. Our results suggest that current pricing models are not rational but simply reflect what the market will bear.

Sham Mailankody, MB BS Vinay Prasad, MD, MPH



For U.S. Companies, Shareholder Wealth Is The Focus:

 eBay Domestic Holdings Inc. v. Newmark (2010): corporate directors are bound by "fiduciary duties and standards" which include "acting to promote the value of the corporation for the benefit of its stockholders."



Consider The Following Alternative Quote:

"Our investigation showed that in considering how to price its cars, Tesla prioritized revenue and profit maximization over consumer access. Furthermore, the company was determined to keep the cars' wholesale prices high and dealer discounts low 'whatever competitors do or whatever the headlines.""

Sovaldi Is A Bargain, But The Cost Impact Is Huge!

Suppose we "mortgaged" Sovaldi? "Buying cures vs.
renting health" $\$84,000 = \frac{P}{r/12} \left[1 - \frac{1}{(1+r/12)^{12n}} \right] \Rightarrow P = \frac{\$84,000r/12}{1 - \frac{1}{(1+r/12)^{12n}}}$

Monthly Payment

| Years | Interest Rate | | | | | | |
|-------|------------------|---------|------------------|------------------|------------------|--|--|
| | 1% | 3% | 5% | 10% | 15% | | |
| 1 | \$7 <i>,</i> 038 | \$7,114 | \$7 <i>,</i> 191 | \$7 <i>,</i> 385 | \$7 <i>,</i> 582 | | |
| 5 | \$1,436 | \$1,509 | \$1,585 | \$1,785 | \$1 <i>,</i> 998 | | |
| 10 | \$736 | \$811 | \$891 | \$1,110 | \$1 <i>,</i> 355 | | |
| 15 | \$503 | \$580 | \$664 | \$903 | \$1,176 | | |
| 30 | \$270 | \$354 | \$451 | \$737 | \$1,062 | | |

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Sovaldi Is A Bargain, But The Cost Impact Is Huge!

- Now pool these healthcare loans (HCLs) and securitize them (consider 12,000 loans)
- Senior tranche, junior tranche, equity tranche
- Create CDS to guarantee senior tranche
- etc.
- Use student-loan data to calibrate

PERSPECTIVE

HEALTH ECONOMICS

Buying cures versus renting health: Financing health care with consumer loans

Vahid Montazerhodjat,^{1,2} David M. Weinstock,^{3,4}* Andrew W. Lo^{1,2,5,6}*

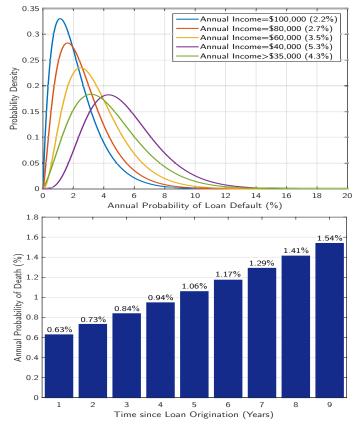
A crisis is building over the prices of new transformative therapies for cancer, hepatitis C virus infection, and rare diseases. The clinical imperative is to offer these therapies as broadly and rapidly as possible. We propose a practical way to increase drug affordability through health care loans (HCLs)—the equivalent of mortgages for large health care expenses. HCLs allow patients in both multipayer and single-payer markets to access a broader set of therapeutics, including expensive short-duration treatments that are curative. HCLs also link payment to clinical benefit and should help lower per-patient cost while incentivizing the development of transformative therapies rather than those that offer small incremental advances. Moreover, we propose the use of securitization—a well-known financial engineering method—to finance a large diversified pool of HCLs through both debt and equity. Numerical simulations suggest that securitization is viable for a wide range of economic environments and cost parameters, allowing a much broader patient population to access transformative therapies while also aligning the interests of patients, payers, and the pharmaceutical industry.

STM 24 Feb 2016

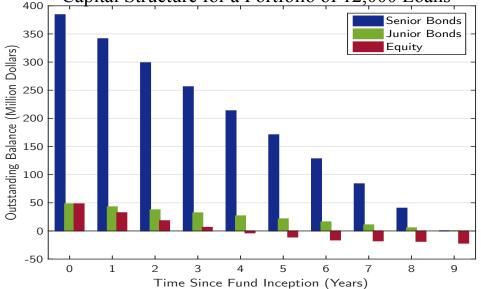
currently reduces the affordability of curative therapies.

Others have suggested HCLs, both at the individual consumer level (5) and nationally, through government-agency debt-financing (6), but thus far, no specific methods have been proposed for implementing them or raising the funds to pay for them. In this article, we present such a proposal and analyze the financial viability of HCLs for funding transformative therapies using portfolio theory and financial engineering techniques (7).

The motivation for our proposal is not an outright market failure (that is, an economic concept of inefficiency in the allocation of resources that can only be remedied via government intervention). In fact, a number of financial institutions already offer standardized loan contracts that provide large amounts of credit to consumers for a variety of purposes, including medical expenses, so a market for health care loans already exists. However, several fac-



Capital Structure for a Portfolio of 12,000 Loans



IRR = 12.6%, Senior: 2.1%, Junior: 2.5%, PoD_s, PoD_J < 0.1 bps, EL_s, EL_J < 0.1 bps

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Unit 10 - Part 1

Financing Life: Who Pays?

In The Very Long Run, Taxpayers

That's what government is for

In The Long Run, Insurers

That's what health insurance is for

In The Short Run, Patients, Families, Foundations

- That's what consumer loans and charities are for
- Mortgaging your health is offensive
- Letting patients die is even more offensive

Is This Really A Good Idea??

- Debt market has huge capacity (\$39T)
- Consumer credit risk is well understood
- Personal health is a great investment (compared to cars, homes, vacations, renovations, etc.)
- This will create incentives for cures
- This will improve diet, exercise, prevention
- This is consistent with "pay for performance"
- This will make healthcare more effective, more affordable (per quality-adjusted life year), more efficient

Potential Downside

CLINICAL RESEARCH STUDY

Medical Bankruptcy in the Results of a National Stu

David U. Himmelstein, MD,^a Deborah Thorne, PhD,^a ^aDepartment of Medicine, Cambridge Hospital/Harvard Me

Athens; and "Harvard Law School, Cambridge, Mass.

2009 THE AMERICAN

ABSTRACT

BACKGROUND: Our 2001 study in 5 states found that medical problems contributed to at least 46.2% of all bankruptcies. Since then, health costs and the numbers of un- and underinsured have increased, and bankruptcy laws have tightened.

METHODS: We surveyed a random national sample of 2314 bankruptcy filers in 2007, abstracted their court records, and interviewed 1032 of them. We designated bankruptcies as "medical" based on debtors' stated reasons for filing, income loss due to illness, and the magnitude of their medical debts.

RESULTS: Using a conservative definition, 62.1% of all bankruptcies in 2007 were medical; 92% of these medical debtors had medical debts over \$5000, or 10% of pretax family income. The rest met criteria for medical bankruptcy because they had lost significant income due to illness or mortgaged a home to pay medical bills. Most medical debtors were well educated, owned homes, and had middle-class occupations. Three quarters had health insurance. Using identical definitions in 2001 and 2007, the share of bankruptcies attributable to medical problems rose by 49.6%. In logistic regression analysis controlling for demographic factors, the odds that a bankruptcy had a medical cause was 2.38-fold higher in 2007 than in 2001.

CONCLUSIONS: Illness and medical bills contribute to a large and increasing share of US bankruptcies. © 2009 Elsevier Inc. All rights reserved. • The American Journal of Medicine (2009) xx, xxx

KEYWORDS: Bankruptcy; Health care costs; Health economics

But Desperate Consumers Will Persist!

The New Hork Times | http://nyti.ms/28QLCrJ

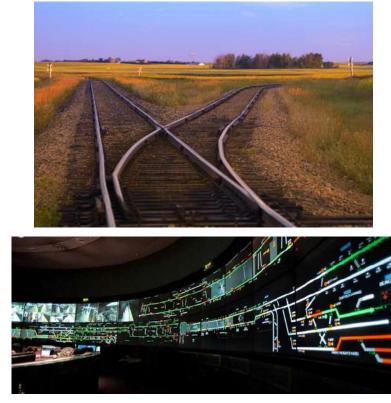
Tests showed that the mass was made up of abnormal, primitive cells and that it was growing very aggressively. Then came the real shocker: The cells did not come from Jim Gass. They were someone else's cells.

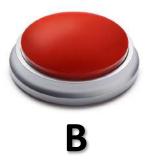
Mr. Gass, it turned out, had had stem cell therapy at clinics in Mexico, China and Argentina, paying tens of thousands of dollars each time for injections in a desperate attempt to recover from a stroke he had in 2009. The total cost with travel was close to \$300,000.

Ethics

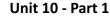
What Role Does Ethics Play?











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What Role Does Ethics Play?









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Neuroscience of Morality

- Moral judgments involve competing systems in the brain: higher cognition (utility) vs. emotion (survival)
- Impersonal vs. personal moral dilemmas (Greene, 2001)
 - Impersonal: utilitarian calculations
 - Personal: "me hurt you" narrative (threat identification and neutralization)
- Moral reasoning likely evolved from the highly social structures of hominid societies
- Morals and ethics are evolutionary adaptations that facilitate cooperation, collective intelligence, and, ultimately, reproductive success among social animals