

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

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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.

Many new drugs offer little or no benefit over currently available and less expensive alternatives, but a small fraction truly transforms medical care. When these transformative products emerge, there is a compelling urgency to maximize their availability. Doing so introduces a new challenge—the financial cost of offering treatment to all who can benefit. Two recent advances have attracted particular attention from the medical and lay communities, both for their transformative effects on disease outcome and for their prices.

The first is curative therapy for hepatitis C virus (HCV) infection. More than 90% of infected individuals appear to be cured of HCV infection after only 6 to 8 weeks of treatment with new drug combinations for a list price of ~\$84,000 (1). At this price, treating all 2.7 million Americans with chronic HCV infection would cost \$227 billion (2), and treating all 180 million infected persons worldwide (3) would cost more than \$15 trillion. This prohibitive cost has substantially limited access to therapy, despite the clinical and public health advantages of universal treatment. Even with

current discounts for HCV therapies (~50% anecdotally), aggregate costs remain larger than would allow for universal access right now.

The second example is Glybera (alipogene tiparvovec), a gene therapy for the highly rare disease lipoprotein lipase deficiency. Glybera was recently approved in Germany and priced at nearly \$1 million. Like curative HCV therapy, the benefit from Glybera may last for the recipient's remaining lifetime, but the entire cost is paid upfront. Ironically, this payment structure makes noncurative drugs that require chronic administration (we call these “mitigators”) more financially accessible for payers than curative therapies because the former are purchased in increments over the duration of benefit (4). High prices are not specific to the two cases described here because many gene therapies, cancer therapeutics, and adoptive cellular therapies are likely to be priced similarly to Glybera. As a result, an impending crisis of highly efficacious but financially restricted therapies looms.

From an economic perspective, the difference between cures and mitigators is much the same as that of buying a home versus renting one. Although the former is considerably more expensive than the latter, home mortgages extend access to more buyers by distributing payments of the purchase price over a longer horizon. A natural method for expanding access to curative therapies is to offer “health care loans” (HCLs) that spread or amortize the cost of cures over many years and thereby overcome the limitation in financial liquidity that

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 factors suggest that there is a gap in this market, particularly for less affluent consumers. First, typical middle-class borrowers cannot obtain a loan for a large health care copayment unless they can pledge some form of collateral (such as a second lien on their homes). For smaller loan amounts, consumers do have access to credit-card borrowing, but these loans typically carry double-digit annual interest rates and the total amount that can be borrowed might be insufficient. Payday loans—a common form of credit among less affluent borrowers—charge even higher interest rates. Such high borrowing rates have a disproportionate impact on lower-income consumers, essentially precluding their ability to purchase expensive medical care. The fact that 62% of all personal bankruptcies in 2007 were related to medical expenses and three-quarters of those filing for bankruptcy had some form of health insurance (8) underscores the need for a more efficient health care loan market.

Our proposal is to bridge the gap in this market in the short run by using diversification and securitization—techniques that have been successfully applied in other consumer loan markets—to reduce the risk and increase the efficiency of these markets. This risk reduction will, in turn, lower borrowing costs to consumers and reduce their financial burden, attract more capital into this market, and improve patient access to curative therapies. In the longer run, we propose that health insurance companies cover the cost of such therapies. Such coverage is currently not sustainable because insurers cannot recoup the cost of

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large one-time outlays through monthly insurance premiums if those beneficiaries switch plans afterward. However, a simple change in health care regulation or legislation—expanding the definition of “preexisting conditions” to include “financial conditions”—can address this issue, as outlined below.

There are, of course, complex ethical considerations and social ramifications related to the pricing of highly effective therapies above a threshold that permits universal access. Moreover, there is growing pushback against the rising cost of prescription drugs from the medical community and policy-makers (9, 10). It has also been argued that because infectious diseases such as HCV impose a public health risk, governments should cover the cost of eradicating such diseases. We do not address these important issues or the cost-effectiveness of individual drugs in this article. Our more modest goal is to explore the feasibility of a private-sector approach to making expensive and highly efficacious therapies more affordable right now. The stark reality is that many patients do not have access to transformative therapies solely because of affordability. As explained below, new financing structures can improve access, drive down per-patient expenditures, and provide the biopharmaceutical industry with greater incentives to develop transformative therapies over incremental ones.

We should note that a law mandating full coverage for curative therapies and allowing for price negotiation would likely be economically more efficient, more sustainable, and socially more acceptable than a purely private-sector solution. However, in the current political atmosphere, patients fail to receive optimal care with each passing day, despite the fact that we have both the methods and the financial means to provide such care. In the interest of extending benefit as broadly and quickly as possible, we consider a practical solution that is available immediately.

HCL FUNDS

We propose two frameworks that would each grant additional access to transformative drugs, but under very different constraints. The first is a short-term approach that is immediately implementable: establishment of a special purpose entity (SPE) to fund expensive drug purchases. In this setting, the patient borrows from the SPE to make their copayment, and the loan is amortized over a repayment period as with other consumer loans such as mortgages, credit card debt, and auto and student loans (Fig. 1). The SPE would be financed by a pool of in-

vestors who purchase various securities—bonds and stock—issued by the SPE. These securities have different risk-return characteristics that appeal to a wide spectrum of investors, and the value of each security is derived from the underlying collection of consumer loans that generate cash flows during the periods when the loans are outstanding (fig. S1). This structure is known collectively as securitization and is actively used in all consumer finance products.

Although the idea of patients assuming debt to obtain life-saving therapies is distasteful, the status quo—patients simply not having access to these critical therapies or having to pay the full price upfront for their therapies because they lack insurance coverage—is even more troubling.

The second framework is a longer-run solution in which private payers and government agencies assume the debt. Such an approach will likely require new regulation or legislation to address disincentives for insurers to cover transformative therapies as well as potential unintended consequences on lower-income patients (Table 1); however, policy-makers have dealt with similar issues in other contexts.

These new financing mechanisms would increase the demand for the new therapy by expanding access to a larger patient population. Hence, standard economic theory suggests that the price of therapy should increase because of this increase in demand, *ceteris paribus*. However, compared with the pricing of therapies for some cancers with much smaller populations, the current pricing of available therapies for prevalent diseases such as heart disease and high cholesterol does not support this trend. Furthermore, multiple companies are currently competing for a limited number of patients, so the creation of a large and liquid HCL market could provide substantial leverage for payers and lenders to negotiate prices downward. Although of little consolation to patients, even if prices increased in response to HCLs, that would be an efficient outcome from a purely economic perspective if the rising price indicated willingness by consumers to pay higher prices for the greater clinical benefit.

In alignment with the move toward value-based reimbursement (11), we propose that payment of the HCL continues until the debt is repaid, the patient or payer defaults, or the benefit from the drug ends, whichever occurs first. In the case of HCV therapy, the end of benefit could result from either a relapse or reinfection from HCV, an end point such as

liver transplantation, or death. By linking payment duration with continued health, we essentially preclude the extension of HCLs to therapies with marginal benefit.

SIMULATING AN HCL FUND

We simulated the performance of a hypothetical HCL fund for financing HCV therapy copayments in a context that assumes payment by the insurance company of \$44,000 for each of 12,500 patients toward the cost for HCV therapy; the remaining \$40,000 is borne by the patient as a copayment. On the basis of anecdotal evidence, it is likely that the actual charge for curative therapy is substantially lower than \$84,000. However, we intend to show that even if patients were required to pay such high copays, the therapy could still be affordable under the appropriate financing structure. In addition, a \$40,000 copay is much lower than the current alternative for patients with early-stage HCV; for such patients, coverage is typically denied, so the cost is the full list price.

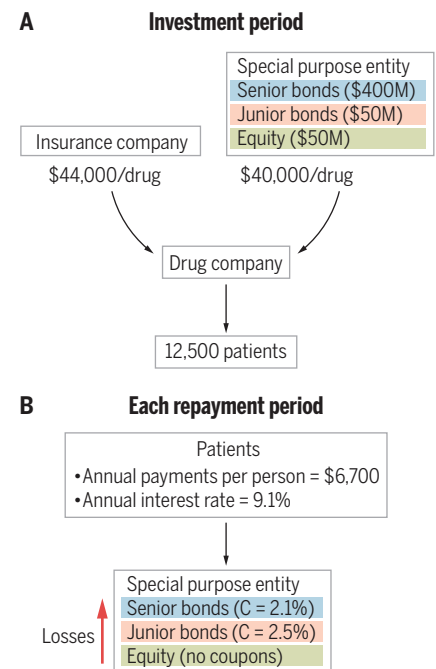


Fig. 1. HCL fund: Cash flow diagram. (A) During the investment period, the investors buy the notes issued by the SPE, and using the cash raised from the sale of the notes, the SPE pays a portion of the drug's price. (B) During the repayment period, the patients make their annual loan payments, and the investors receive cash payments based on the seniority of their notes. The losses, if any, propagate from the bottom to the top (red arrow).

Table 1. Unresolved issues and perceived complications. Each of these issues must be addressed in order to implement a comprehensive HCL strategy that increases the availability of transformative therapies and incentivizes their development.

Issue	Comment
Low median income and/or poor credit of some patients	A subset of patients would continue to “fall through the cracks” that exist in any multipayer system. Government guarantees, rebates, or incentives could address this gap, as in the case of mortgages, student loans, and other forms of consumer finance.
Economic externalities of infections such as HCV	An “externality” refers to a cost or a benefit affecting an individual who has not chosen that cost or benefit. An infectious disease imposes a negative externality on infected individuals, and eradicating such a disease provides a positive externality on all who would be exposed to infection. These externalities have implications for policy decisions and have not been considered in our analysis.
Differences between U.S. and foreign pricing	U.S. drug prices are among the highest in the world. Thus, proposing that U.S. patients assume larger copayments seems even more inequitable. There are many factors that cause U.S. prices to be higher than those in other countries, including the fact that our multipayer health care system is based on principles of competition and free-market pricing. One benefit of such a system is that transformative therapies are often available first to U.S. patients and, in some cases, unavailable in single-payer countries. The consequence of such access is higher U.S. prices, which can be interpreted as U.S. patients subsidizing drugs for non-U.S. patients. These price differences have political and ethical implications that are outside the scope of our analysis.
Impact of price increases owing to a larger market resulting from HCLs	HCLs could cause drug prices to increase in the short term because of increased demand for therapies that were previously unaffordable. Over longer terms, the price impact of HCLs is unclear given countervailing forces, such as increased competition due to greater incentives for producing transformative therapies, greater negotiating power via HCL lenders, and cheaper financing of copayments. There may also be unintended income-distributional consequences of the emergence of liquid HCL markets—for example, the lowest-income patients getting priced out of certain therapies, even as middle-class patients gain greater access. These effects must be monitored carefully and may require government intervention, as in other consumer-finance contexts such as housing and education.
Limitations of consumer credit risk model	Our proposed statistical model for the financial risk of HCLs can be improved by use of proprietary data available only to payers. For example, one regional insurer may tend to attract healthier policyholders, whereas another insurer may be subject to the opposite tendency; such selection biases could affect statistical estimates of HCL default rates. Publicly available data on student loans and other consumer financing might not fully capture such risks of HCLs.
Misaligned incentives	To avoid problematic practices from the recent financial crisis, approaches such as a risk-retention policy should be considered. This would impose partial ownership of each securitization on the issuer (the bank) and thereby align stakeholder interests.
Limitations on default	Since the passage of the Bankruptcy Abuse Prevention and Consumer Protection Act of 2005, consumers with student loans are prevented from defaulting by excluding them from bankruptcy proceedings except in cases of “undue hardship.” This feature of the student loan market has received mixed reviews from various stakeholders. Some argue that it is essential protection for consumers who are unable to afford the legal expense of bankruptcy proceedings. Others counter that it is tantamount to indentured servitude and subsidizes lenders by reducing default risk at the expense of borrowers and taxpayers. Almost by definition, many patients face “undue hardship”; hence, preventing those with HCLs from declaring bankruptcy is unlikely to be either practical or socially acceptable.
Tracking value over the amortization period	Systems, metrics, and legal frameworks currently do not exist for determining ongoing patient benefit, but are necessary for the implementation of health-contingent amortization payment agreements. These elements are likely to emerge rapidly to support HCL markets as they grow and become more liquid. Privacy issues must be balanced with requirements for tracking individual outcomes.

Patients would obtain HCLs from funds raised by the SPE through various tiers of bonds and equity that total \$500 million (Fig. 1A). Default rates were calibrated to typical values for consumer loans by borrower-income levels. We considered three scenarios—pessimistic, baseline, and optimistic—that cover a range of probabilities for HCL default based on the borrower’s income (Fig. 2, A and B, and fig. S2). These default models were derived by using student loan data (Supplementary materials, table S1 and figs. S3 and S4). Studies on interferon and ribavirin treatment for chronic HCV

infection have reported that all-cause mortality rates for patients with a sustained virological response—which equates to cure in nearly all cases—are not statistically different from those of an age-matched general population (12–14). Therefore, we used general-population mortality rates as a proxy for patients who receive new HCV-directed therapies (15, 16). More than 75% of the HCV-infected population in the United States are baby-boomers (that is, born between 1945 and 1965), so we used U.S. Census Bureau projections for the baby-boomer cohort (fig. S5) (17). The estimated survival

curve and annual death probabilities are depicted in Fig. 2, C and D. Our estimated 10-year survival rate (89.3%) is close to the rates reported elsewhere (12, 16, 18).

We used 10 million Monte Carlo simulation paths per each scenario of HCL default probability to evaluate the performance of the HCL fund, assuming that individual HCLs have 9-year terms with a 9.1% annual interest rate. The term and interest rate of the HCLs were selected to be close to those of private student loans and to avoid too high a payment burden on borrowers—based on the

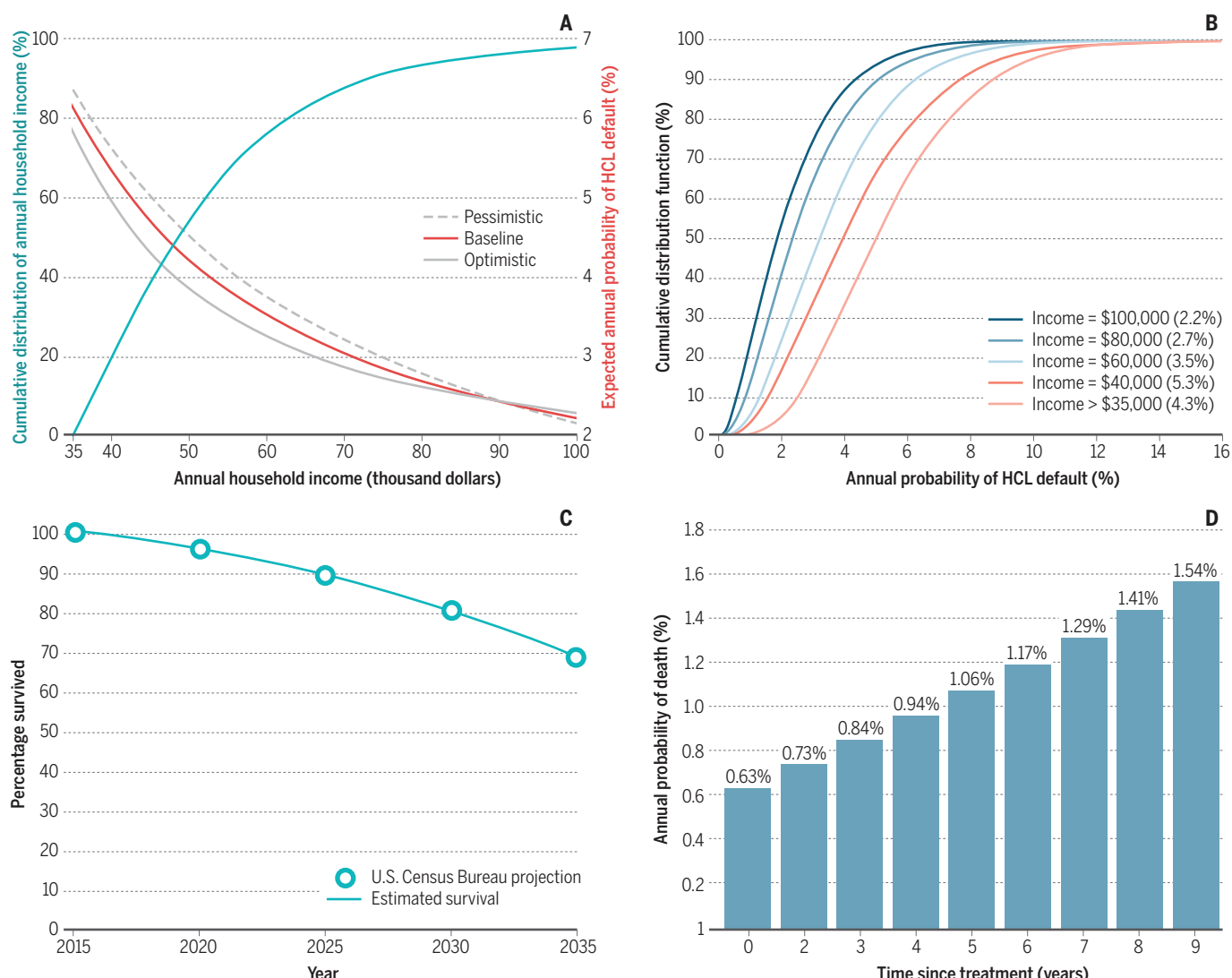


Fig. 2. Assumptions used in the simulations. (A) The cumulative distribution function (CDF) of the annual household income for patients with chronic HCV (blue line and left axis) and the estimated expected default probability as a function of income for three different scenarios (right axis). (B) The CDF of annual default probability, in the baseline scenario, for multiple incomes as well as the whole pa-

tient population (income >\$35,000). The numbers in parentheses denote the expected default probability associated with that category. (C) The U.S. Census Bureau's projected numbers for the baby-boomer generation as well as our estimated postmedication survival curve for each patient (16). (D) The annual probability of death based on the survival curve in (C) over the 9-year HCL term.

patient population income distribution—without jeopardizing investment performance. In practice, the interest rate on HCLs could be determined specifically for each borrower. However, for simplicity and transparency, we used a single interest rate across the HCLs in the portfolio to represent an average over the population. The SPE is financed by senior and junior debt yielding current market rates (2.1 and 2.5%, respectively) and by equity that receives any remaining cash flows after the senior and junior debt payments are made (Fig. 1B) (details of the simulation parameters and risk-return computations are provided in the supplementary materials).

Overall, the risk-reward profiles across all three scenarios are within an acceptable range to attract investors. In the baseline case, the average and median simulated internal rate of return (IRR, a standard measure of investment performance) for equity investors in the SPE are 12.5 and 12.7%, respectively. The standard deviation of the IRR—the industry-standard measure of an investment's riskiness—is 3.1%. For comparison, over the most recent 9-year period from September 2006 to August 2015, the compound annual return of the Standard & Poor's 500 index—a popular measure of U.S. stock market performance—was 7.0% with an annualized return standard deviation

of 15.5% (authors' calculations). Thus, the metrics for the HCL fund indicate a very attractive risk-reward profile for most investors (the complete set of SPE performance metrics is shown in table S2). We emphasize that these results depend critically on the assumptions regarding parameters such as default rates, interest rates, the economic environment, and lending practices.

ALIGNING INCENTIVES USING HCLS

As outlined above, the performance of HCL bonds would be linked directly to the continued efficacy of the borrower's therapy, as payments end upon death or other predefined

end points. The prospect of premature terminations of payments increases the risk to bondholders and will drive up HCL interest rates, other things being equal. Such risk can be reduced by offering bondholders guarantees of all or a fraction of their principal. Moreover, although our simulations were motivated by a single therapy for HCV, in practice HCL funds would cover multiple therapies across a diversified population of borrowers, further reducing the risk to the guarantor. These guarantees could be provided by third parties such as philanthropists, patient advocacy groups, government agencies, insurance companies, and even pharmaceutical companies seeking to expedite the adoption of their therapies. Counterparts for all of these types of entities have played a comparable role in housing markets; hence, the HCL market would be a natural extension of their purview.

Based on our models for the \$40,000 HCL scenario and using student-loan-based default data, the cost of a guarantee would be a tiny fraction of the face value of the bonds (0.006% in the pessimistic scenario) (supplementary materials). Because the wider accessibility of treatments would improve overall health among beneficiaries, insurance companies and the government have an incentive to guarantee the bonds at this low cost. This, in turn, would attract bond investors willing to accept lower interest rates and thereby reduce the financial burden of the HCLs on patients. Other natural guarantors for the bonds are pension funds, whose financial liabilities vary inversely with mortality rates. Either purchasing or guaranteeing the bonds would act as a natural hedge for their investment by reducing their exposure to changes in mortality rates. Similarly, life insurance companies have large ongoing obligations in the form of annuities, which are contracts in which the insurer agrees to pay individuals a fixed amount of money each month for as long as they are alive in exchange for a one-time fee. Assets that move in the opposite direction from beneficiary longevity are natural hedges to the annuities.

The pharmaceutical company whose drug is financed by this fund might wish to take a position in the equity tranche, further aligning its interests with those of the patients and demonstrating confidence in its product. If the marketed therapy were not as effective as advertised by the pharmaceutical company (that is, if the assumptions made here were more optimistic than the true underlying parameters), the equity position would suffer losses, effectively penalizing the pharmaceuti-

cal company. On the other hand, if posttherapy mortality rates were at least as good as shown in the clinical trials, the pharmaceutical company would benefit from its equity position, effectively being rewarded for its innovation. This provides additional incentive for the pharmaceutical company to monitor patient adherence, establish patient training programs, and otherwise promote the maximum benefit.

HCLs also help disincentivize both the development and market release of ineffective drugs by tying payment to pharmaceutical companies to the clinical benefits of their drugs. HCLs represent a practical implementation of value-based reimbursement strategies that have lately received a great deal of attention from pharma, private insurance companies, and public payers (11). Value-based reimbursement contrasts with mandated price ceilings for drugs because the former incentivizes the development of truly transformative therapies, whereas the latter disincentivizes them.

Having patients participate in the payment for their curative therapies might impart an additional motivation to be informed and responsible consumers of health care. This active engagement might further encourage patients' adherence to prescribed regimens and discourage behaviors that undermine the medical benefits of the therapy. However, a substantial copay (in the form of an HCL) could conceivably drive patients to postpone curative therapy for chronic diseases such as HCV infection until their disease has advanced to a more severe stage. Although this is a possibility, the historical experience with HIV therapies suggests that the large majority of patients are eager to treat even in the absence of major clinical symptoms on the basis of their understanding of the highly negative consequences of delaying therapy and the risk it poses to their close contacts. Therefore, with proper educational programs, a large majority of patients will likely seek curative therapies upon diagnosis if affordable.

HCLs can also create more options for patients in countries with nationalized health care, in which a central health agency dictates the formulary. For example, the UK's national health care system (NHS) recently decided to forgo more than 20 cancer drugs because they were deemed too expensive given the expected benefit (19). The NHS presumably uses cost-effectiveness analyses to determine whether each drug should be covered. However, a binary decision to either allow or disallow a given therapy does not reflect the continuous nature of cost-effectiveness. If there is some price, p^* , at which a given therapy is cost-

effective, it is more appropriate from a cost-effectiveness standpoint for the NHS to cover this amount on behalf of patients, and anything that pharma charges above p^* could be covered by the patient in the form of HCLs. This approach provides patients with more options than does the current all-or-nothing policy. The enhanced flexibility inherent to HCLs also provides patients a sense of participation in and control over their own health care.

SENSITIVITY ANALYSIS

As noted above, our simulation results depend critically on the assumptions regarding parameters such as default rates, interest rates, the economic environment, and lending practices, and we have calibrated the HCL default rates using student loan data. Because the population of student-loan borrowers is not identical to the population of potential HCL borrowers, the HCL default rates observed in practice might be different from the values presumed above. Hence, we performed additional simulations to explore HCL fund performance across different terms of HCLs, HCL (copay) amounts, interest rates on HCLs, and coupon rates of the bonds issued by the HCL fund (fig. S6). For the HCL fund to be a viable investment vehicle, the bonds must offer a market yield with the corresponding default risks associated with those yields; the equity tranche must offer an expected return that is competitive with other equity investments (that is, at least 12%); and the cost of the guarantee for the senior tranche of bonds should be relatively low (at most, 1% of the bond's face value).

Given these constraints and using the income distribution of the patient population and the baseline default model, for any HCL term and any interest rate assumptions, we can determine a range for the HCL amounts over which the fund would have an attractive performance profile (12% equity return and 1% cost of guarantee). Using current market rates for bond yields, a 9.1% HCL interest rate, and a 5-year maturity for HCLs, the maximum amount of borrowing for each HCL is \$27,000; loans beyond this amount will cause the performance of the HCL fund to deteriorate below the constraints described above. However, if we extend the maturity to 9 years, the borrowing capacity for each HCL increases to \$40,000 before fund performance violates the constraints. For a fund providing 15-year HCLs, the amount of each HCL can be set as high as \$50,000 while still maintaining attractive performance to fund investors. However, the relationship between maturity and borrowing

capacity is not linear because of mortality; for a fund providing patients with 30-year HCLs, the maximum borrowing capacity of each HCL is only \$20,000 (supplementary materials and fig. S6). These results indicate that HCLs would be a feasible approach to expand access to patients under the specified constraints.

One can model amortization schedules to generate HCL funds for even \$1 million therapies with financial performance that is attractive enough to appeal to investors. For medications with six- or seven-figure price tags, long-term HCLs—debt with 30- to 50-year maturities and collateralized by assets such as homes or income streams—would be the only viable options but would still remain far out of reach for a large fraction of consumers. To allow readers to explore the full range of applicability for HCLs in various contexts, our open-source MATLAB simulation software is available for download (supplementary materials).

THE ROLE OF HEALTH INSURANCE

Large copays are antithetical to the very purpose of health insurance. Hence, our proposal for patients to cover these costs with HCLs is only a short-run bridging solution. A more sustainable and economically more efficient approach to address the high cost of transformative therapies is for insurance companies to cover these costs, spread the amortized costs across their policyholders, finance the upfront payments using securitization, and set premiums at the appropriate levels to cover these costs. For medications priced similarly to or higher than Glybera, including gene and cellular therapies, this is the only approach that would be both financially viable and politically acceptable. In return for larger drug purchases, insurance companies would wield substantial leverage to negotiate lower prices. Also, insurers would presumably borrow at lower interest rates than would individual patients, further reducing the overall financing cost of these therapies.

A key impediment to insurance companies bearing the upfront costs is the relatively high rate at which policyholders in the United States switch from one plan to another because of, for example, job changes, relocation, or retirement. (20). If a policyholder switches from insurer A to insurer B 3 years after insurer A reimbursed the policyholder for a life-saving therapy, insurer B reaps the benefits of an ongoing stream of premiums from a now-healthy policyholder whose longer life expectancy was acquired at insurer A's expense. The uncertainties surround-

ing policyholder turnover—not to mention therapeutic innovations, health care legislation, and financial market conditions—impose substantial hurdles to quantifying the actuarial risks that insurers face when covering such expenses.

Therefore, new regulation or legislation is needed requiring all insurance companies to assume the remaining amortized debt obligations of new policyholders who are switching plans. In the example above, if a policyholder switches from insurer A to insurer B today, and was the recipient of a transformative therapy 3 years ago that insurer A amortized via a 9-year HCL, insurer B would be required to assume the payments of this HCL over the remaining 6 years for this policyholder as part of the switch. This is the financial equivalent of the current requirement for insurers to cover preexisting conditions (including the costs of mitigators that the patient is currently receiving). In fact, the only change needed is to include HCL obligations as part of a patient's "preexisting conditions." Transferring amortized debt from one insurance company to another would link ongoing payment to ongoing benefit and thereby obviate concerns over large upfront costs being decoupled from subsequent premiums.

QUALIFICATIONS, LIMITATIONS, AND DISCUSSION

Several challenges to HCL fund implementation are beyond the scope of our simulation analysis but should be addressed by the relevant stakeholders (Table 1). In addition, our HCL simulation results must be qualified in several respects. First, they are based on a number of assumptions and simplifications that might not hold in practice; hence, any implementation of an HCL fund will require a more customized simulation that reflects the specific parameters of the fund and the relevant business conditions at launch. For example, patients with annual household incomes of less than \$35,000 were excluded from our calibration because many of them have Medicaid coverage. For patients below this income threshold who do not have Medicaid coverage, the government might offer special programs for financing health care in the same way that the government offers various housing assistance programs.

Second, the realized HCL default characteristics may differ from trends reported for student loans because of systematic differences in the characteristics of student loan borrowers and those of the HCL borrowers. However, any other estimate would have the same uncertainty surrounding its predictive power because the proposed HCLs do not yet exist in

the market. There are also inherent selection biases in observed student loan data; for example, the fact that borrowers have been granted loans implies that at least some fraction of them have passed credit screening tests conducted by the lender and are therefore likely to be less risky than an unscreened borrower in the same income bracket. Moreover, the U.S. student loan market benefits from several government programs that can affect market rates and other parameters. Therefore, our simulation results are, at best, suggestive, not conclusive. The purpose of our analysis is to demonstrate the feasibility of HCL financing under a plausible set of parameter values and to stimulate their expedient implementation, which will require further research and policy discussion. We do not argue that our particular choice of parameters is appropriate for any given fund or therapy.

Last, it is appropriate to raise concerns about any application of financial engineering techniques to health care, especially because securitization was chief among the techniques involved in the most recent financial crisis. Although this powerful tool is actively used in many markets today and plays a critical role in financing mortgages, student loans, consumer credit, and other major business expenditures, securitization can still be abused if the proper protections are not present. Thus, regulatory oversight—including risk-retention requirements for HCL securitization issuers and risk transparency for HCL investors—is essential for the creation of robust and sustainable HCL funding markets. To argue that securitization is simply too risky without a feasible alternative is to relegate patients who could otherwise benefit from HCLs right now to the status quo.

CONCLUSION

The burden of upfront payment for curative therapies makes it challenging for public and private payers to afford universal access to potentially life-saving therapies. To address this issue, we considered a new financing paradigm in which portfolio theory and securitization techniques are used to finance HCLs whose repayment is linked to ongoing value. By estimating the post-treatment mortality rates of the patients and using statistical models to gauge the default characteristics of these loans, we demonstrate viability under current practical conditions. Securitization brings new participants (for example, pension funds, mutual funds, and life insurance companies) into the financing pool and helps transform a set of disjointed and sometimes

competing interests into a more cooperative system focused on improving care. HCLs, not unlike student loans, auto loans, and home mortgages, can improve access to the best health care for the less affluent.

HCLs and securitization are only two of many potential financial innovations that could increase access to transformative therapies. One practical next step is to convene a meeting of essential stakeholders—biopharma executives, payers, patient advocates, regulators, financial engineers, and investors—to identify the most promising methods for financing expensive therapies. The MIT Laboratory for Financial Engineering and the Dana-Farber Cancer Institute will be jointly hosting such a conference in 2016.

Considering the extremely large burden of certain diseases, such as HCV, for which cures already exist, and the many transformative therapies on the horizon, developing more efficient financing methods is now a matter of life and death. Taking action is no longer a choice but has become a necessity.

SUPPLEMENTARY MATERIALS

www.sciencetranslationalmedicine.org/cgi/content/full/8/327/327ps6/DC1

Portfolio theory: A simple example

Securitization

HCL portfolio assumptions

Credit enhancement techniques

HCL default assumptions

Post-treatment survival curve estimation

HCL fund performance results

Table S1. Model parameters

Table S2. Simulated performance results

Fig. S1. Risk, return, diversification, and securitization

Fig. S2. HCL default model

Fig. S3. Student-loan data

Fig. S4. Goodness-of-fit of default models

Fig. S5. Estimated post-treatment survival rates

Fig. S6. Sensitivity analysis of simulated performance

References (21–31)

REFERENCES AND NOTES

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