Published in final edited form as:

Health Aff (Millwood). 2008 ; 27(1): 122–129. doi:10.1377/hlthaff.27.1.122.

Drug Licenses: A Better Model for Pharmaceutical Pricing

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Abstract

High drug prices are a substantial barrier to patient access and compliance. Yet, low drug prices are often argued to provide inadequate incentives for innovation. We propose a “drug-licensing” model for health care which has the promise of increasing drug utilization without altering patient out-of-pocket spending, health plan costs, or pharmaceutical profits. In such a model, individuals purchase annual drug licenses which guarantee unfettered access to a clinically optimal number of prescriptions over the course of a year. For the case of statins, we illustrate how such a model may be implemented in practice.

Spending on pharmaceuticals is outpacing growth in total health care expenditures in the US and many Westernized countries—in the US alone, drug spending grew 10 percent from 1998 to 2003 compared to 5 percent for health care overall.¹ Despite its modest contribution to overall health care spending, increased drug spending has raised concerns about increasing costs in health care more generally and the impact high prices may have on access to much needed pharmaceutical products.

For clinicians, the most important consequence of this trend may be the dramatic increase in patient out-of-pocket spending and how it affects patient behavior and health outcomes. Physicians, out of concern for patient compliance and access to treatment, regularly encourage behavior designed to mitigate high prices. Physicians often distribute free samples to patients with financial need.² Pill splitting—the act of dividing higher dose tablets to avoid expensive co-pays—is commonplace. These practices are not limited to patients and physicians; Illinois’ Medicaid program now requires the practice for some drugs, and United Healthcare in Arizona recently began requesting that its beneficiaries engage in the practice as well. But pill splitting entails risks and is not possible for all drugs.

The fundamental clinical problem is that high prices are a substantial barrier to patient compliance. In a Wall Street Journal/Harris Interactive poll,³ 35% of adults cited financial considerations as a reason for noncompliance. The results of this poll are corroborated by numerous studies.⁴ The impact of high prices on patient compliance is important because poor compliance can lead to worse health outcomes through uncontrolled hypertension, high cholesterol, untreated psychiatric illness, and resistant bacterial infection to name a few. But

non-compliance is particularly unfortunate, not only because it can worsen patient health, but because it can reduce productivity and significantly increase medical costs as well.⁵

Given the impediment of high co-pays and high prices for access and compliance, what can be done? The solution most discussed is to mandate lower drug prices—for example, by allowing re-importation of drugs or by requiring Medicare to negotiate drug prices. But there are two enormous obstacles to regulating prices in this manner. The first is that lowering prices can defeat the purpose of the patent system and can potentially reduce incentives for future pharmaceutical innovation. While some prominent critics have rightfully questioned the link between profits and R&D,⁶ the absence of R&D into unprofitable third-world diseases and the increase in R&D for certain rare diseases after the US Orphan Drug Acts suggest otherwise. Moreover, the (limited) economic evidence suggests that price regulation can delay the launch of new drugs,⁷ limit the availability of new drugs⁸, and reduce the pace of innovation.⁹ Critics contend that this link is tenuous, and that the status quo may offer too much incentive for R&D, especially “me-too” innovation. These concerns are particularly relevant to health care, where the existence of health insurance may encourage too much costly innovation.¹⁰ Nonetheless, whatever view one may take, the reality is that lower prices are avidly opposed by the drug industry, and therefore, may be difficult to implement politically.

We propose an alternative approach to pricing pharmaceuticals that has the potential to improve patient compliance *without* lowering profits to pharmaceutical firms and insurers. We propose a drug licensing model in which all patients are required to pay an annual “licensing fee” for the drugs they take; in return, they can purchase medication with nominal or non-existent co-pays up to some therapeutically optimal level, e.g. twelve monthly prescriptions per year. In this model, pharmaceutical firms would charge health insurers a license fee for each patient receiving unfettered access to their product(s) up to the predetermined level. In return, pharmaceutical firms would sell their drugs to the plan at very low cost, rather than at the typical mark-ups that characterize patent-protected, brand medications. To prevent resale, the number of units dispensed to the insurer would be bounded by the number of licenses sold multiplied by the maximum number of prescriptions allowed per license. The health plan would then pass this cost structure on to its beneficiaries in the form of a separate but similar drug license with low or non-existent co-pays—in effect, patients would purchase drug licenses from insurers and insurers would purchase drug licenses from manufacturers.

Such a model would naturally apply to any disease for which repeated medications are required for effective treatment and in which treatment costs depend on the level of utilization. This would, of course, be true for chronic diseases such as asthma and diabetes in which medications are taken over a long period of time and prescriptions are financed, say, monthly. Drug licensing would also apply, however, to slightly more acute diseases in which prescriptions must still be filled and financed monthly, e.g. a nine-month antibiotic treatment of tuberculosis.

The licensing model we propose is referred to by economists as “two-part pricing.” Numerous examples exist in the non-medical world including internet service, cable and satellite television, all-you-can-eat buffets, country club memberships, and cell phone plans. But perhaps the most relevant example is software. Rather than charging a fee every time a person starts their computer, Microsoft elects to charge a one-time fee for the use of Windows. What makes pharmaceuticals similar to these products—and distinguishes them from other health services—are the very low costs of production and few good substitutes.

In each of these instances, consumers pay a fixed fee upfront, after which they pay a very low (or nonexistent) amount for use of the good or service. Because usage fees are lower than they would be if charged on a per-unit basis—the manufacturer makes up for this cost with the license fee—those purchasing the product end up consuming more than they would if prices were higher. For example, in the case of pharmaceuticals, license fees combined with zero or low co-pays would increase drug utilization (i.e. compliance) in the same way that buffets induce individuals to eat more and free music-sharing programs induce individuals to download more (Napster versus i-Tunes). And because increased utilization is beneficial to patients (at least in the case of pharmaceuticals), patients, health plans and manufacturers can share some of this added value generated by the licensing model.

To demonstrate how patient compliance can be improved while leaving health plan costs and pharmaceutical profits unchanged, we consider an *illustrative* example of drug licensing for statins, for which ample empirical evidence exists that co-payments have a large effect on compliance. Defining compliance as the proportion of prescribed days for which prescriptions are filled, Goldman et al.¹¹ estimate the relationship between average co-payments and average statin compliance for 88 private health plans. For each 10 dollar increase in co-pay, statin compliance *falls* on average 5-6 percentage points. This estimate is conservative—Schultz et al.¹² find even larger effects. Moreover, for a monthly co-pay of 25 dollars—the average co-pay in 2005 in this same data—average compliance is only 65 percent. Based on these studies, a reduction in co-pay from 25 dollars to zero would improve compliance to nearly 80 percent, the threshold argued for statins to have therapeutically optimal effects (see e.g. Wei et al.).¹³

Based on these studies, Exhibit 1 provides a realistic illustration of how a properly designed license model for statins could improve patient compliance while maintaining the status quo in out-of-pocket spending, health plan costs, and pharmaceutical revenues. We consider a health plan with 10,000 beneficiaries, 1,000 of whom likely would be taking branded statin medications. We consider three scenarios: (1) a pure co-payment model (the status quo), (2) a drug licensing model with zero co-payment and license fees paid by both the health plan and the statin user (3) a mixed model in which a license fee is paid in return for lower, but not zero, co-payments. In the second and third instances, the drug license would allow up to 12 monthly prescriptions per license.

Based on the literature, statin compliance averages 7.8 months at the mean co-payment of \$25, as opposed to 9.6 months when the co-payment is reduced to zero. In the pure co-payment model, annual out-of-pocket payments for statin users would therefore average 195 dollars (= 7.8 prescriptions × \$25 co-payment). In the license example, statin users pay this amount up front as a license fee, and the co-payment is eliminated. Compliance would improve to 9.6 months. Total out-of-pocket payments for statins would therefore remain the same in the license model, but average compliance would improve nearly 25%.

It is straightforward to show that for a correctly chosen drug license fee, both the costs to the health plan and the profits to the drug manufacturer can remain unchanged. We start with the status quo in which the drug manufacturer charges the health plan a price for each prescription that exceeds the cost of production, even net of rebates. In the 88 health plans we studied, the average amount paid by private health plans for branded statins was 73 dollars per 30-day equivalent. Some of this amount is paid by statin patients in the form of co-payments—the remainder is paid by the health plan and is financed through normal premiums charged to both statin and non-statin users. In our example, the health plan's total statin prescription costs are 374,400 dollars—this is simply the average number of prescriptions filled (= 1,000 users × 7.8 prescriptions per user × \$48 net price paid by the health plan).

In the pure drug licensing model, health plans would be charged a license fee (\$569) for each statin user, to be paid to the manufacturer. This fee would give the health plan the right to 12 prescriptions annually at zero cost for each license. Part of this fee would be financed by a separate drug license sold to statin users (\$195, similar to their out-of-pocket costs under status quo), while the remainder would be paid by the health plan (\$374). Since the net cost to the health plan is 374 dollars per statin user, the total prescription plan costs would be the same as in the status quo (\$374,400).

A similar analysis can be applied to the drug manufacturer. Under the status quo, the total profits from sales to the health plan are \$569,400—this is equal to the price charged by the manufacturer net of costs (\$73 per prescription) times the number of prescriptions filled annually (when the co-pay is 25 dollars) times the number of statin users. Under a licensing model, the health plan simply pays an upfront fee of 569 dollars per statin user, which leaves manufacturer profits unchanged compared to the status quo.

This example demonstrates that with a properly chosen drug licensing fee, patient compliance can be significantly improved at no additional cost to patients or health plans and no change in profits to manufacturers. And although the recent introduction of generic Zocor (simvastatin) makes an illustration with statins less forceful today than perhaps two years ago, top-selling Lipitor still remains on patent and makes the basic conclusions of our illustration still salient. To the extent that patients value the health benefits associated with improved compliance and/or health plans experience cost-savings due to reduced medical expenditures from better compliance, both health plans and drug manufacturers can share in these welfare gains so that *all* parties—patients, health plans, and drug manufacturers—can be better off with drug licensing.

The infrastructure for such a licensing model already exists in health care. Insurance itself closely resembles a two-part pricing arrangement between insurers and patients—patients pay a fixed amount up front (through premiums) for the right to purchase health care services at lower cost. Our proposal is tantamount to designing a plan with very low co-payments—with one important difference. Today, if an insurer offered a plan that covered chronic medications for essentially zero co-payments, then the plan would need to worry about attracting the sickest patients. In fact, it is likely that concerns about risk selection have been at least partially responsible for the recent increase in out-of-pocket payments. In our model, the insurer pays the same amount regardless of utilization, so it has less incentive to avoid patients who utilize more therapy.

It is worthwhile to consider some possible limitations of and objections to the licensing model. First, drug licensing will not eliminate the need for health plans to correctly identify those patients who should receive a given therapy. For example, patients whose clinical diagnoses do not warrant a specific treatment will not be offered the opportunity to purchase a drug license. Rather, for those patients for whom coverage *is appropriate*, drug licenses can ensure therapeutically optimal utilization without increasing out-of-pocket spending. Drug licenses can help those individuals who stand to benefit from a drug, actually benefit from it. In this sense, drug licenses may complement other measures proposed to improve efficiency in utilization, e.g. Value Based Insurance Design (VBID)¹⁴, by identifying patients who are most likely to benefit from a drug and offering them unfettered access at a fixed price.

Second, while compliance will surely improve for those taking the licensed drug, it is possible some patients may be discouraged from *initiating* therapy if the license fee is set too high. We propose three solutions to this problem. The first is to implement a mixed model in which patients pay a lower drug license fee in return for lower co-payments than the status

quo. We illustrate this in the third column of Exhibit 1. With a co-payment of 11 dollars, we estimate that patients initiating statin therapy will have an average compliance of 8.75 months. If patients pay a license fee of 95 dollars (slightly less than the co-payment for a 4-month supply under the status quo), their total out-of-pocket spending is unchanged (\$195) and compliance is still improved relative to the status quo. In this case, costs to the health plan and profits to the drug manufacturer are unchanged as well.

The second solution is to offer “non-response insurance” for patients who discontinue statin use within a given period of time. For example, those patients who discontinue use within three months of initiating therapy may be eligible for a partial or full refund of the license fee. Since profits to manufacturers and health plans are likely to be higher under drug licensing and the vast majority of statin sales are likely due to patients who use these drugs for longer than three months, such a money-back guarantee may face little opposition by drug manufacturers and health plans. In fact, such insurance is likely a good idea even outside of a licensing model. The third solution for individuals who would otherwise utilize the drug but cannot afford the upfront license fee is to offer a “drug loan.” In this case, rather than pay the license fee upfront, patients would pay in monthly installments until the license fee is fully paid.

Another concern with a licensing model is that minimal co-payments will encourage excessive and inappropriate drug use—in economic terms, licenses induce “moral hazard.” Indeed, the impetus behind many “consumer-driven” approaches to health care is to require more prudent spending through health savings accounts and high-deductible health plans. However, closer inspection reveals that this criticism is irrelevant to the license model. First, increased use of prescription drugs need not come at additional cost to health plans, even when such use has no effect on lowering costs elsewhere in the health plan. Our example demonstrates that total prescription plan costs under drug licensing may be equivalent to—or even lower than—plan costs under co-payments. Second, while co-payments deter excessive drug use, they also deter appropriate use. Because appropriate use lowers the likelihood of expensive hospitalizations, health plans may benefit from reductions in medical costs as well. In fact, the empirical evidence on statins suggests that the reductions in medical costs due to lower co-payments can be substantial.

The drug license model could also reduce manufacturer incentives to aggressively market drugs to patients on therapy. For example, the recent Food and Drug Administration “black box” warning about the potential overuse of erythropoietin to treat anemia is a salient recent example. Under a licensing model, profits are tied to the number of patient licenses rather than the number of prescriptions filled, so manufacturers have fewer incentives to encourage too much use. Rather, marketing efforts would be directed towards individuals who have not yet initiated therapy (as they are now).

Drug licenses also preserve incentives to advance medicine. Recent research has demonstrated that pharmaceutical therapy generates enormous social value. This suggests the importance of a pricing mechanism that (a) reduces the cost of compliance and ensures benefits from these medical advancements and (b) preserves manufacturers’ incentives to develop new technologies. We believe there is a strong basis for changing the current pricing structure for pharmaceuticals to the licensing model that we propose, thereby ensuring patient compliance without potentially comprising the supply of future drugs. We urge pharmaceutical companies, Medicare, and private health plans - along with other parties responsible for purchasing or selling pharmaceuticals, such as employers and pharmacy benefits managers - to explore the possibilities of drug licensing. We believe a pilot study of drug licensing, that involves agreement between health insurers and

manufacturers, would be a useful way to examine and demonstrate the benefits of this model.

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Exhibit 1**Benefits to Patients, Health Plans, and Manufacturers of Drug Licensing: The Case of Statins**

	Status Quo (Co-pays)	Drug License	License & Co-pay Model
No. of covered lives	10,000	10,000	10,000
Prevalence of statin use (%)	10	10	10
No. of statin users	1,000	1,000	1,000
<u>Patients (per statin user)</u>			
Co-pay per prescription (\$)	25	n/a	11
Cost-share on the license (\$)	n/a	195	95
Avg. compliance (%) ⁽¹⁾	65	80	73
(No. of 30-day prescriptions annually)	(7.80)	(9.60)	(8.75)
<i>Out-of-pocket payments for statins</i> ⁽²⁾	195	195	195
<u>Health plan</u>			
Plan prescription costs ⁽³⁾	374,400	n/a	374,400
Plan license costs ⁽⁴⁾	n/a	374,400	0
<i>Total costs for statins (\$)</i>	374,400	374,400	374,400
<u>Manufacturer</u>			
Manufacturer price per prescription (\$) ⁽⁵⁾	73	0	54
Manufacturing cost per prescription (\$) ⁽⁶⁾	0	0	0
Drug license fee (\$)	n/a	569	95
<i>Manufacturer profits (\$)</i>	569,400	569,400	569,400

Notes: Author's calculations.

⁽¹⁾ Based on compliance rates reported in Goldman DP, Joyce GF, Karaca-Mandic P. Varying pharmacy benefits with clinical status: the case of cholesterol-lowering therapy. *American Journal Managed Care*. 12, no.1 (2006):21-28.

⁽²⁾ Excludes premiums for statin coverage; in these examples, premiums would not change because plan costs are the same across scenarios.

⁽³⁾ The number of statin users times the number of prescriptions annually times the price (net of co-pays).

⁽⁴⁾ License fee net of patient cost-share on the license.

⁽⁵⁾ Based on average amount paid for branded statins (per 30-day equivalent) by 88 private health plans in 2004 exclusive of rebates.

⁽⁶⁾ Assumed minimal for convenience.